

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Informed Consent**

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11111092]
2.	Birth Date:	(b) (6) 1954
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** DATE OF VISIT

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**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 _____
----	----------------------------------------	-------------------------

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Disposition - Screening**

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

**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Kidney stones]
	Start Date:	UNK/UNK/2008
	Ongoing:	NO End Date: UNK/UNK/2010
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Farsighted]
	Start Date:	UNK/UNK/2004
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Muscle spasms (back)]
	Start Date:	UNK/UNK/1983
	Ongoing:	YES

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Overweight]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/11/2020
2.	Weight:	[248.6]
3.	Unit:	LB
4.	Height:	[72.5]
5.	Unit:	in
6.	Body Mass Index:	[33.2]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** RANDOMIZATION

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/11/2020
2.	Randomization Number:	[225457]
3.	Randomization Group:	[ ]

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1111**Site Name:** (1111) Fleming Island Center for Clinical Research**Subject No:** 11111092**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 21-Apr-2021 18:02[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5C92]
5.b	Sample ID	[BP5C93]
5.c	Sample ID	[BP5C94]
5.d	Sample ID	[BLD2R9]
5.e	Sample ID	[BLD2RB]

**Header Text:** c4591001

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

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

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5C95]
-----	-----------	----------

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** VACCINATION

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vaccination**

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
----	---------------------------------------------------------------------	------------------------------------------------------------

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:30

**Site No:** 1111

**Subject No:** 11111092

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

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

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

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vital Signs**

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

**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
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	[BPY9YJ]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** VACCINATION

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[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/1/2020 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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

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

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research**Subject No:** 11111092 **Subject Initials:** ---**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/1/2020
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	[BP9RK7]
5.b	Sample ID	[BP9RK8]
5.c	Sample ID	[BP9RK9]
5.d	Sample ID	[BNW9KM]
5.e	Sample ID	[BNW9KN]

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** DATE OF VISIT

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001**Visit:** V4\_MONTH6\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1111**Site Name:** (1111) Fleming Island Center for Clinical Research**Subject No:** 11111092**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 21-Apr-2021 18:02[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	[BP9R8K]
5.b	Sample ID	[BP9R8L]
5.c	Sample ID	[BP9R8M]
5.d	Sample ID	[BRTJ04]
5.e	Sample ID	[BRTJ05]

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**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:** 1111

**Subject No:** 11111092

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**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	[ ]
----	-----------	-----

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**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:** 1111

**Subject No:** 11111092

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/6/2021
2.	Erroneous Visit	ERRONEOUS VISIT

**COVID-19 Illness Visit**

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021**Form Version:** 10-Dec-2020 02:29**Site No:** 1111**Subject No:** 11111092**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19**Form Status:** Data Complete, Frozen**Site Name:** (1111) Fleming Island Center for Clinical  
Research**Subject Initials:** ---**Generated Time (GMT):** 21-Apr-2021 18:02[Form Comments](#)[eCRF Audit Trail History](#)**Signs and Symptoms**

1.	Date of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Date of First Symptom Started:	Not Applicable _____ //	<a href="#">Comments</a>
3.	Symptoms Ongoing?	Not Applicable _____	<a href="#">Comments</a>

**Symptoms**

4.a	Symptoms:	FEVER	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.b	Symptoms:	NEW OR INCREASED COUGH	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

4.d	Symptoms:	CHILLS	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.g	Symptoms:	NEW OR INCREASED SORE THROAT	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.h	Symptoms:	DIARRHEA	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.i	Symptoms:	VOMITING	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
<b>Symptoms - Other</b>			
5.	Symptoms - Other Text:	Not Applicable _____ [ ]	

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	//
2.	Specimen Type:	
3.	Specimen Collection Location:	
4.	Assay Code and Description:	
5.	Device Type:	
6.	Trade Name:	
7.	Test Result:	
8.	Comments/Findings /Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

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

**Form Status:** Not Started

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**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 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

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

**Form Status:** Not Started

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**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	[ ]
----	-----------	-----

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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?	
----	----------------------------------------------------------------------	--

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Respiratory Treatment**

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ILLNESS DETAILS

**Form Status:** Not Started

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**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\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Lab Chemistry Details**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Laboratory Data Hematology**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Date:	Vital Signs Details			Form Instance
1.		<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

**Form:** VITAL SIGNS - COVID

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Date:	Vital Signs Details		Form Instance
1.		<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Status:** Not Started

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Concomitant Medications**

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

**Form:** IMAGING

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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**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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit    **Form:** UNPLANNED VISIT

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

**Site No:** 1111    **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 21-Apr-2021 18:02

**Unplanned Assessments**

1.	Assessments	
----	-------------	--

**Header Text:** c4591001

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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**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:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

**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	[ ]
----	-----------	-----

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Intermittent Angioedema (lips)	Sep/1/2020 UNK:UNK	NO End Date Time:  Dec/24/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Intermittent Angioedema (tongue)	Sep/1/2020 UNK:UNK	NO End Date Time:  Dec/24/2020 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Angioedema (right side of face)	Jan/29/2021 UNK:UNK	NO End Date Time:  Jan/31/2021 UNK:UNK	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Angioedema (left hand center palm to heel of hand)	Feb/6/2021 UNK:UNK	NO End Date Time:  Feb/7/2021 UNK:UNK	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	Angioedema (left sole of foot)	Feb/6/2021 UNK:UNK	NO End Date Time:	<a href="#">Repeating Pages</a>

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
					Feb/7/2021 UNK:UNK	
6.	ADVERSE EVENT	6	Angioedema (isolated around lips)	Feb/20/2021 UNK:UNK	NO End Date Time: Feb/21/2021 UNK:UNK	<a href="#">Repeating Pages</a>
7.	ADVERSE EVENT	7	Angioedema (left side of jaw bone area)	Feb/23/2021 UNK:UNK	NO End Date Time: Feb/25/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[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)	[Intermittent Angioedema (lips)]
4.	Start Date Time:	Sep/1/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/24/2020 UNK:UNK
6.	Toxicity Grade:	1

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[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)	[Intermittent Angioedema (tongue)]
4.	Start Date Time:	Sep/1/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/24/2020 UNK:UNK
6.	Toxicity Grade:	1

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Angioedema (right side of face)]
4.	Start Date Time:	Jan/29/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/31/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Angioedema (left hand center palm to heel of hand)]
4.	Start Date Time:	Feb/6/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/7/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Angioedema (left sole of foot)]
4.	Start Date Time:	Feb/6/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/7/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Angioedema (isolated around lips)]
4.	Start Date Time:	Feb/20/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/21/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Angioedema (left side of jaw bone area)]
4.	Start Date Time:	Feb/23/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/25/2021 UNK:UNK
6.	Toxicity Grade:	1



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[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	[ ]

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flulaval Quadrivalent	Oct/2/2020	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
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).	[Flulaval Quadrivalent]
5.	Date:	Oct/2/2020

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Concomitant Medications**

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**Radiation Treatment**

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Vital Signs**

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

**Vital Signs Details**

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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?	

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT  
Unscheduled

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

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1111**Site Name:** (1111) Fleming Island Center for Clinical  
Research**Subject No:** 11111092**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 21-Apr-2021 18:02**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1111**Site Name:** (1111) Fleming Island Center for Clinical  
Research**Subject No:** 11111092**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 21-Apr-2021 18:02**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:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT  
Unscheduled

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

**Site No:** 1111      **Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[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:** TREATMENT UNBLINDED

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/4/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/1/2020

**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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-05-2021 10:53:02 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, (b) (6) 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.

**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-11-2020 12:19:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

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

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable
Form	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	
Form	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
1	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable
1	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
1	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
2	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable
2	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
2	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
3	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable
3	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
3	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4.a	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable
4.a	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
4.a	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4.b	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable
4.b	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	
4.b	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4.c	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable
4.c	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	
4.c	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4.d	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable
4.d	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
4.d	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4.e	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable
4.e	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	
4.e	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4.f	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable
4.f	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
4.f	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4.g	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable
4.g	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	
4.g	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4.h	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable
4.h	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
4.h	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Item	Date	User	Comment
4.i	Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable
4.i	Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
4.i	Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[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
(b) (6)	Approved	Mar-05-2021 10:53:02 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, (b) (6) , 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-01-2021 10:38:09 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Michael Stephens	Approved	Feb-26-2021 07:11:33 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**Affidavit:**

