

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[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	08 SEP 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: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/30/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11101321]
2.	Birth Date:	(b) (6)/1966
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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: 15-Sep-2020 21:52

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Sep/30/2020
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: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hyperlipidemia]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anxiety]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	---	---

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/30/2020
2.	Weight:	[219.1]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[29.7]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.2]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/30/2020
2.	Randomization Number:	[102238]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
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	[BPY0CW]
5.b	Sample ID	[BRVHT7]
5.c	Sample ID	[BRVHT8]

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
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	[BPW971]
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090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[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/30/2020 12:05
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

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[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: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/20/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPW9CF]
-----	-----------	----------

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/20/2020 11:26
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

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[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: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[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	[BRVHWW]
5.b	Sample ID	[BRVHWX]
5.c	Sample ID	[BPW5BG]

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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?	
----	--	--

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: Unplanned 1 - Unscheduled Visit on
Oct/22/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/22/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/22/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/22/2020 Contact Outcome: VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY
3.	Comments:	[]

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Oct/23/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Oct/23/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Oct/23/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/23/2020 Contact Outcome: VISIT ARRANGED
3.	Comments:	[Subject present 2 lymph node in the neck, left side. Lymphadenopathy]

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Oct/23/2020

Form: VITAL SIGNS - TEMP

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/23/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Unplanned Assessment Of Local Reaction

1.	Date of Assessment:	Oct/23/2020
2.	Injection Site Location	DELTOID MUSCLE
3.	Injection Site Body Side:	LEFT

Reaction

4.a	Reaction:	REDNESS
	Reaction Present:	NO
4.b	Reaction:	SWELLING
	Reaction Present:	NO

Symptom

5.a	Symptom:	PAIN AT INJECTION SITE
	Symptom Present:	NO
5.b	Symptom:	FATIGUE/TIREDNESS
	Symptom Present:	NO
5.c	Symptom:	HEADACHE
	Symptom Present:	NO
5.d	Symptom:	VOMITING
	Symptom Present:	NO
5.e	Symptom:	DIARRHEA
	Symptom Present:	NO
5.f	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Symptom Present:	NO
5.g	Symptom:	NEW OR WORSENERED JOINT PAIN
	Symptom Present:	NO

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.h	Symptom:	CHILLS
	Symptom Present:	NO

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Lymphadenopathy to left neck	Oct/21/2020 UNK:UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	Neutropenia	Oct/26/2020 UNK:UNK	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Lymphadenopathy to left neck]
4.	Start Date Time:	Oct/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Neutropenia]
4.	Start Date Time:	Oct/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[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	[]

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Concomitant Medications

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

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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Concomitant Medications

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

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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?	

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/25/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/25/2021
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPZXB6]
5.b	Sample ID	[BSGVTF]
5.c	Sample ID	[BSGVTD]

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN4Z6H]
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090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Disposition - Follow-Up

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

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled **Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE
Visit on Mar/11/2021

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/11/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
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Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Visit on Mar/11/2021

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR16GN]
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090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[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: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/20/2021
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: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/18/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jeffrey Rosen	Approved	Mar-12-2021 18:52:01 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, JeffreyRosen, 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.

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
Form	Oct-05-2020 19:51:31 (UTC-05:00) Eastern 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, Signed, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jeffrey Rosen	Approved	Mar-12-2021 18:52:01 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, JeffreyRosen, 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	Mar-11-2021 15:39:34 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jeffrey Rosen	Approved	Mar-01-2021 18:27:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, JeffreyRosen, 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	Feb-25-2021 15:55:24 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Jeffrey Rosen	Approved	Feb-23-2021 22:05:48 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, JeffreyRosen, 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	Feb-22-2021 15:01:02 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jeffrey Rosen	Approved	Dec-10-2020 17:26:35 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, JeffreyRosen, 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-18-2020 13:38:08 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Jeffrey Rosen	Approved	Nov-12-2020 09:19:08 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Status: Data Complete, Signed, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Affidavit:

By my dated signature below, I, JeffreyRosen, 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.

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-05-2020 19:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 19:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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I. Consent Was:

Date	Location	User	Value	Reason
Oct-05-2020 19:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/30/2020	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Subject ID

Date	Location	User	Value	Reason
Oct-05-2020 19:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11101321	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-05-2020 19:50:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1966	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-05-2020 19:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-05-2020 19:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 19:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRICAN AMERI CAN	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-05-2020 19:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-05-2020 19:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-05-2020 19:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-05-2020 19:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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I.a

Date	Location	User	Value	Reason
Oct-05-2020 19:52:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: hypertension Start Date: UNK/UNK/2006 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-05-2020 19:52:41 (UTC-05:00) Eastern 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
Oct-05-2020 19:52:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypertension	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Oct-05-2020 19:52:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2006	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Oct-05-2020 19:52:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Oct-05-2020 19:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: hyperlipidemia Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-05-2020 19:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 19:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hyperlipidemia	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Oct-05-2020 19:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-05-2020 19:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-05-2020 19:53:49 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)			Medical History Term:	anxiety
			Start Date:	UNK/UNK/2006
			Ongoing:	YES

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-05-2020 19:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 19:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: anxiety	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-05-2020 19:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2006	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-05-2020 19:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Oct-05-2020 19:53:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date:

Date	Location	User	Value	Reason
Oct-05-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-05-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 219.1	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-05-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-05-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 72.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-05-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-05-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29.7	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

7.a

Date	Location	User	Value	Reason
Oct-05-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.2 Temperature Unit: C Temperature Locat FOREHE ion:: AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-05-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-05-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-05-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-05-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-05-2020 19:55:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-05-2020 19:55:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 102238	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Oct-05-2020 19:57:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-05-2020 19:57:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-05-2020 19:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-05-2020 19:57:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-05-2020 19:57:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-05-2020 19:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPY0CW	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 19:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPY0CW	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-05-2020 19:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRVHT7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 19:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVHT7	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-05-2020 19:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRVHT8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 19:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVHT8	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Oct-05-2020 19:56:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-05-2020 19:56:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-05-2020 19:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-05-2020 19:56:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-05-2020 19:56:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-05-2020 19:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPW971	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 19:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW971	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-05-2020 19:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-05-2020 19:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-05-2020 19:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-05-2020 19:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 12:05	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-05-2020 19:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-05-2020 19:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

7. Route:

Date	Location	User	Value	Reason
Oct-05-2020 19:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-05-2020 19:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 19:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-05-2020 19:55:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-20-2020 18:16:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date:

Date	Location	User	Value	Reason
Oct-20-2020 18:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-20-2020 18:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.3 Temperature Unit: C Temperature Locat ion:: FOREHE AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-20-2020 18:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-20-2020 18:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-20-2020 18:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Oct-20-2020 18:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Oct-20-2020 18:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-20-2020 18:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-20-2020 18:18:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 18:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-20-2020 18:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 18:18:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPW9CF	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 18:18:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW9CF	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-20-2020 18:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-20-2020 18:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-20-2020 18:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-20-2020 18:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020 11:26	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-20-2020 18:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-20-2020 18:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

7. Route:

Date	Location	User	Value	Reason
Oct-20-2020 18:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-20-2020 18:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 18:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-18-2020 13:38:08 (UTC-05:00) Eastern 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, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Nov-18-2020 13:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-18-2020 13:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-18-2020 13:40:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-18-2020 13:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-18-2020 13:38:22 (UTC-05:00) Eastern 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-18-2020 13:40:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRVHWW	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a Sample ID

Date	Location	User	Value	Reason
Nov-18-2020 13:40:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVHWW	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-18-2020 13:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRVHWX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-18-2020 13:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVHWX	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-18-2020 13:40:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPW5BG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-18-2020 13:40:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW5BG	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/22/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-22-2020 18:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Oct/22/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/22/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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I. Assessments

Date	Location	User	Value	Reason
Oct-22-2020 18:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 18:12:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-22-2020 18:12:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/22/2020

Form Version: 22-Apr-2020 21:04

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Contact Type:

Date	Location	User	Value	Reason
Oct-22-2020 18:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Oct-22-2020 18:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: YES Date of Contact: Oct/22/2020 Contact Outcome: VISIT NOT REQUIRED, DA TA ENTRY ERROR IN E-DI ARY	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Oct/23/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-23-2020 17:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Oct/23/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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I. Assessments

Date	Location	User	Value	Reason
Oct-23-2020 17:42:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-23-2020 17:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-23-2020 17:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001**Visit:** Unplanned 2 - Unscheduled Visit on Oct/23/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1110**Subject No:** 11101321**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1110) Clinical Research of South Florida**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Oct-23-2020 17:42:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-23-2020 17:42:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Oct-23-2020 17:42:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Oct/23/2020 Contact Outcome: VISIT ARRANGED	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Oct-23-2020 17:46:25 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject present 2 lymph node in	Transcription Error

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form Version: 22-Apr-2020 21:04

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)		(b) (4), (b) (6)	the neck, left side. Lymphadeno pathy	
Oct-23-2020 17:45:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: lymphadenopathy	Initial Entry

Header Text: c4591001**Visit:** Unplanned 2 - Unscheduled Visit on
Oct/23/2020**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:01**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1110**Site Name:** (1110) Clinical Research of South Florida**Subject No:** 11101321**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Oct-23-2020 17:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Oct/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-23-2020 17:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Record Identifier:: 1 Temperature: 36.3 Temperature Unit: C Temperature Locat ion:: FOREHE AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-23-2020 17:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-23-2020 17:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: 36.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Oct-23-2020 17:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry
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2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-23-2020 17:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001**Visit:** Unplanned 2 - Unscheduled Visit on Oct/23/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1110**Subject No:** 11101321**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1110) Clinical Research of South Florida**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/23/2020	Initial Entry

2. Injection Site Location

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-23-2020 17:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: REDNESS Reaction Present:: NO	Initial Entry

4.a Reaction:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

		(b) (4), (b) (6)		
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4.a Reaction Present:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Reaction:: SWELLIN G Reaction Present: NO :	Initial Entry

4.b Reaction:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: PAIN AT INJECT ION SITE Symptom Pr NO esent::	Initial Entry
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5.a Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGUE/TIRE DNESS Symptom Pre NO sent::	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 15:57

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

5.b Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE/TIREDNESS	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACH E Symptom Present NO ::	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 15:57

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

5.c Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VOMITIN G Symptom Present: NO :	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 15:57

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

5.d Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIARRHE A Symptom Present: NO :	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 15:57

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

5.e Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR WORSEN :: ED MUSCLE PAIN Symptom NO Present::	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.f Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER MUSCLE PAIN	Initial Entry

5.f Symptom Present:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR WORSENER JOINT PAIN Symptom Present:: NO	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 15:57

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

5.g Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

5.g Symptom Present:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CHILLS Symptom Present:: NO	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 15:57

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

5.h Symptom:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

5.h Symptom Present:

Date	Location	User	Value	Reason
Oct-23-2020 17:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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Date	Location	User	Value	Reason
Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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Date	Location	User	Value	Reason
Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted] [Redacted]	Form Created	

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Category:

Date	Location	User	Value	Reason
Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-27-2020 12:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Oct-27-2020 12:17:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-27-2020 12:17:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Lymphadenopathy to left neck	Transcription Error
Oct-26-2020 13:07:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify the term: 1) Please remove "reactive to" if it means study drug related, as this point is reflected in the causality field; 2) Please add location in the term, e.g., axillary, etc.

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: reactive to left lymphadenopath y	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-18-2020 09:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 2: Closed	Response satisfies query
Dec-14-2020 15:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	still ongoing
Dec-14-2020 06:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 2: Opened	Clin: Please confirm if this AE is still ongoing
Nov-09-2020 12:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Nov-09-2020 12:24:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	still ongoing
Nov-09-2020 10:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please confirm if this AE is still ongoing
Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

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Site Name: (1110) Clinical Research of South Florida

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Oct-23-2020 17:59:08 (UTC-05:00) Eastern 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
Oct-23-2020 17:59:08 (UTC-05:00) Eastern 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
Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Visit: Logs - Unscheduled

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Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-23-2020 17:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-06-2020 17:47:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Closed	Response satisfies query
Nov-06-2020 16:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	As verbally reporter by subject no prior history of neutropenia.
Nov-05-2020 21:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Opened	GPDClin: Any historic data for neutrophil count? Any other lab abnormalities?
Nov-05-2020 06:56:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-04-2020 18:48:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated

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Header Text: c4591001

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Nov-03-2020 09:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	clinical: per appendix 2 500-999 cells/mm3 =grade 3 toxicity. Based on prior response of 858 cells, AE would meet criteria for G3 toxicity. Pls clarify discrepancy.
Nov-02-2020 17:46:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Grading is mild grade 1 base on appendix 2 of protocol. Neutropenia still ongoing.
Oct-30-2020 14:20:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	clinical-Thank you, please see appendix 2 of protocol for grading of labs and update CRF to reflect grading by this scale. pls also confirm that ongoing or update end date. Thanks
Oct-30-2020 10:19:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Per labs neutrophils 858 cells/uL
Oct-29-2020 19:35:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	clinical-pls advise on lab value for neutropenia
Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Neutropenia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

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Generated By: (b) (4)

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Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-04-2020 18:48:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Transcription Error
Oct-27-2020 12:21:05 (UTC-05:00) Eastern 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
Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

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Form Status: Data Complete

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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
Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-11-2020 12:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 12:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	is related because there is no other etiology.
Nov-10-2020 07:49:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	clinical: thank you, pls comment on relatedness determination.
Nov-09-2020 17:24:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	still ongoing
Nov-09-2020 16:43:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise on biological basis for assessment of AE as 'related' and confirm AE is ongoing or update CRF with end date
Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete

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Site Name: (1110) Clinical Research of South Florida

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Subject Initials: ---

Generated By: (b) (4)

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-27-2020 12:21:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 16:41:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Transcription Error
Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

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Subject No: 11101321

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

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Oct-27-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted] [Redacted]	Data Entry: NO	Initial Entry
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090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-18-2020 13:38:38 (UTC-05:00) Eastern 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 13:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-18-2020 13:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-25-2021 15:55:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/25/2021	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 14-Jan-2021 02:29

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

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1. Consent Was:

Date	Location	User	Value	Reason
Feb-25-2021 15:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/25/2021	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

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1. Data Origin

Date	Location	User	Value	Reason
Feb-25-2021 16:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-25-2021 16:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-25-2021 16:22:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-25-2021 16:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 16:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-25-2021 16:22:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZXB6	Initial Entry

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Header Text: c4591001

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Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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5.a Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 03:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Closed	Closed as data updated on SWAB PFE form of this visit.
Feb-27-2021 18:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Answer red	this barcode is correct for this subject
Feb-26-2021 16:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Opened	DMW7478451;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-25-2021 16:22:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZXB 6	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-25-2021 16:22:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSGVTF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 16:22:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGVTF	Initial Entry

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Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
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Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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Form Status: Data Complete, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

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5.c

Date	Location	User	Value	Reason
Feb-25-2021 16:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSGVTD	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 16:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGVTD	Initial Entry

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1110**Subject No:** 11101321**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1110) Clinical Research of South Florida**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-25-2021 16:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-25-2021 16:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-25-2021 16:25:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-25-2021 16:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 16:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-27-2021 18:01:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN4Z6H	Transcription Error

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

		(b) (4), (b) (6)		
Feb-25-2021 16:25:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZXB6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 02:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Closed	Response satisfies query
Feb-27-2021 18:01:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Answered	Transcription Error
Feb-27-2021 18:01:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN4Z6 H	Transcription Error
Feb-26-2021 17:35:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Opened	DMW7478552;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-25-2021 16:25:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZXB 6	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Mar/11/2021

Form: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE - eCRF
Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 15:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/11/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Mar-11-2021 15:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK2	Initial Entry

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled Visit on Mar/11/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Mar-11-2021 15:39:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-11-2021 15:39:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-11-2021 15:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 15:39:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-11-2021 15:39:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-11-2021 15:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR16GN	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled Visit on Mar/11/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR16GN	Initial Entry

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: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-22-2021 15:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/20/2021	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, Frozen

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Date	Location	User	Value	Reason
Feb-22-2021 15:01:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 15:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-22-2021 15:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return fo r Vaccination 3 Participant is: eligible and NOT confirmed t o have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-26-2021 08:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-25-2021 19:02:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-25-2021 19:02:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Feb/20/2021	Transcription Error
Feb-24-2021 04:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7391049;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Feb-22-2021 15:01:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Feb/18/2021	Initial Entry

2. Primary Reason for Unblinding:

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Feb-22-2021 15:01:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1110

Subject No: 11101321

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1110) Clinical Research of South Florida

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Subject Status

Date	Location	User	Value	Reason
Nov-18-2020 13:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-05-2020 19:55:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-05-2020 19:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-18-2020 13:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/18/2020	Initial Entry
Oct-05-2020 19:55:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/30/2020	Initial Entry
Oct-05-2020 19:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/30/2020	Initial Entry

090177e196ae3d92\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101321

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-08-2020 20:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry