

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

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	30 JUN 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jul/29/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11201002]
2.	Birth Date:	(b) (6)/1955
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

090177e196ae3ff9\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: 11201002

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, 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	Jul/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

eCRF Audit Trail History

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00
1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00

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Header Text: c4591001

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Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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1.d	Inclusion Number:	4
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

Exclusion Criteria

2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00

2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00

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Header Text: c4591001

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Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00
2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01
2.k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.1	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, 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	Jul/29/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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:	[Diabetes Mellitus Type II]
	Start Date:	UNK/UNK/1986
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypercholesterolemia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Laminectomy Lumbar]
	Start Date:	Feb/7/2020
	Ongoing:	NO End Date: Feb/7/2020
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Onychomycosis toe nails]
	Start Date:	Apr/UNK/2020
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/29/2020
2.	Weight:	[86.0]
3.	Unit:	kg
4.	Height:	[165.0]
5.	Unit:	cm
6.	Body Mass Index:	[31.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jul/29/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, 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 :	Jul/29/2020
2.	Randomization Number:	[220363]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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: Jul/29/2020
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	[BP5R31]
5.b	Sample ID	[BP5R32]
5.c	Sample ID	[BP5R33]
5.d	Sample ID	[BPR2VB]
5.e	Sample ID	[BPR2VC]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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: Jul/29/2020
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	[BP5R34]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, 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:	Jul/29/2020 20:33
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: 11201002

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, 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: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

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	Aug/19/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

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?	NO
2.c	Symptom:	HEADACHE
	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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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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
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
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

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Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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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: 30-Jul-2020 21:28

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, 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:	Aug/19/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/19/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

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Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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: Aug/19/2020
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	[BP8VD3]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, 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:	Aug/19/2020 11:57
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

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **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	Sep/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **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?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3ff9\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: 17-Jul-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:09

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
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
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

090177e196ae3ff9\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: 17-Jul-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:09

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: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **Subject Initials:** ---

Generated By: (b) (4) **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: Sep/16/2020
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	[BM50V4]
5.b	Sample ID	[BPR2MF]
5.c	Sample ID	[BPR2MG]

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1120

Subject No: 11201002

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/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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: Feb/10/2021
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	[BHVSS9]
5.b	Sample ID	[BHDKVL]
5.c	Sample ID	[BHDKVM]

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1120

Subject No: 11201002

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: 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: 11201002

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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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1120

Subject No: 11201002

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: 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: 11201002

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	[]
----	-----------	-----

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

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: 11201002

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_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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:	[]
----	------------------------	-----

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

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	[]
----	-----------	-----

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: 11201002

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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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

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: 11201002

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:	[]
----	-------------------------------------	-----

Health Care Utilization

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

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: 11201002

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: 11201002

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: 11201002

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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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **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 - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:09

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Sep/16/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

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:	
----	-----------------------	--

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: 11201002 **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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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

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: 11201002

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	fibroids	Dec/27/2020 U NK:UNK	NO End Date Time: Jan/26/2021 UNK: UNK	Repeating Pages

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[fibroids]
4.	Start Date Time:	Dec/27/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/26/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae3ff9\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:** 11201002**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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [unknown]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[2021148932]

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

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: 11201002

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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: 11201002

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.	[]			[]		Repeating Pages

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: 11201002

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:	//

090177e196ae3ff9\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: 11201002

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

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.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

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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: 11201002

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Radiation Treatment

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

090177e196ae3ff9\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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

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: 11201002

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: 11201002

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:	

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

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: 11201002

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?	

090177e196ae3ff9\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: 11201002

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: 11201002

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 - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **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: 11201002

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:** 11201002**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: 11201002

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	[]
----	-----------	-----

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **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/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/10/2021
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: 11201002

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

	Withdrawal of Consent Date :	Not Done _____ //	Comments
1.	Withdrawal of Consent Date :	Not Done _____ //	Comments

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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 _____ //	Comments
----	--	-------------------------	--------------------------

Cause of Death

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

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 11201002

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: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Not Started

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	
----	---	--

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	
----	---	--

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/16/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

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: 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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Feb-24-2021 09:22:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: Disposition

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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-24-2021 09:22:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - 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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-24-2021 09:22:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: Disposition

Form: DEATH DETAILS CODED - 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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-24-2021 09:22:45 (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: Data Complete, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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
(b) (6)	N/A	Feb-11-2021 14:01:17 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Paul Bradley	Approved	Sep-17-2020 15:30:12 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, PaulBradley, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Sep-16-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

