

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[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	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/11/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10931128]
2.	Birth Date:	(b) (6)/1963
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/11/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	---	-------------------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/11/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERTROPHIC CARDIOMYOPATHY]
	Start Date:	UNK/UNK/1976
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERTENSION]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERCHOLESTEROLEMIA]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SEPTAL MYECTOMY]
	Start Date:	Jul/12/2019
	Ongoing:	NO End Date: Jul/12/2019

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/11/2020
2.	Weight:	[301.0]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[40.8]

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: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/11/2020
2.	Randomization Number:	[258143]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/11/2020
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	[BP5DDW]
5.b	Sample ID	[BPR6NR]
5.c	Sample ID	[BPR6NP]

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/11/2020
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	[BPR6NN]
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090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[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:	Sep/11/2020 16:54
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

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	--	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/30/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/30/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[SUBJECT NOT VACCINATED DUE TO HAVING HIGH BP. SUB TO F/U WITH PCP AND/OR CARDIOLOGIST.]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Sep/30/2020 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS	
2.	Treatment Name	[]	
3.	Formulation:		
4.	Dose Date Time:	Not Done _____ //	Comments
5.	Anatomical Location:		
6.	Body Side:	Not Applicable _____	Comments
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?	Not Applicable _____	Comments

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/18/2020
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	[BN5HBD]
5.b	Sample ID	[BSHLTK]
5.c	Sample ID	[BSHLTJ]

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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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090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/18/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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 - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	WORSENING HYPERTENSION	Sep/30/2020 00:00	NO End Date Time: Oct/21/2020 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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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)	[WORSENING HYPERTENSION]
4.	Start Date Time:	Sep/30/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/21/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [UNDERLYING MEDICAL CONDITION]
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

#	Category	Medication Error	Start Date	Is the medication error Still On going	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[Back to Form](#)

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	[]

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

[Back to Form](#)

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:	//

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[Back to Form](#)

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?	

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[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?	

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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?	

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/28/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Queries

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/28/2021
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: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/18/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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Item	Date	User	Comment
Form	Sep-11-2020 17:35:45 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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Item	Date	User	Comment
4	Nov-18-2020 15:36:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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Item	Date	User	Comment
6	Nov-18-2020 15:37:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
6	Nov-18-2020 15:36:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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Item	Date	User	Comment
11	Nov-18-2020 15:36:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

[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	Nov-18-2020 15:33:59 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

David Ensز	Approved	Nov-17-2020 17:48:12 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, DavidEnsز, 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	Nov-17-2020 09:15:58 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

Affidavit:

N/A

David Ensز	Approved	Oct-29-2020 08:33:23 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, DavidEnsز, 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.

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-11-2020 17:35:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 17:35:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Sep-11-2020 17:35:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/11/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Subject ID

Date	Location	User	Value	Reason
Sep-11-2020 17:35:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10931128	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-11-2020 17:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1963	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-11-2020 17:35:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-11-2020 17:35:33 (UTC-06:00) Central 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
Sep-11-2020 17:35:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-19-2020 05:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	opened on v2
Nov-17-2020 11:39:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Nov-17-2020 09:16:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	AE UPDATED
Nov-16-2020 17:40:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Liaw (b) (4)	Query 2: Reissued:Opened	GPD CLIN: Please update AE log as soon as possible as per query response.
Nov-16-2020 16:59:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	WILL UPDATE AE PAGE WITH WORSENING HYPERTENSION
Nov-14-2020 01:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	to follow up: VISIT 2 IS SCHEDULED FOR 18NOV2020
Nov-13-2020 17:34:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	VISIT IS SCHEDULED FOR 18NOV2020
Nov-13-2020 06:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: As per the previous response, kindly confirm when is Visit 2 is rescheduled, thank you.
Nov-12-2020 10:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Per information provided in query response it appears visit 2 has been delayed due to review with cardiologist for conditions (AF,

