

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/3/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11461200]
2.	Birth Date:	(b) (6) 1968
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:	

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/3/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Sep/3/2020
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: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[High Cholesterol]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vasovagal Syncope]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/3/2020
2.	Weight:	[193.0]
3.	Unit:	LB
4.	Height:	[69.0]
5.	Unit:	in
6.	Body Mass Index:	[28.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: RANDOMIZATION

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/3/2020
2.	Randomization Number:	[79525]
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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
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	[BP19GB]
5.b	Sample ID	[BPHD1H]
5.c	Sample ID	[BPHD1G]

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
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	[BP19GC]
-----	-----------	----------

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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/3/2020 09:45
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/25/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/25/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/25/2020
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	[BP9CD2]
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090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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/25/2020 11:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/28/2020
2.	Erroneous Visit	

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/28/2020
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	[BSMW6L]
5.b	Sample ID	[BRC054]
5.c	Sample ID	[BSMW6P]

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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?	
----	--	--

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/28/2020
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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB -
New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	syncope	Sep/27/2020 10:00	NO End Date Time: Sep/29/2020 16:00	Repeating Pages
2.	ADVERSE EVENT	2	1 Degree A V block	Sep/27/2020 UNK:UNK	NO End Date Time: Sep/27/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Acute Bradycardia	Sep/27/2020 UNK:UNK	NO End Date Time: Sep/28/2020 UNK:UNK	Repeating Pages

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[syncope]
4.	Start Date Time:	Sep/27/2020 10:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/29/2020 16:00
6.	Toxicity Grade:	2

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1146**Subject No:** 11461200**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1146) Amici Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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	[2020377669]

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Adverse Event Report

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

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1146**Subject No:** 11461200**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1146) Amici Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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[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)	[Acute Bradycardia]
4.	Start Date Time:	Sep/27/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/28/2020 UNK:UNK
6.	Toxicity Grade:	3

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1146**Subject No:** 11461200**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1146) Amici Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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	[2020377669]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Medication Error

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

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Concomitant Medications

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

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Concomitant Medications

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

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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Radiation Treatment

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

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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?	

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

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

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

Site No: 1146 **Site Name:** (1146) Amici Clinical Research

Subject No: 11461200 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/21/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/21/2021
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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/28/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-03-2020 10:47:25 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-12-2021 15:12:44 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

(b) (6)	Approved	Dec-01-2020 10:45:44 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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	Nov-25-2020 11:56:52 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-15-2020 08:49:21 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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	Nov-14-2020 04:37:32 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-10-2020 15:03:27 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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	Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Robert Falcone	Approved	Nov-03-2020 14:53:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, RobertFalcone, 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.

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-03-2020 10:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 10:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-03-2020 10:46:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Sep/3/2020	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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:** 1146**Site Name:** (1146) Amici Clinical Research**Subject No:** 11461200**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Subject ID**

Date	Location	User	Value	Reason
Oct-01-2020 00:16:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-30-2020 09:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	added
Sep-30-2020 06:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020377669 loss of consciousness(onset date:27Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-03-2020 10:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11461200	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
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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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Sep-03-2020 10:45:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1968	Enrollment Entry
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3. Sex:

Date	Location	User	Value	Reason
Sep-03-2020 10:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-03-2020 10:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR L ATINO(A) OR OF SPA NISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 10:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 10:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-03-2020 10:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-03-2020 10:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-03-2020 10:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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:** 1146**Site Name:** (1146) Amici Clinical Research**Subject No:** 11461200**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Sep-03-2020 10:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 1 mber: Medical Hist High Chol ory Term: esterol Start Date: UNK/UN K/2003 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 10:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 10:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: High Cholesterol	Initial Entry

1.a Start Date:

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Sep-03-2020 10:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2003	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 10:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-03-2020 10:48:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Depression Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 10:48:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 15:16:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Sep-30-2020 14:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Sep-30-2020 13:13:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per case report on SDB, subject has a history of vasovagal syncope yet not recorded on Med Hx in CRF. Please update/revise accordingly.
Sep-03-2020 10:48:45	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Depression	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

1.b Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 10:48:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 10:48:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-30-2020 14:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 3 mber: Medical Hist Vasovagal ory Term: Syncope Start Date: UNK/UN K/2000 Ongoing: YES	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 14:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 14:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Vasovagal Syncope	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 14:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 14:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date:

Date	Location	User	Value	Reason
Sep-03-2020 10:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/3/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-03-2020 10:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 193.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 10:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-03-2020 10:49:14	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 69.0	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

5. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 10:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-03-2020 10:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-03-2020 10:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 97.9 Temperature Unit:	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

			Temperature Location: ORAL CAVITY	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 10:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 10:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 10:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Sep-03-2020 10:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-03-2020 10:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/3/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-03-2020 10:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 79525	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 10:49:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 10:49:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 11:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 10:49:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

				correct as appropriate.
Sep-03-2020 10:49:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 11:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP19GB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 11:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP19GB	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 11:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHD1H	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 11:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHD1H	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 11:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHD1G	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 11:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHD1G	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 10:49:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 10:49:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 11:48:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 10:49:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

				correct as appropriate.
Sep-03-2020 10:49:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 11:48:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP19GC	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 11:48:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP19GC	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-03-2020 10:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 10:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-03-2020 10:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-03-2020 10:50:07 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/3/2020 09:45	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Eastern Time (US & Canada)				
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 10:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-03-2020 10:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 10:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-03-2020 10:50:07 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PE	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Time (US &
Canada)

RIOD

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

Date	Location	User	Value	Reason
Sep-03-2020 10:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-03-2020 10:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENI TY E-DIARY NOT CO LLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-25-2020 14:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date:

Date	Location	User	Value	Reason
Sep-25-2020 14:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-25-2020 14:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 98.7 Temperature Unit: Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-25-2020 14:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

2.a Temperature:

Date	Location	User	Value	Reason
Sep-25-2020 14:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-25-2020 14:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-25-2020 14:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

Date	Location	User	Value	Reason
Sep-25-2020 14:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-25-2020 14:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-28-2020 11:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-26-2020 05:32:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146 **Site Name:** (1146) Amici Clinical Research
Subject No: 11461200 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

				correct as appropriate.
Sep-25-2020 14:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-25-2020 14:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-28-2020 11:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP9CD2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 11:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP9CD2	Initial Entry

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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-25-2020 14:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-25-2020 14:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-25-2020 14:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-25-2020 14:02:04 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020 11:10	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Eastern Time (US & Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-25-2020 14:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-25-2020 14:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-25-2020 14:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-25-2020 14:02:04 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PE	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Time (US &
Canada)

RIOD

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

Date	Location	User	Value	Reason
Sep-25-2020 14:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-28-2020 08:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/28/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

Date	Location	User	Value	Reason
Oct-28-2020 08:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-28-2020 08:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-28-2020 10:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 08:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

				correct as appropriate.
Oct-28-2020 08:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-28-2020 10:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSMW6L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 10:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSMW6L	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-28-2020 10:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRC054	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.b Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 10:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRC054	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-28-2020 10:41:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSMW6P	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 10:41:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSMW6P	Initial Entry

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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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-28-2020 08:33:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-28-2020 08:33:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-28-2020 08:33:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-30-2020 09:28:49 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Category:

Date	Location	User	Value	Reason
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-25-2020 11:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: syncope	Final diagnosis
Oct-24-2020 19:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	THANK YOU.

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

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Oct-24-2020 12:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Follow up SAE form was submitted. See notes section of form at bottom of page. Hospital performed COVID test which was negative. There was no place on the form specific to COVID testing so it was noted in the narrative.
Oct-21-2020 11:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form to provide whether COVID testing was performed (yes/no) and if yes, the results. Thank you.
Oct-15-2020 19:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1146**Site Name:** (1146) Amici Clinical Research**Subject No:** 11461200**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

Oct-15-2020 13:54:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medical records pending. Will update once recieved.
Oct-02-2020 14:37:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: SAE report states "He was admitted to hospital...due to concussion...". Please assess if concussion should be the 2nd SAE term. If yes, please add it in CRF AE log, and send SAE update report to add it as 2nd SAE term to the same SAE case.
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Loss of consciousness	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/27/2020 10:00	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/29/2020 16:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-01-2020 00:15:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020 09:28:49	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Loss of consciousness:

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Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)				Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p>	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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			NO	
			Other medically important serious event	
			NO	

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

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

Date	Location	User	Value	Reason
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-05-2020 11:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Oct-05-2020 08:03:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medical records from hospital stay were requested on 10/2/2020 will update once we get the info.
Oct-04-2020	ACV0PFEINFP6000	Giselle	Query 1: Opened	Case narrative

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1146**Site Name:** (1146) Amici Clinical Research**Subject No:** 11461200**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

18:57:04 (UTC-05:00) Eastern Time (US & Canada)		Castillo (b) (4)		on SAE reports "loss of conciseness", however there is lack of information about the event (medical course) in itself. Please provide information on hospitalization with FU SAE form. Thanks
Sep-30-2020 09:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> History of vasovagal syncope	Transcription Error
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

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Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Sep-30-2020 09:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-01-2020 00:15:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020377669	Initial Entry

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Site Name: (1146) Amici Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1 Degree AV block	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/27/2020 UNK:UN K	Initial Entry

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Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Eastern Time (US & Canada)

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/27/2020 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

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Eastern Time (US & 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
Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Idiopathic origin	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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& Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 11:18:40 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

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Eastern Time (US & Canada)				
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Header Text: c4591001

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Form Status: Data Complete, Frozen

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Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-27-2020 06:16:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Loss of consciousness no longer listed in SDB. Issue resolved
Nov-25-2020 05:50:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 3: AE#1 Unlock and unfrozen. Please also submit a follow up AEM form to Pfizer safety to clarify that syncope is the updated term for loss of

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1146**Site Name:** (1146) Amici Clinical Research**Subject No:** 11461200**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

				consciousness since it was still reported as a separate event in Safety database
Nov-23-2020 08:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Line 1 of logs noting Loss of consciousness is locked-final diagnosis is syncope- please unlock loss of consciousness SAE in order to update-thank you
Nov-23-2020 03:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 2:Sent request to unlock form.However, per latest SAE listing loss of consciousness was still reported in Safety database.Please submit a follow up AEM form to clarify that syncope is the updated term for loss of consciousness per query response
Nov-20-2020 08:24:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Syncope is final diagnosis- (Syncope is the term for loss of consciousness) there is no new SAE
Nov-20-2020 03:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 1: In safety database, Loss of consciousness was still recorded as SAE. Please confirm if SYNCOPE is the final term for Loss of consciousness or it is a separate SAE.

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:** 1146**Site Name:** (1146) Amici Clinical Research**Subject No:** 11461200**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

Nov-19-2020 12:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unlock AE/SAE 2020377669-Loss of consciousness- so final diagnosis of syncope can be entered.
Nov-19-2020 07:20:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020377669 Syncope(onset date: 27Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acute Bradycardia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-16-2020 04:38:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Onset date updated in SDB to 27Sep2020. Issue resolved
Nov-15-2020 04:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	PSSR review

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Nov-14-2020 13:30:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE onset date occurred 27SEP2020. Date recorded on SAE form is 27SEP2020 faxed to safety. Date SAE form was completed, signed and faxed was 23OCT2020. Please clarify where you are seeing a discrepancy
Nov-14-2020 07:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020377669 ,onset date was recorded as 27Oct2020 in Safety database however, recorded as 27Sep2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/27/2020 UNK: UNK	Initial Entry

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Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/28/2020 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-14-2020 04:35:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

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Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

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<p>Nov-13-2020 10:04:45 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 2: Answered</p>	<p>SAE was sent 10/23/2020 in 19 page fax that included SAE for Acute Brady and the syncopal episode. Will separate and send SAE for Acute Bradycardia again.</p>
<p>Nov-13-2020 06:12:23 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 2: Reissued: Opened</p>	<p>SAE RECON 1: Per the DSU: The site did not list the SAE on the form. Please confirm ACUTE BRADYCARDIA event seriousness and please submit a SAE form to report ACUTE BRADYCARDIA to Safety.</p>
<p>Nov-12-2020 07:20:24 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 2: Reissued: Candidate</p>	<p>For PSSR review</p>
<p>Nov-11-2020 10:28:05 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 2: Answered</p>	<p>SAE documents for Severe Bradycardia were submitted on 23OCT2020. Please advise if a second report is</p>

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Generated By: (b) (4)

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Nov-11-2020 07:34:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: Acute Bradycardia(Onset date:27Sep2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Nov-11-2020 07:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Acute Bradycardia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with c	Initial Entry

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Site No: 1146

Site Name: (1146) Amici Clinical Research

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<p>& Canada)</p>			<p>ongenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site Name: (1146) Amici Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-14-2020 14:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Closed	Response satisfies query
Nov-14-2020 13:44:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Answered	Follow up SAE form line 18 will be updated and submitted.
Nov-14-2020 08:02:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Opened	SAE RECON:AER#2020377669,causality was recorded as NO DATA in Safety database but was recorded as NOT RELATED in AE CRF. Please confirm correct causality. If safety update is required, please submit a follow-up form.
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

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Header Text: c4591001

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Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 11:20:44 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

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Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Eastern Time (US
& Canada)

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

Date	Location	User	Value	Reason
Nov-10-2020 11:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-14-2020 04:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020377669	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-18-2021 10:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION -
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Feb-18-2021 10:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT co nfirmed to have rece ived only placebo at Vaccination 1/2	Initial Entry

090177e196ae3ecc\Final\Final On: 01-Apr-2021 05:02 (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: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461200

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-12-2021 15:12:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-12-2021 15:12:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL V ACCINATION	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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1. Subject Status

Date	Location	User	Value	Reason
Oct-28-2020 08:33:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-03-2020 10:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMI ZED	Initial Entry
Sep-03-2020 10:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-28-2020 08:33:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/28/2020	Initial Entry
Sep-03-2020 10:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Sep-03-2020 10:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461200

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail
History

Form Status: Data Complete, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-03-2020 14:53:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Robert Falcone (b) (4)	Data Entry: Click Here to Enable	Initial Entry