N/A

Paul Bradley	Approved	Sep-01-2020 16:49:08 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, PaulBradley, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jul-30-2020 12:21:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 12:21:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Jul-30-2020 12:21:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jul/29/2020	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Jul-30-2020 12:21:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11201002	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jul-30-2020 12:21:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1955	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jul-30-2020 12:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Jul-30-2020 12:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
---	-----------------	---------------------	--	---------------

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

Date	Location	User	Value	Reason
Jul-30-2020 12:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRIC AN AMERICAN	Initial Entry

090177e196ae3ff9\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: 11201002

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Jul-30-2020 12:22:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 1 usio n N um ber: Crit Male or femal erio e participants n D between the ag eser es of 18 and 5 ipti 5 years, inclusi on: ve, 65 and 85 years, inclusiv e, or 18 and 85 years, inclusiv e, at randomiz ation (depende nt upon study stage) Crit YES erio n m et?:	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

			Crit IN01A00 erion I D: (For Pfizer use only) :	
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1.a Inclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

1.a Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

1.a Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 2 usio n N umb er:	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

			<p>Crit Participants w erio ho are willing n De and able to co scri mply with all ptio scheduled visi n: ts, vaccination plan, laborator y tests, lifestyl e consideratio ns, and other s tudy procedur es</p> <p>Crit YES erio n m et?:</p> <p>Crit IN02A00 erio n ID : (F or P fizer use only):</p>	
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

1.b Inclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

1.b Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b Criterion ID: (For Pfizer use only)

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

I.c

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 3 usio n N umb er: Crit Healthy partic erio ipants who are n De determined by scri medical histor ptio y, physical exa n: mination, and clinical judgm ent of the inve stigator to be e ligible for incl usion in the st udy Crit YES erio n m et?:	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

			Crit IN03A00 erion ID : (F or Pfizer use only):	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

1.c Inclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

1.c Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Healthy participants who are determined by medical history, p hysical examination, and clinical judgment of the investigator t o be eligible for incl usion in the study	Initial Entry

1.c Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c Criterion ID: (For Pfizer use only)

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

1.d

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 4 usio n N umb er: Crit Capable of giv erio ing personal si n De gned informed scri consent, whic ptio h includes co n: mpliance with the requireme nts and restrict ions listed in t he ICD and in this protocol Crit YES erio n m et?:	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

			Crit IN04A00 erion ID : (F or P fizer use only):	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

1.d Inclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

1.d Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.d Criterion ID: (For Pfizer use only)

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 1 usio n N um ber: Crit Other medical erio or psychiatric n D condition incl. eser recent (within ipti past year) or a on: ctive suicidal i deation/behavi or/lab abnorm ality that may increase the ri sk of study par ticipation Crit NO erio n m et?:	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

			Crit EX01A00 erion ID : (F or P fize r us e on ly):	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Other medical or psy chiatric condition inc l. recent (within past year) or active suicid al ideation/behavior/l ab abnormality that may increase the risk of study participation	Initial Entry

2.a Criterion met?

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 2 usion Num ber:	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

			<p>Crite Known infect ri ion with hum on an immunode Desc ficiency virus ripti (HIV), hepati on: tis C virus (H CV), or hepat itis B virus (HBV)</p> <p>Crite NO ri ion on met? :</p> <p>Crite EX02A00 ri ion ID: (For Pfize r use only) :</p>	
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.b Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

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Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX02A00	Initial Entry
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2.c

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 3 usio n N umb er: Crit History of sev erio ere adverse re n De action associat scri ed with a vacc ptio ine and/or sev n: ere allergic re action (eg, ana phylaxis) to a ny component of the study in tervention(s) Crit NO erio n m et?:	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

			Crit EX03A00 erion ID : (F or P fizer use only):	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.c Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: History of severe ad verse reaction associ ated with a vaccine a nd/or severe allergic reaction (eg, anaphyl axis) to any compon ent of the study inter vention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c Criterion ID: (For Pfizer use only)

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusi 4 on Nu mber: Criteri Receipt of on Desc medication ription: s intended to prevent COVID-19 Criteri NO on met ?: Criteri EX04A00 on ID: (For Pfi zer use only):	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Generated By: (b) (4)

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

2.d Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of medicatio ns intended to preve nt COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

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Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00)
Eastern Time (US
& Canada)

(b) (4), (b) (6)