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

				elevated BP). Please review if these are considered adverse events to be captured in the CRF
Nov-10-2020 00:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	To be tracked for Visit 2 scheduling
Nov-09-2020 15:53:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SUBJECT WILL BE RESCHEDULED FOR VISIT
Nov-07-2020 09:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM2: Thank you for response, please consider to update the data when actual visit performed.
Oct-15-2020 03:47:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	DM2: Thank you for response, please consider to update the data when actual visit performed.
Oct-14-2020 13:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SUBJECT NOT VACCINATED DUE TO NEEDING TO FOLLOW UP WITH PCP/CARDIOLOGIST DUE TO ATRIAL FIBRILATION AND ELEVATED BP.
Oct-07-2020 08:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thank you for your response. However, please keep the query open until updates are made. Else clarify.
Oct-06-2020 07:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THERE ARE NO DETAILS TO ENTER INTO VISIT 2, SUBJECT WAS NOT VACCINATED THIS DAY
Oct-06-2020 04:24:26	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Details on visit

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		'V2VX2L' are missing. Kindly consider to update or else clarify. Thank you.
Sep-11-2020 17:35:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-11-2020 17:35:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-11-2020 17:35:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-11-2020 17:35:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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I.a

Date	Location	User	Value	Reason
Sep-11-2020 17:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 1 umber: Medical His HYPERTROPHIC C tory Term: ARDIOMYOPATHY Start Date: UNK/UNK/1976 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 17:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 17:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HYPERTROPHIC CARDIOMYOP ATHY	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 17:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1976	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 17:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Sep-11-2020 17:37:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History Term: HYPERTENSION Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 17:37:20 (UTC-06:00) Central 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
Sep-11-2020 17:37:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HYPERTENSION	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 17:37:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 17:37:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-11-2020 17:37:30 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

(US & Canada)			Number: Medical History Term: HYPERCHOLESTEROLEMIA Start Date: UNK/UNK/2018 Ongoing: YES
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1.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 17:37:30 (UTC-06:00) Central 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
Sep-11-2020 17:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HYPERCHOLESTEROLEMIA	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 17:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 17:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Sep-11-2020 17:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: SEPTAL MYEC TOMY Start Date: Jul/12/2019	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

			Ongoing:	NO
				End Date:
				Jul/12/2019

I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 17:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 17:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SEPTAL MYECTOMY	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 17:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/12/2019	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 17:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jul/12/2019	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Date:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-18-2020 04:54:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-17-2020 10:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	OUT OF RANGE VALUE IS NCS
Sep-12-2020 03:38:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Confirmation on the out of range value as clinically significant or not is expected. Please review and confirm. Thank you.
Sep-11-2020 17:57:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-11-2020 17:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Weight 301 is outside of Normal Range 25 - 136 for kg or 50 - 300 for lb.
Sep-11-2020 17:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 301.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

4. Height:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 72.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 40.8	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-11-2020 17:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.6 Temperature Unit: F Temperature Locat ion:: ORAL CAVI TY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:13 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.6	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

(US & Canada)		(b) (4), (b) (6)	
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7.a Unit:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-11-2020 17:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 258143	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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1. Data Origin

Date	Location	User	Value	Reason
Sep-11-2020 17:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-11-2020 17:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-11-2020 17:59:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 17:38:32 (UTC-06:00) Central 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.
Sep-11-2020 17:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-11-2020 17:59:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5DDW	Initial Entry

5.a Sample ID

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Sep-11-2020 17:59:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP5DDW	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-11-2020 18:00:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPR6NR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 18:00:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPR6NR	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-11-2020 18:00:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPR6NP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 18:00:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPR6NP	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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1. Data Origin

Date	Location	User	Value	Reason
Sep-11-2020 17:38:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-11-2020 17:38:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-11-2020 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 17:38:40 (UTC-06:00) Central 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.
Sep-11-2020 17:38:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-11-2020 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPR6NN	Initial Entry

5.a Sample ID

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Sep-11-2020 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPR6NN	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-11-2020 17:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-11-2020 17:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020 16:54	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