By my dated signature below, I, MichaelStephens, 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 13:32:22 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Michael Stephens	Approved	Jan-29-2021 12:48:32 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

(b) (6)	N/A	Jan-27-2021 10:34:49 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Michael Stephens	Approved	Jan-26-2021 10:03:38 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

(b) (6)	N/A	Jan-22-2021 09:21:08 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Michael Stephens	Approved	Jan-21-2021 10:38:39 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

(b) (6)	N/A	Jan-13-2021 11:13:13 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Michael Stephens	Approved	Jan-06-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

(b) (6)	N/A	Jan-05-2021 15:10:34 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Michael Stephens	Approved	Oct-12-2020 14:22:55 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

(b) (6)	N/A	Oct-01-2020 16:38:30 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Michael Stephens	Approved	Sep-15-2020 10:48:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

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

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

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

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

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-11-2020 12:18:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 12:18:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Consent Was:*

Date	Location	User	Value	Reason
Aug-11-2020 12:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/11/2020	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** DEMOGRAPHY - eCRF Audit Trail History

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-11-2020 12:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11111092	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-11-2020 12:18:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1954	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-11-2020 12:19:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Aug-11-2020 12:19:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
-------------------------------------------------------------------------	-----------------	---------------------	----------------------------------------------------------------------------	---------------

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

Date	Location	User	Value	Reason
Aug-11-2020 12:19:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

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

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-11-2020 12:19:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-11-2020 12:19:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-11-2020 12:19:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-11-2020 12:19:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1.a*

Date	Location	User	Value	Reason
Aug-11-2020 12:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 1 <b>Number:</b> <b>Medical H</b> Kidney sto <b>istory Ter</b> nes <b>m:</b> <b>Start Date</b> UNK/UN : K/2008 <b>Ongoing:</b> NO End Date : UNK/U NK/201 0	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-11-2020 12:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Aug-11-2020 12:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Kidney stones	Initial Entry

***1.a Start Date:***

Date	Location	User	Value	Reason
Aug-11-2020 12:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2008	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Aug-11-2020 12:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2010	Initial Entry

***1.b***

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

<p>Aug-11-2020 12:22:41 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p><b>Data Entry:</b> <b>Line/MH N umber:</b> 2 <b>Medical His tory Term:</b> Farsight ed <b>Start Date:</b> UNK/UNK/2004 <b>Ongoing:</b> YES</p>	<p>Initial Entry</p>
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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-11-2020 12:22:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 12:22:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Farsighted	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-11-2020 12:22:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2004	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Aug-11-2020 12:22:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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*I.c*

Date	Location	User	Value	Reason
Aug-11-2020 12:23:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 3 <b>Number:</b> <b>Medical History Term:</b> Muscle spasms (back) <b>Start Date:</b> UNK/UNK/1983 <b>Ongoing:</b> YES	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

***I.c Line/MH Number:***

Date	Location	User	Value	Reason
Aug-11-2020 12:23:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 12:23:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Muscle spasms (back )	Initial Entry

***I.c Start Date:***

Date	Location	User	Value	Reason
Aug-11-2020 12:23:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1983	Initial Entry

***I.c Ongoing:***

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Aug-11-2020 12:23:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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*1.d*

Date	Location	User	Value	Reason
Aug-11-2020 12:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 4</b> <b>umber:</b> <b>Medical His</b> Overwei <b>tory Term:</b> ght <b>Start Date:</b> UNK/U NK/200 8 <b>Ongoing:</b> YES	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Aug-11-2020 12:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 12:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Overweight	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Aug-11-2020 12:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2008	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Aug-11-2020 12:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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*I.e*

Date	Location	User	Value	Reason
Aug-11-2020 12:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 5</b> <b>umber:</b> <b>Medical His</b> Hyperte <b>tory Term:</b> nsion <b>Start Date:</b> UNK/U NK/200 2 <b>Ongoing:</b> YES	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

***1.e Line/MH Number:***

Date	Location	User	Value	Reason
Aug-11-2020 12:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

***1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-11-2020 12:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypertension	Initial Entry

***1.e Start Date:***

Date	Location	User	Value	Reason
Aug-11-2020 12:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2002	Initial Entry

***1.e Ongoing:***

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Aug-11-2020 12:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES	Initial Entry
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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-11-2020 12:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-11-2020 12:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 248.6	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-11-2020 12:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1111

Site Name: (1111) Fleming Island Center for Clinical Research

Subject No: 11111092

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Aug-11-2020 12:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 72.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-11-2020 12:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-11-2020 12:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 33.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-11-2020 12:20:47 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Ide 1	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)			<b>ntifier::</b>	
			<b>Temperatur</b> 98.4	
			<b>e:</b>	
			<b>Temperatur F</b>	
			<b>e Unit:</b>	
			<b>Temperatur FORE</b>	
			<b>e Location::</b> HEAD	

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-11-2020 12:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-11-2020 12:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.4	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-11-2020 12:20:47	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

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

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-11-2020 12:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-11-2020 12:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-11-2020 12:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 225457	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

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

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Aug-11-2020 12:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-11-2020 12:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-11-2020 12:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-11-2020 12:45:27	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candida te	'Sample Collected?' is

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-11-2020 12:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-11-2020 12:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BP5C9 D: 2	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-11-2020 12:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5C92	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**5.b**

Date	Location	User	Value	Reason
Aug-11-2020 12:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BP5C9 <b>D:</b> 3	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-11-2020 12:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5C93	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-11-2020 12:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BP5C9 <b>D:</b> 4	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-11-2020 12:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5C94	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-11-2020 12:46:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BLD2 <b>D:</b> R9	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-11-2020 12:46:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLD2R9	Initial Entry

**5.e**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Aug-11-2020 12:46:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I BLD2</b> <b>D: RB</b>	Initial Entry
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**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-11-2020 12:46:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLD2RB	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

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

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Aug-11-2020 12:30:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-11-2020 12:30:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-11-2020 12:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-11-2020 12:30:24	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candida te	'Sample Collected?' is

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-11-2020 12:30:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-11-2020 12:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BP5C9 D: 5	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-11-2020 12:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5C95	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-11-2020 12:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-11-2020 12:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-11-2020 12:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Aug-11-2020 12:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020 11:11	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-11-2020 12:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-11-2020 12:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-11-2020 12:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-11-2020 12:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 12:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-11-2020 12:21:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGEN ICITY E-DIARY CO LLECTED FOR THI S SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1111

**Subject No:** 11111092

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

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

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-01-2020 13:20:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry
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**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F A T I G U E  <b>Were fever or s</b> N <b>ystemic sympto</b> O <b>ms present on t</b> <b>he last day the S</b> <b>ubject Diary wa</b> <b>s completed?:</b>	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1111

Site Name: (1111) Fleming Island Center for Clinical Research

Subject No: 11111092

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

2.b Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

			Were fever or systemic symptoms present on the last day the Subject Diary was completed? :	
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**2.c Symptom:**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Sep-01-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

13:21:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	<b>Symptom::</b> C HI L L S  Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:
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**2.d Symptom:**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

2.e

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG <b>Were fever or s</b> NO <b>ystemic sympto</b> <b>ms present on t</b> <b>he last day the</b> <b>Subject Diary</b> <b>was completed</b> <b>?:</b>	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**2.e Symptom:**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

			Were fever or systemic symptoms present on the last day the Subject Diary was completed? :	
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**2.f Symptom:**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Sep-01-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

13:21:10  
(UTC-05:00)  
Eastern Time (US  
& Canada)

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

**Symptom::** NEW  
OR W  
ORSE  
NED  
MUS  
CLE P  
AIN

**Were fever or  
r systemic sy  
mptoms pre  
sent on the l  
ast day the S  
ubject Diary  
was complet  
ed?:**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1111

Site Name: (1111) Fleming Island Center for Clinical Research

Subject No: 11111092

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

2.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED JOIN T PAI N	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

			Were fever or NO r systemic sy mptoms pres ent on the la st day the Su bject Diary was complet ed?:	
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**2.h Symptom:**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSEN ED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
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**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RE D NE SS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site</b> SW <b>Reaction::</b> EL LI NG	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site PAI	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1111

Site Name: (1111) Fleming Island Center for Clinical Research

Subject No: 11111092

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	<b>Reaction::</b> N AT INJE CTI ON SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> 97.5 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVIT <b>Y</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:12 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)				
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**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.5	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Sep-01-2020 15:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-01-2020 15:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-01-2020 15:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 15:44:22	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 15:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/1/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-01-2020 15:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BPY9Y : J	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-01-2020 15:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPY9YJ	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Sep-01-2020 13:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020 11:26	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-01-2020 13:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-01-2020 16:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/1/2020	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?*

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  <b>Were fever or sy N</b> <b>stemic symptom O</b> <b>s present on the</b> <b>last day the Sub</b> <b>ject Diary was c</b> <b>ompleted?:</b>	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry
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**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F A T I G U E  <b>Were fever or s</b> N <b>ystemic sympto</b> O <b>ms present on t</b> <b>he last day the S</b> <b>ubject Diary wa</b> <b>s completed?:</b>	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

**2.b Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

			<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b> :	
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**2.c Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Oct-01-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

16:39:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	<b>Symptom::</b> C HI L L S  Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:
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**2.d Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

2.e

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG <b>Were fever or s</b> NO <b>ystemic sympto</b> <b>ms present on t</b> <b>he last day the</b> <b>Subject Diary</b> <b>was completed</b> <b>?:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

**2.e Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

			Were fever or systemic symptoms present on the last day the Subject Diary was completed? :	
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**2.f Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Oct-01-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

16:39:09  
(UTC-05:00)  
Eastern Time (US  
& Canada)

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

**Symptom::** NEW  
OR W  
ORSE  
NED  
MUS  
CLE P  
AIN

**Were fever o NO  
r systemic sy  
mptoms pre  
sent on the l  
ast day the S  
ubject Diary  
was complet  
ed?:**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

**2.g Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED JOIN T PAI N	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

			Were fever or NO r systemic sy mptoms pres ent on the la st day the Su bject Diary was complet ed?:	
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**2.h Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSEN ED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
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**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RE D NE SS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site</b> SW <b>Reaction::</b> EL LI NG	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site PAI	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1111 Site Name: (1111) Fleming Island Center for Clinical Research

Subject No: 11111092 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 21-Apr-2021 18:02

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	<b>Reaction::</b> N AT INJE CTI ON SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-01-2020 16:39:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-01-2020 16:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 16:39:24	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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: 1111 Site Name: (1111) Fleming Island Center for Clinical Research

Subject No: 11111092 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 21-Apr-2021 18:02

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-01-2020 16:39:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-01-2020 16:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BP9RK : 7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 16:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9RK7	Initial Entry

5.b

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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: 1111 Site Name: (1111) Fleming Island Center for Clinical Research

Subject No: 11111092 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Oct-01-2020 16:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BP9RK : 8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 16:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9RK8	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-01-2020 16:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BP9RK : 9	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-01-2020 16:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9RK9	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Oct-01-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BNW9K D: M	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-01-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNW9KM	Initial Entry

**5.e**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (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:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

Oct-01-2020 16:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BNW9K <b>D:</b> N	Initial Entry
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**5.e Sample ID**

Date	Location	User	Value	Reason
Oct-01-2020 16:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNW9KN	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1111

**Subject No:** 11111092

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

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

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-01-2021 10:38:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/25/2021	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1111

**Subject No:** 11111092

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

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

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

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Mar-01-2021 10:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-01-2021 10:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-01-2021 10:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 10:39:01	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-01-2021 10:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/25/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-01-2021 10:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BP9R8 : K	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-01-2021 10:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9R8K	Initial Entry

**5.b**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Mar-01-2021 10:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BP9R8 : L	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Mar-01-2021 10:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9R8L	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Mar-01-2021 10:40:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BP9R8 : M	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**5.c Sample ID**

Date	Location	User	Value	Reason
Mar-01-2021 10:40:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9R8M	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Mar-01-2021 10:40:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRTJ04	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Mar-01-2021 10:40:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRTJ04	Initial Entry

**5.e**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Mar-01-2021 10:41:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRTJ05	Initial Entry
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**5.e Sample ID**

Date	Location	User	Value	Reason
Mar-01-2021 10:41:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRTJ05	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

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

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

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-19-2021 02:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Query is invalid or does not apply
Jan-19-2021 02:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Jan-19-2021 00:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	Query is invalid or does not apply
Jan-13-2021 14:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1111**Subject No:** 11111092**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1111) Fleming Island Center for Clinical  
Research**Subject Initials:** ---**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-13-2021 11:13:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-13-2021 11:13:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-13-2021 11:13:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-13-2021 14:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry
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**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Jan-13-2021 11:13:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**4.a**

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> <b>Present:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.a Was symptom present?**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1111

Site Name: (1111) Fleming Island Center for Clinical  
Research

Subject No: 11111092

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App : licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App : licable	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

& Canada)			<b>Symptom Present:</b>	
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**4.b Symptoms:**

Date	Location	User	Value	Reason
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.c**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
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**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> <b>Present:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**4.c Symptoms:**

Date	Location	User	Value	Reason
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.d**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> <b>Present:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**4.d Symptoms:**

Date	Location	User	Value	Reason
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.e**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> <b>Present:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**4.e Symptoms:**

Date	Location	User	Value	Reason
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.f**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> <b>Present:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

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**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**4.f Symptoms:**

Date	Location	User	Value	Reason
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.g**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> <b>Present:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



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Unscheduled Visit on Jan/06/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**4.g Symptoms:**

Date	Location	User	Value	Reason
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.h**

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**4.h**

Date	Location	User	Value	Reason
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> <b>Present:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**4.h Symptoms:**

Date	Location	User	Value	Reason
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.i**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> <b>Present:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> Not App :           licable <b>Symptom</b> Not App <b>Present:</b> licable	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/06/2021

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

**4.i Symptoms:**

Date	Location	User	Value	Reason
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Jan-13-2021 14:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-13-2021 14:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-13-2021 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-01-2020 16:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/1/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-01-2020 16:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-01-2020 16:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-01-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1111

Site Name: (1111) Fleming Island Center for Clinical Research

Subject No: 11111092

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-01-2021 09:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Feb-01-2021 09:33:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Allergy testing was done but no

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(UTC-05:00) Eastern Time (US & Canada)				definitive etiology given
Jan-28-2021 12:17:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	clinical: pls advise if any allergy testing was performed. Thanks
Jan-27-2021 12:04:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-27-2021 11:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	As of the second vax date (09/01 /2020), it was not present the day of the visit. However, it "flared up" after the second vax. The episodes occurred every 10-14 days up until 12/2020. No prior hx so need to update Med Hx.
Jan-27-2021 10:42:16	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	clin: Thanks for clarification. Pls

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(UTC-05:00) Eastern Time (US & Canada)				advise if subject had angioedema present when received vax 2 or if there was any flare of symptoms after Vax 2. Confirm subject has no prior hx of angioedema or update MedHx CRF as appropriate.
Jan-27-2021 10:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Specific date is not known as subject states it started/occurred late August. Per subject, symptom is updated to reflect intermittent as it was not the entire time period. It occurred post vax 1
Jan-27-2021 10:34:49 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Intermittent Angioedema (lips)	Specific date is not known as subject states it

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)				started/occurred late August. Per subject, symptom is updated to reflect intermittent as it was not the entire time period. It occurred post vax 1
Jan-25-2021 13:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	clinical: pls clarify timing. There is no start DAY for AE 1 and 2. Did AE start pre or post vax 1, provide specific date if possible. Was angioedema present for the entire period from August to December? was there any improvement during this period?
Jan-25-2021 13:22:40	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	clinical: reissued.

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

(UTC-05:00) Eastern Time (US & Canada)				
Jan-22-2021 10:34:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	clinical: pls confirm that subject had angioedema of lips and tongue for the entire period from August to December. Was there any improvement of symptoms during this time period? Thanks
Jan-20-2021 12:06:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-20-2021 11:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Info updated
Jan-20-2021 01:48:41 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	AE is unfreeze. Please consider to update data as

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)				appropriate.
Jan-19-2021 11:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	clinical: requesting DM unfreeze so that you can update CRF as per your last response. Thanks
Jan-19-2021 11:00:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Lisinopril was started in 2003 and per the allergist, the angioedema could have been caused by Lisinopril. Please unfreeze so that I may add notation for causality.
Jan-18-2021 13:05:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	clinical: Thanks. When was the lisinopril started and is there any concern that this may have been cause of the angioedema? If so, pls update CRF causality to

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

				reflect this.
Jan-18-2021 11:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject discontinued Lisinopril 10/30/2020. No known treatment received.
Jan-18-2021 08:59:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise if subject has any prior hx of angioedema, and if they are on an ACE inhibitor or ARB. Confirm subject did not receive any treatment Thanks
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Angioedema (lips )	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-08-2021 10:39:40 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)				
Mar-08-2021 10:24:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	No PMH of angioedema and no angioedema before second vax.
Mar-07-2021 12:42:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	clinical: re issued.
Mar-07-2021 12:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	clinical: Start for AE 1 and 2 changed from UNK Aug to 1 Sept. Pls confirm subject had no symptoms or signs of angioedema until after Vax 2 ie no angioedema after Vax 1 and prior to vax 2. Confirm no past med history of

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

				angioedema. Thank
Mar-07-2021 12:33:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	clinical: Start time for AE 1 and 2 has been changed from UNK August to 1 September. Please confirm subject had no symptoms or signs of angioedema until after Vax 2 ie no angioedema before or immediately after Vax 1. Thanks
Jan-28-2021 00:16:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Jan-27-2021 13:15:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Time is unknown but occurred post vax #2

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-27-2021 13:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Intermittent Angioedema (lips): Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Jan-27-2021 13:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020 UNK: UNK	Changed Information
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/UNK/2020 U NK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

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Subject No: 11111092

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

& Canada)

Dec/24/2020 UNK  
:UNK

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jan-20-2021 11:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  CONCOMITANT DRUG TREATMENT	New Information
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify</i> :  Unknown as subject has scheduled a visit w	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1111

Site Name: (1111) Fleming Island Center for Clinical Research

Subject No: 11111092

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

			ith an allergist	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 14:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-27-2021 12:01:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-27-2021	ACV0PFEINFP6000	auto query	Query 1: Answered	Changed

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

11:57:26 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)		Information
Jan-27-2021 11:57:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Intermittent Angioedema (tongue)	Changed Information
Jan-27-2021 10:53:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	clinical: CRF appears unfrozen, you should be able to update.
Jan-27-2021 10:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze
Jan-27-2021 10:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: per response to query on AE #1 pls review and update AE term to intermittent if appropriate. Thanks
Jan-13-2021 14:05:47	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Angioedema (tongue)	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

e)

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-28-2021 00:15:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-27-2021 13:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Time is unknown but occurred post vax #2
Jan-27-2021 13:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Intermittent Angioedema (tongue): Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-27-2021 13:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Sep/1/2020 UNK: UNK	Changed Information
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Aug/UNK/2020 U NK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO End Date Time:  Dec/24/2020 UNK :UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

*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
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jan-22-2021 09:42:05 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1111

Site Name: (1111) Fleming Island Center for Clinical Research

Subject No: 11111092

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

(US & Canada)				
Jan-22-2021 09:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-22-2021 09:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  CONCOMITANT DRUG TREATMENT	New Information
Jan-21-2021 16:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	clinical: site to update causality for AE#2 based on prior assessment of AE #1
Jan-21-2021 12:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	clinical: site to update causality for AE#2 based on prior assessment of AE #1

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-21-2021 12:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Answered	Please unfreeze so that I may correct
Jan-21-2021 11:22:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	clin: pls review causality for AE#1 and update causality for AE #2 if appropriate. Thanks
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Unknown as subject has scheduled a visit with an allergist	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Jan-20-2021 15:40:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Jan-20-2021 11:40:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-20-2021 11:40:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Jan-19-2021 14:27:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: AE is reported to have led to study discontinuation. However, the Disposition

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

				follow up page has not been completed to match to end of study. Please review if entry is correct. If correct, update FUP tab
Jan-19-2021 06:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candi date	CLINQUERY: AE is reported to have led to study discontinuation. However, the Disposition follow up page has not been completed to match to end of study. Please review if entry is correct. If correct, update FUP tab
Jan-13-2021 14:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Angioedema (right side of face)	Initial Entry

**4. Start Date Time:**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/29/2021 UNK:U NK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Jan/31/2021 UNK: UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

*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
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**  
*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

			<i>If Other, specify:</i>	
			unknown	

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 10:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Mar-01-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-01-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-04-2021 15:48:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No further

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

<p>15:37:36 (UTC-05:00) Eastern Time (US &amp; Canada)</p>		<p>(b) (4), (b) (6)</p>		<p>ACE inhibitor given as subject is already taking an ACE inhibitor in the past. Also, subject is in the process of getting an appt with an allergist.</p>
<p>Mar-03-2021 10:13:07 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 1: Opened</p>	<p>clinical: pls confirm additional AEs of angioedema #3-7 have occurred in absence of any further ACE inhibitor or ARB use. Has subject had follow up with allergist and has any further testing (after initial skin test) been done. Thanks</p>
<p>Mar-01-2021 10:53:23</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> Angioedema (left h</p>	<p>Initial Entry</p>

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

and center palm to  
heel of hand)

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-01-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/6/2021 UNK:UN K	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-01-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Feb/7/2021 UNK: UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-01-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

**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
Mar-01-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-01-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-01-2021 10:53:23 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to stu	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Eastern Time (US & Canada)			dy treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unknown
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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Mar-01-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-01-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-01-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

10:53:23  
(UTC-05:00)  
Eastern Time (US  
& Canada)

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

NO

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

Date	Location	User	Value	Reason
Mar-01-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-09-2021 19:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-09-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	All

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

14:50:53 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		angioedema events were assessed by a physician
Mar-08-2021 13:07:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise which, if any of these events of angioedema (AE# 1-7) were assessed by a physician or if they are all self report. Thanks
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Angioedema (left sole of foot)	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/6/2021 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Feb/7/2021 UNK: UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

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**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

& Canada)

**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
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to stu dy treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unknown	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Mar-01-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

10:54:59  
(UTC-05:00)  
Eastern Time (US  
& Canada)

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

NOT APPLICABLE

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESO LVED	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Mar-01-2021 10:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Angioedema (isolated around lips)	Initial Entry

**4. Start Date Time:**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/20/2021 UNK:U NK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Feb/21/2021 UNK :UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

*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
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**  
*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

			<i>If Other, specify:</i>	
			unknown	

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 10:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Angioedema (left side of jaw bone area)	Initial Entry

**4. Start Date Time:**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/23/2021 UNK:U NK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Feb/25/2021 UNK :UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;**

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1111

Site Name: (1111) Fleming Island Center for Clinical Research

Subject No: 11111092

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

*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
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**  
*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

			<i>If Other, specify:</i>	
			unknown	

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

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

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESO LVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 10:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-02-2020 13:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1111

Site Name: (1111) Fleming Island Center for Clinical Research

Subject No: 11111092

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 21-Apr-2021 18:02

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-02-2020 13:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-02-2020 13:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-02-2020 13:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic*

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

*name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Oct-02-2020 13:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Flulaval Quadrivalent	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-02-2020 13:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/2/2020	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111      **Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-25-2021 13:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1111 **Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject No:** 11111092 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-25-2021 13:32:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccinati on 3 Participant is:  eligible and NOT confirmed to have received only plac ebo at Vaccination 1/2	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-05-2021 15:10:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/4/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-26-2021 07:20:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-25-2021 13:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-22-2021 22:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Puig (b) (4)	Query 1: Opened	DM: Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

				ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Jan-05-2021 15:10:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

**1. Subject Status**

Date	Location	User	Value	Reason
Oct-01-2020 16:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-11-2020 12:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-11-2020 12:19:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-01-2020 16:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/1/2020	Initial Entry
Aug-11-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111092

**Subject Initials:** ---

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

**Generated Time (GMT):** 21-Apr-2021 18:02

12:21:06 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Aug/11/2020	
Aug-11-2020 12:19:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1111

**Subject No:** 11111092

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

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

**Site Name:** (1111) Fleming Island Center for Clinical  
Research

**Subject Initials:** ---

**Generated Time (GMT):** 21-Apr-2021 18:02

[Back to Form](#)

*1. Casebook Signature*

Date	Location	User	Value	Reason
Sep-15-2020 09:39:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196d8902c\Final\Final On: 22-Apr-2021 02:13 (GMT)