2.e

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 8 usio n Nu mbe r: Crit Immunocomp erio romised indivi n De duals with kn scri own or suspec ptio ted immunode n: ficiency, as de termined by hi story and/or la boratory/physi cal examinati on Crit NO erio n me t?:	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

			Crit EX08A00 erio n ID : (Fo r Pfi zer use only):	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.e Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX08A00	Initial Entry
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2.f

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 10 usio n N umb er: Crit Bleeding diath erio esis or conditi n De on associated scri with prolonge ptio d bleeding tha n: t would, in the opinion of the investigator, c ontraindicate i ntramuscular i njection Crit NO erio n m et?:	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

			Crit EX10A00 erio n ID : (Fo r Pfi zer use only):	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.f Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f Criterion ID: (For Pfizer use only)

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Women who are pregnant or breastfeeding Criterion met?: NO Criterion ID: (For Pfizer use only): EX11A00	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.g Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are preg nant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00)
Eastern Time (US
& Canada)

(b) (4), (b) (6)

2.h

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: (Formerly Pfizer use only): EX12A00	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.h Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00)
Eastern Time (US
& Canada)

(b) (4), (b) (6)

2.i

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids Criterion met?: Criterion ID: EX13A01 Dose or Frequency: (F or Pfizer only):	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.i Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.i Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry
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2.j

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 15 usio n N umb er: Crit Receipt of blo erio od/plasma pro n De ducts or immu scri noglobulin, fr ptio om 60 days be n: fore study inte rvention admi nistration or p lanned receipt throughout the study Crit NO erio n m et?:	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

			Crit EX14A01 erio n ID : (Fo r Pfi zer use only):	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.j Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.j Criterion ID: (For Pfizer use only)

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

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2.k

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 16 usio n Nu mbe r: Crit Participation erio in other studi n De es involving scrip study interve tion: ntion within 28 days prior to study entry and/or during study particip ation Crit NO erio n me t?: Crit EX15A01 erio n ID : (Fo r Pfi zer u se on ly):	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.k Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.k Criterion ID: (For Pfizer use only)

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry

2.1

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclu 17 sion Num ber: Crite Previous par rion ticipation in Descr other studies iption involving st : udy interven tion containi ng lipid nan oparticles Crite NO rion met?:	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

			Crite EX16A01 rion I D: (F or Pfi zer u se onl y):	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous participatio n in other studies in volving study interv ention containing lip id nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry
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2.m

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exc 22 lusi on Nu mbe r: Crit Investigator si erio te staff or Pfiz n D er employees escr directly involv ipti ed in the cond on: uct of the stud y, site staff oth erwise supervi sed by the inv estigator, and t heir respective family membe rs Crit NO erio n m et?:	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

			Crit EX21A01 erio n I D: (For Pfiz er u se o nly) :	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.m Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.m Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-30-2020 12:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Jul-30-2020 12:22:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jul-30-2020 12:22:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Jul-30-2020 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 1 H Num ber: Medical Diabetes History Mellitus Term: Type II Start D UNK/U ate: NK/198 6 Ongoin YES g:	Transcription Error
Jul-30-2020 13:21:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 1 H Numb er: Medical Dbetes History Mellitus Term: Type II Start Da UNK/U te: NK/198 6 Ongoing YES :	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

1.a Line/MH Number:

Date	Location	User	Value	Reason
Jul-30-2020 13:21:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Jul-30-2020 13:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetes Mellitus Type II	Transcription Error
Jul-30-2020 13:21:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dbetes Mellitus Type II	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Jul-30-2020 13:21:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1986	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

1.a Ongoing:

Date	Location	User	Value	Reason
Jul-30-2020 13:21:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Jul-30-2020 13:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 2 umber: Medical His Hyperte tory Term: nsion Start Date: UNK/U NK/199 5 Ongoing: YES	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Jul-30-2020 13:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Jul-30-2020 13:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jul-30-2020 13:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1995	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Jul-30-2020 13:23:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00)
Eastern Time (US
& Canada)

(b) (4), (b) (6)

I.c

Date	Location	User	Value	Reason
Jul-30-2020 13:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 3 Number: Medical History Term: Hypercholesterolemia Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

1.c Line/MH Number:

Date	Location	User	Value	Reason
Jul-30-2020 13:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Jul-30-2020 13:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypercholesterolemi a	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Jul-30-2020 13:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Jul-30-2020 13:24:12	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00)
Eastern Time (US
& Canada)

(b) (4), (b) (6)

1.d

Date	Location	User	Value	Reason
Jul-30-2020 13:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 4 H Num ber: Medical Laminect History omy Lum Term: bar Start D Feb/7/20 ate: 20 Ongoin NO g: End Da te: Feb/7/ 2020	Transcription Error
Jul-30-2020 13:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 4 H Numb er: Medical Laminec History tomy Lu Term: mbar Start Da Feb/7/2 te: 020	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

			Ongoing YES	
			:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Jul-30-2020 13:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Jul-30-2020 13:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Laminectomy Lumb ar	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Jul-30-2020 13:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/7/2020	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Jul-30-2020 13:36:06	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	End Date: Feb/7/2020	
Jul-30-2020 13:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Jul-30-2020 13:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 5 Number: Medical Onychomy History T cosis toe n erm: ails Start Date Apr/UNK/ : 2020 Ongoing: YES	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Jul-30-2020 13:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Jul-30-2020 13:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Onychomycosis toe nails	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Jul-30-2020 13:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2020	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Jul-30-2020 13:35:36	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00)
Eastern Time (US
& Canada)

(b) (4), (b) (6)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jul-30-2020 13:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jul-30-2020 13:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 86.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jul-30-2020 13:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Jul-30-2020 13:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 165.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Jul-30-2020 13:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Jul-30-2020 13:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 31.6	Initial Entry

7.a

Date	Location	User	Value	Reason
Jul-30-2020 13:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 98.6	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

			Temperatu F re Unit: Temperatu ORAL re Locatio CAVIT n:: Y	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Jul-30-2020 13:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jul-30-2020 13:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jul-30-2020 13:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Jul-30-2020 13:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Jul-30-2020 13:46:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-30-2020 13:46:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jul-30-2020 13:46:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Jul-30-2020 13:46:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Jul-30-2020 13:46:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jul-30-2020 13:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

6.a Sponsor ID:

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jul-30-2020 13:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jul-30-2020 13:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jul-30-2020 13:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3ff9\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: 11201002

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Jul-30-2020 13:41:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jul-30-2020 13:41:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 220363	Initial Entry

090177e196ae3ff9\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: 11201002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1120) Meridian Clinical Research

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Jul-30-2020 13:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-30-2020 13:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-30-2020 13:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-30-2020 13:42:11 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3ff9\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, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jul-30-2020 13:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Jul/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-30-2020 13:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP5R3 : 1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 13:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5R31	Initial Entry

5.b

090177e196ae3ff9\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, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jul-30-2020 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP5R3 : 2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5R32	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-30-2020 13:43:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP5R3 : 3	Initial Entry

090177e196ae3ff9\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, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 13:43:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5R33	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-30-2020 13:43:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPR2V D: B	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 13:43:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPR2VB	Initial Entry

5.e

Date	Location	User	Value	Reason
Jul-30-2020 13:43:49	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPR2V	Initial Entry

090177e196ae3ff9\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, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	D: C	
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5.e Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 13:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPR2VC	Initial Entry

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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, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

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
Jul-30-2020 13:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-30-2020 13:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-30-2020 13:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-30-2020 13:44:22 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

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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, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jul-30-2020 13:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Jul/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-30-2020 13:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP5R3 : 4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 13:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5R34	Initial Entry

090177e196ae3ff9\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: 11201002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Jul-30-2020 13:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jul-30-2020 13:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jul-30-2020 13:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** VACCINATION - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1120**Site Name:** (1120) Meridian Clinical Research**Subject No:** 11201002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09

Aug-13-2020 02:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Aug-12-2020 16:46:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Original value is correct
Aug-11-2020 21:56:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	Please can you review the time subject was dosed as it appears to be later than expected? Thank you
Jul-30-2020 13:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Jul/29/2020 20:33	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jul-30-2020 13:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

6. Body Side:

Date	Location	User	Value	Reason
Jul-30-2020 13:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jul-30-2020 13:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jul-30-2020 13:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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
Jul-30-2020 13:45:18	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ff9\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: 11201002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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)

(b) (4), (b) (6)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Jul-30-2020 13:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGE NICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3ff9\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: 11201002

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Aug-19-2020 16:41:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

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
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or sy N stemic symptoms O present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or sy N stemic symptom O s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

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.c Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C HI	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)			L LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.d Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TI NG Were fever or s NO ystemic sympto ms present on t he last day the S ubject Diary wa s completed?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.g

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR W ORSE NED MUSC LE PA IN</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO</p>	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D 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
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED J OINT PAIN	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? :	
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2.h Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-19-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

16:41:39
(UTC-05:00)
Eastern Time (US
& Canada)

(autocalc)

DELTOID MUSCLE

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Re RE action:: D NE SS Were injection si N te reactions pres O ent on the last d ay the Subject D iary was comple ted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry
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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
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT I NJE CTI ON S ITE	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

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?:	NO
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Aug-19-2020 16:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Aug-19-2020 16:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-19-2020 16:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: Temperature Unit: Temperature Location: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:00 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Aug-19-2020 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-19-2020 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

6.a Sponsor ID:

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-19-2020 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin B eta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3ff9\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, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

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
Aug-19-2020 16:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 16:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-20-2020 08:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-20-2020 03:33:13 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM query: 'Sample Collected?' is

090177e196ae3ff9\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, Locked, Frozen, Verified
Site No: 1120
Site Name: (1120) Meridian Clinical Research
Subject No: 11201002
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 11:09

Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate. Thank you.
Aug-19-2020 16:42:14 (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.
Aug-19-2020 16:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Aug/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-20-2020 08:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP8VD D: 3	Initial Entry

5.a Sample ID

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, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-20-2020 08:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8VD3	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Aug-19-2020 16:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-19-2020 16:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Aug-19-2020 16:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020 11:57	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-19-2020 16:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-19-2020 16:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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
Aug-19-2020 16:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ff9\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, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **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
Sep-16-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sep/16/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **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
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or sys N temic symptoms O present on the las t day the Subject Diary was comple ted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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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: 17-Jul-2020 21:54 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120 Site Name: (1120) Meridian Clinical Research

Subject No: 11201002 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:09

Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or sys N temic symptoms O present on the las t day the Subject Diary was compl eted?:	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120 Site Name: (1120) Meridian Clinical Research

Subject No: 11201002 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:09

2.b Symptom:

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (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
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120 Site Name: (1120) Meridian Clinical Research

Subject No: 11201002 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.c Symptom:

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: C HI	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120 Site Name: (1120) Meridian Clinical Research

Subject No: 11201002 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:09

Eastern Time (US & Canada)			L LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.d Symptom:

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (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
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae3ff9\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: 17-Jul-2020 21:54 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120 Site Name: (1120) Meridian Clinical Research

Subject No: 11201002 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:09

Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TI NG Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

090177e196ae3ff9\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: 17-Jul-2020 21:54 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120 Site Name: (1120) Meridian Clinical Research

Subject No: 11201002 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or sy NO stemic symptoms present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:09

2.g

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED MUSC LE PA IN Were fever or NO systemic sym ptoms presen t on the last d ay the Subjec t Diary was c ompleted?:	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120 Site Name: (1120) Meridian Clinical Research

Subject No: 11201002 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:09

2.g Symptom:

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D 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
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED J OINT PAIN	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:09

			Were fever or NO systemic symptoms present on the last day the Subject Diary was completed?:	
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2.h Symptom:

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120 Site Name: (1120) Meridian Clinical Research

Subject No: 11201002 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:09

(UTC-05:00)
Eastern Time (US
& Canada)

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Re RE action:: D NE SS Were injection si N te reactions prese O nt on the last day the Subject Diar y was completed ?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e196ae3ff9\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: 17-Jul-2020 21:54 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1120 Site Name: (1120) Meridian Clinical Research

Subject No: 11201002 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:09

Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry
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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
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Re SW action:: EL LI NG Were injection si NO te reactions pres ent on the last d ay the Subject D iary was comple ted?:	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:09

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site PAIN Reaction:: AT I NJE CTIO N SI TE	Initial Entry

090177e196ae3ff9\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: 17-Jul-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **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.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Sep-16-2020 16:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

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, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **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
Sep-16-2020 16:07:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 16:07:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 16:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 16:07:08 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

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, Locked, Frozen, Verified

Site No: 1120 Site Name: (1120) Meridian Clinical Research

Subject No: 11201002 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:09

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 16:07:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 16:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM50V4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 16:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM50V4	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

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, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:09

Sep-16-2020 16:07:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPR2MF	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 16:07:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPR2MF	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-16-2020 16:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPR2M : G	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 16:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPR2MG	Initial Entry

090177e196ae3ff9\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: 11201002

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
Feb-11-2021 14:01:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/10/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Feb-16-2021 15:17:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-16-2021 15:17:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-16-2021 15:18:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-16-2021 15:17:16 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-16-2021 15:17:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-16-2021 15:18:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BHVSS9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 15:18:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHVSS9	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Feb-16-2021 15:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BHDKV : L	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 15:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHDKVL	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-16-2021 15:18:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BHDKV : M	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 15:18:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHDKVM	Initial Entry

090177e196ae3ff9\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: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-17-2020 12:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-17-2020 12:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-17-2020 12:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3ff9\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: 11201002

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
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-08-2021 17:30:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	ok. Closing query to FU at a later date.
Mar-04-2021 14:59:51 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	WE DO NOT HAVE THAT INFORMATION

090177e196ae3ff9\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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				
Mar-04-2021 08:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for your response, no need to change information on CRF. Pls provide, in a FU letter, clinical presentation, workup (lab work/imaging), evolution after procedure, which is missing in the safety report. Thanks
Feb-26-2021 14:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	WHAT DOES THIS NEED TO BE CHANGED TOO?
Feb-22-2021 01:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Response does not satisfy query
Feb-19-2021 12:09:36 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Candidate	Response does not satisfy query

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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, Frozen

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
Feb-18-2021 09:18:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SUBJECT RECIEVED A HYSTERECTOMY WHICH PUT HER IN HOSTPITAL AND THAT IS THE SAE.
Feb-17-2021 05:09:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Medical Monitor_ Missing information on safety report - clinical presentation, workup (lab work/imaging), evolution after procedure. Pls provide MEd records. Thanks.
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fibroids	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-15-2021 14:06:59 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/27/2020 UNK:UNK	Initial Entry

090177e196ae3ff9\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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-21-2021 22:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 14:27:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-18-2021 14:27:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/26/2021 UN K:UNK	Changed Information
Feb-18-2021 13:30:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: End date reported on Safety database is 26-JAN-2021 however End date on CRF is 25-JAN-2021. Please confirm event end date.

090177e196ae3ff9\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:** 11201002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09

				If safety update is required, submit a follow-up SAE Form.
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/25/2021 UN K:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	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
Feb-18-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2:	Response satisfies query

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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

13:28:49 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Closed	
Feb-18-2021 10:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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?	Changed Information

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

			<p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Feb-18-2021 09:18:27 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SUBJECT WAS IN HOSPITAL FOR HYSTERECTOMY

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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, Frozen

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
Feb-17-2021 04:04:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 2: Opened	SAE RECON:AER#2021148932 Fibroids(onset date:27Dec2020)was reported as serious in Safety database but downgraded to on serious in AE CRF. Please confirm event seriousness. If safety update is required, submit a follow-up SAE Form.
Feb-17-2021 04:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Deleted	Query can be addressed internally
Feb-16-2021 00:03:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE fibroids : Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

090177e196ae3ff9\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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

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
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae3ff9\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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-18-2021 10:17:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	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, Frozen

Site No: 1120

Site Name: (1120) Meridian Clinical Research

Subject No: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-15-2021 14:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-16-2021 00:03:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021148932	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **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-24-2021 09:21:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/10/2021	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **Subject Initials:** ---

Generated By: (b) (4) **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-24-2021 09:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 09:22:01 (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-24-2021 09:22:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccina tion 3 Participant is: eligible per local/ national recomm endations and co nfirmed to have r	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1120 **Site Name:** (1120) Meridian Clinical Research

Subject No: 11201002 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:09

			received only plac ebo at Vaccinatio n 1/2	
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - 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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-24-2021 09:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/10/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-24-2021 09:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILIT Y FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT - 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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

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1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Feb-24-2021 09:22:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - 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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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-24-2021 09:22:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject Status

Date	Location	User	Value	Reason
Sep-17-2020 12:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jul-30-2020 13:41:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jul-30-2020 12:22:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Feb-16-2021 00:04:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-15-2021 14:07:16	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ae updated

090177e196ae3ff9\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: 11201002

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Feb-15-2021 05:51:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Op ened	SAE RECON:AER#2021148932 Fibroids(onset date:27Dec2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-17-2020 12:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/16/2020	Initial Entry
Jul-30-2020 13:41:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/29/2020	Initial Entry
Jul-30-2020 12:22:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/29/2020	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1120

Subject No: 11201002

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - 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. Casebook Signature

Date	Location	User	Value	Reason
Sep-01-2020 16:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3ff9\Final\Final On: 01-Apr-2021 05:27 (GMT)