7. Route:

Date	Location	User	Value	Reason
Sep-11-2020 17:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-11-2020 17:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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
Sep-11-2020 17:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-11-2020 17:39:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-02-2020 00:39:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-01-2020 10:16:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PLEASE UNFREEZE FORM SO THIS MAY BE DONE.
Nov-26-2020 04:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM2: EOT details are present. If subject was not vaccinated, please consider to remove existing data on Vaccination CRF and add form level 'Not Done' comment. Thanks
Nov-25-2020 14:48:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	VACCINATION WAS NOT GIVEN AT V2. V2 VISIT IS UPDATED.
Nov-23-2020 01:12:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Kindly confirm if vaccination is given at V2VX2L visit and other assessments are performed at this visit. If yes then update data on all the required forms under 'V2VX2L' visit as appropriate. Else clarify.
Nov-20-2020 17:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	WILL UPDATE V2 FORM
Nov-19-2020 05:49:28 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: As per the previous response on

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Time (US & Canada)				V1, kindly verify and update V2 form. Thank you.
Nov-18-2020 15:33:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Date:

Date	Location	User	Value	Reason
Nov-18-2020 15:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-18-2020 15:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.9 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-18-2020 15:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-18-2020 15:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-18-2020 15:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Nov-18-2020 15:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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1. Data Origin

Date	Location	User	Value	Reason
Nov-18-2020 15:35:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-18-2020 15:35:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-18-2020 15:35:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-23-2020 04:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	AF removed from description
Nov-20-2020 17:03:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-20-2020 17:03:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SUBJECT NOT VACCINATED D UE TO HAVING HIGH BP. SUB TO F/U WITH PCP AND/OR CA RDILOGIST.	Transcription Error
Nov-20-2020 05:25:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Elevated BP has been entered in as an AE but not the Atrial Fibrillation. Please

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

				review and clarify whether this AF information is to be added as an AE
Nov-18-2020 15:35:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SUBJECT NOT VACCINATED DUE TO BEING IN ATRIAL FIBRILLATION AS WELL AS HAVING HIGH BP. SUB TO F/U WITH PCP AND/OR CARDIOLOGIST.	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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I. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-18-2020 15:36:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First Delay: Sep/30/2020 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-18-2020 15:36:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-18-2020 15:37:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-18-2020 15:36:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Nov-18-2020 15:36:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-18-2020 15:37:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/18/2020	Initial Entry

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, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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1. Data Origin

Date	Location	User	Value	Reason
Nov-18-2020 15:37:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-18-2020 15:37:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-06-2021 08:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-05-2021 16:00:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	ENTERIES ADDED
Jan-05-2021 12:17:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	HOLDS: For Visit 3, the lab has received a sample with a barcode of BSHLTJ and BSHLTK; however, the barcodes have not been reported for this Visit. Please review and update as appropriate. Otherwise, please clarify.
Nov-19-2020 09:48:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (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, Frozen, Verified**Site No:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931128**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31

Nov-19-2020 03:37:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-18-2020 15:37:43 (UTC-06:00) Central 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.
Nov-18-2020 15:37:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-19-2020 09:48:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN5HBD	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 09:48:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN5HBD	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-05-2021 16:00:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHLTK	Initial Entry

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, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

5.b Sample ID

Date	Location	User	Value	Reason
Jan-07-2021 01:59:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-06-2021 14:22:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ENTRY UPDATED
Jan-05-2021 22:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6706090;The barcode BSHLTK is recorded for two subjects 10931128 and 10931143, please review and update as appropriate.
Jan-05-2021 16:00:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHLTK	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-05-2021 16:00:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHLTJ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-05-2021 16:00:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHLTJ	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-18-2020 15:38:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-18-2020 15:38:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-01-2020 14:59:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_DS001_25
Dec-01-2020 11:24:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Dec-01-2020 10:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	AE WILL BE UPDATED.
Nov-30-2020 20:19:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW6279323;Status is reported as Adverse Event, but there is no Adverse Event with 'Latest Action Taken with

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (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, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

				Study Treatment' reported as DRUG WITHDRAWN. Please review and update as appropriate.
Nov-30-2020 16:08:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-30-2020 16:08:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ADVERSE EVENT	Transcription Error
Nov-26-2020 06:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued: Opened	CLINQUERY: EOT due to Worsening Hypertension: Please update status on EOT page to ADVERSE EVENT and on the AE log update q10 'Last Action Taken with study treatment' to DRUG WITHDRAWN
Nov-25-2020 14:47:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SUBJECT WAS NOT VACCINATED DUE TO PROVIDER DISCRETION OF WORSENING HYPERTENSION.
Nov-23-2020 07:27:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: End of treatment status is reported as COMPLETED. However, second vaccination was not given. Please review status field and update to reflect

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (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, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

				reason for EOT.
Nov-18-2020 15:38:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Nov-17-2020 09:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Category:

Date	Location	User	Value	Reason
Nov-17-2020 09:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-17-2020 09:15:58 (UTC-06:00) Central 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
Nov-17-2020 09:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WORSENING HYPERTENSION	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-17-2020 09:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-01-2020 10:15:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/21/2020 UNK:UNK	Transcription Error
Nov-23-2020 01:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data entered.
Nov-20-2020 17:05:54 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	FORM UPDATED

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Time (US & Canada)				
Nov-17-2020 23:23:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete item # 6 to 14. Thank you.
Nov-17-2020 09:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-20-2020 17:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-20-2020 17:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-20-2020 17:05:27 (UTC-06:00) Central 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
Nov-20-2020 17:07:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:	Transcription Error

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Generated Time (GMT): 29-Mar-2021 10:31

			OTHER <i>If Other, specify:</i> UNDERLYING MEDICAL CONDITION	
Nov-20-2020 17:05:27 (UTC-06:00) Central 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> UNDERLYING MEDICAL CONDITION	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-01-2020 11:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Dec-01-2020 10:15:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Dec-01-2020 10:15:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Transcription Error
Dec-01-2020 05:03:23 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: EOT tab reported subject was discontinued from treatment due to

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Canada)				worsening hypertension. If correct, please review this entry on the AE line.
Nov-25-2020 20:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_AE001_32
Nov-25-2020 14:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-25-2020 14:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Transcription Error
Nov-22-2020 23:10:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5441224;The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Disposition-Treatment Form Status is not DEATH OR ADVERSE EVENT. Please review and update as appropriate.
Nov-20-2020 17:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

II. Was a Concomitant Medication given?

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1093) Meridian Clinical Research

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Generated Time (GMT): 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Nov-20-2020 17:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-20-2020 17:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-01-2020 14:59:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_AE001_35
Dec-01-2020 10:16:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	END DATE HAS BEEN UPDATED.
Nov-25-2020 20:25:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW6245515;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Nov-25-2020 14:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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Generated Time (GMT): 29-Mar-2021 10:31

Nov-25-2020 14:46:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : REC OVE RED/ RESO LVED	New Information
Nov-20-2020 17:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Op ened	For AE WORSENING HYPERTENSION: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Nov-20-2020 17:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : UNK NOW N	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 17:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-26-2021 13:53:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Queries

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Mar-13-2021 00:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Vaccination 3 is reported in IRT, however, this form indicates that the participant was not confirmed as placebo. Please review, reconcile the response with the source as well as enter the Vax 3 and/or Vax 4 visits, if completed or explain otherwise.
Feb-26-2021 13:54:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-26-2021 13:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-26-2021 13:53:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADD ITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1. Subject Status

Date	Location	User	Value	Reason
Nov-30-2020 16:08:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Transcription Error
Nov-18-2020 15:38:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-11-2020 17:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-11-2020 17:35:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-30-2020 16:08:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/18/2020	Transcription Error
Nov-18-2020 15:38:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/18/2020	Initial Entry
Sep-11-2020 17:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/11/2020	Initial Entry
Sep-11-2020 17:35:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/11/2020	Initial Entry

090177e196ae2f50\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1093

Subject No: 10931128

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-28-2020 15:11:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry