

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: 11461152

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: 11461152

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 Aug/28/2020
----	--------------	--

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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11461152]
2.	Birth Date:	(b) (6)/1959
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:	

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_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: 11461152

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	Aug/28/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1146

Subject No: 11461152

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
----	--	----------------

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461152

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	Aug/28/2020
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: 11461152

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:	[Claudication]
	Start Date:	Jun/UNK/2005
	Ongoing:	NO End Date: Jul/UNK/2019
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Chronic cough (smokers cough)]
	Start Date:	Dec/UNK/2019
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Myocardial Infarction]
	Start Date:	Jul/10/2010
	Ongoing:	NO End Date: Jul/13/2010

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Bradycardia]
	Start Date:	Jul/UNK/2010
	Ongoing:	NO End Date: Jul/13/2010
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Lung Cancer]
	Start Date:	Dec/UNK/2017
	Ongoing:	NO End Date: Dec/28/2017

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1146

Subject No: 11461152

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:	Aug/28/2020
2.	Weight:	[144.4]
3.	Unit:	LB
4.	Height:	[69.0]
5.	Unit:	in
6.	Body Mass Index:	[21.3]

Vital Signs Details

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

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: 11461152 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/28/2020
2.	Randomization Number:	[244831]
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: 11461152

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: Aug/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	[BP199Z]
5.b	Sample ID	[BP19B0]
5.c	Sample ID	[BP19B1]
5.d	Sample ID	[BPHCYB]
5.e	Sample ID	[BPHCYC]

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

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: Aug/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	[BP199W]
-----	-----------	----------

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461152

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:	Aug/28/2020 13:05
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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1146

Subject No: 11461152

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: 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: 11461152

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	Sep/16/2020
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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/16/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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: 11461152

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/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9C88]
-----	-----------	----------

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461152

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/16/2020 12:00
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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152 **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/14/2020
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: 11461152 **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/14/2020
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	[BRTWWS]
5.b	Sample ID	[BRTWWT]
5.c	Sample ID	[BPW22F]

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: DATE OF VISIT

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](#)

Date of Visit

1.	Date of Visit	Mar/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

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: Mar/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR49S6]
5.b	Sample ID	[BS1YHV]
5.c	Sample ID	[BS1YHR]

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461152

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: 11461152

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461152

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: 11461152

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

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	Feb/8/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Feb/8/2021
2.	Date of First Symptom Started:	Feb/6/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Feb/12/2021

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	YES
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.	Symptoms - Other Text:	[]

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Applicable _____ //	Comments
2.	Specimen Type:	Not Applicable _____	Comments
3.	Specimen Collection Location:	Not Applicable _____	Comments
4.	Assay Code and Description:	Not Applicable _____	Comments
5.	Device Type:	Not Applicable _____	Comments
6.	Trade Name:	Not Applicable _____	Comments
7.	Test Result:	Not Applicable _____	Comments
8.	Comments/Findings/Details:	Not Applicable _____ []	Comments
9.	Trade Name Other, Specify:	Not Applicable _____ []	Comments

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

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_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Patient was in the hospital at time of telehealth call.]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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: Feb/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Subject was in hospital so was not able to self swab]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRR4W5]
-----	-----------	----------

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO
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?	YES Has the subject been in intensive care due to potential COVID-19 illness? NO

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Feb/6/2021	NO Discharge Date: Feb/12/2021	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Feb/6/2021
4.	Ongoing?	NO Discharge Date: Feb/12/2021

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	1	YES	HIGH FLOW OXYGEN THERAPY	HIGH FLOW OXYGEN THERAPY	Feb/9/2021	Repeating Pages

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Respiratory Treatment

1.	What is the treatment Identifier?	[1]
2.	Concomitant Non-drug Treatment Pre-specified:	YES
3.	Treatment:	HIGH FLOW OXYGEN THERAPY
4.	Treatment:	[HIGH FLOW OXYGEN THERAPY]
5.	Start Date:	Feb/9/2021
6.	Ongoing?	NO End Date: Feb/9/2021

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

#	Category f or Lab Test	Vendo r Nam e	Collect ion Dat e:	Specim en Typ e	Lab Result			Form Insta nce
1.	CLINICAL CHEMIST RY	[]	Feb/11/ 2021	BLOO D	Sponsor-De fined Identi fier	Test:	Res ult:	Repeating Pages
					[]	C Reactive Pro tein_PX329	[]	
					[]	Alanine Amin otransferase_P X30	[]	
					[]	Aspartate Ami notransferase_ PX28	[]	
					[]	Alkaline Phosp hatase_PX35	[]	
					[]	Bilirubin_PX2 1	[]	
					47	Blood Urea Nit rogen_PX47	19	
					48	Creatinine_PX 48	.62	

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[]
3.	Collection Date:	Feb/11/2021
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[]
	Test:	C Reactive Protein_PX329
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.b	Sponsor ID:	[]
	Test:	Alanine Aminotransferase_PX30
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

5.c	Sponsor ID:	[]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	[]
	Test:	Alkaline Phosphatase_PX35
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit
5.e	Sponsor ID:	[]
	Test:	Bilirubin_PX21
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[19]
	Not Done:	
	LNMT	Low [7] High [20] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[.62]
	Not Done:	
	LNMT	Low [.9] High [1.3] Unit mg/dL

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	HEMATOLOGY	Hematology general	Feb/6/2021	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					1	Hemoglobin_PX1	13.3	
					2	Hematocrit_PX2	39	
					3	Erythrocytes_PX3	[]	
					5	Platelets_PX5	153	
					7	Leukocytes_PX7	[]	
					608	Neutrophils_PX608	[]	
					609	Eosinophils_PX609	0.2	
					612	Monocytes_PX612	0.7	
					610	Basophils_PX610	0.2	
					611	Lymphocytes_PX6	1.3	

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
						11		

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Hematology general]
3.	Collection Date:	Feb/6/2021
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[13.3]
	Not Done:	
	LNMT	Low [13] High [18] Unit g/dL

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[39]
	Not Done:	
	LNMT	Low [45] High [62] Unit %
5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[153]
	Not Done:	
	LNMT	Low [150] High [350] Unit g/dL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.2]
	Not Done:	
	LNMT	Low [1] High [6] Unit %

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.7]
	Not Done:	
	LNMT	Low [.2] High [1] Unit g/L
5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.2]
	Not Done:	
	LNMT	Low [0] High [300] Unit /uL

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.j

Sponsor ID:	[611]
Test:	Lymphocytes_PX611
Result:	[1.3]
Not Done:	
LNMT	Low [1] High [4.8] Unit 10^3/uL

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.	Feb/6/2021	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	135	90	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Vital Signs

1.	Date:	Feb/6/2021
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[135]
	Diastolic:	[90]
	Respiratory Rate in respirations/minute:	[24]
	Heart Rate in beats/minute:	[82]

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.	Feb/6/2021	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	92.0	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Vital Signs

1.	Date:	Feb/6/2021
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[92.0]

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Oxygenation Parameters

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

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: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Feb/6/2021	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i> Worsening opacification in the right upper lung with history of right upper lobectomy. Findings are concerning for pneumonia.No acute osseous abnormality.	Repeating Pages
2.	Feb/6/2021	CHEST	CT SCAN	ABNORMAL <i>If abnormal, specify findings:</i> Consolidation with air bronchograms, within the right middle lobe which is suggestive of atelectasis versus pneumonia. Few peripheral areas of groundglass within the left upper lobe. No Effusion	Repeating Pages

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Imaging

1.	Date of Assessment:	Feb/6/2021
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Worsening opacification in the right upper lung with history of right upper lobectomy. Findings are concerning for pneumonia.No acute osseous abnormality.]

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Imaging

1.	Date of Assessment:	Feb/6/2021
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Consolidation with air bronchograms, within the right middle lobe which is suggestive of atelectasis versus pneumonia. Few peripheral areas of groundglass within the left upper lobe. No Effusion]

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/10/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

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	Mar/10/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/10/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1146**Subject No:** 11461152**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**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](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR49S7]
5.b	Sample ID	[BS1YHW]
5.c	Sample ID	[BS1YHS]

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: 11461152 **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: 11461152 **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: 11461152

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/14/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

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: 11461152

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: 11461152 **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: 11461152 **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	[]
----	-----------	-----

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

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	Fall off ladder	Oct/7/2020 UNK:UNK	NO End Date Time: Oct/7/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Bruised ribs	Oct/7/2020 UNK:UNK	NO End Date Time: Oct/21/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Chronic Obstructive Pulmonary Disease with acute exacerbation	Feb/6/2021 UNK:UNK	NO End Date Time: Feb/12/2021 UNK:UNK	Repeating Pages

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461152

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fall off ladder]
4.	Start Date Time:	Oct/7/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/7/2020 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1146**Subject No:** 11461152**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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461152

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Bruised ribs]
4.	Start Date Time:	Oct/7/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/21/2020 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461152

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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	[]

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chronic Obstructive Pulmonary Disease with acute exacerbation]
4.	Start Date Time:	Feb/6/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/12/2021 UNK:UNK
6.	Toxicity Grade:	3

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1146**Subject No:** 11461152**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Answered Queries**Site Name:** (1146) Amici Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

7.	<p>Is the adverse event serious? 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: [Pneumonia]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021139031]

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

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: 11461152

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: 11461152

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

[Back to Form](#)

Medication Error

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Radiation Treatment

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

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: 11461152

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:	

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

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: 11461152

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?	

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

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: 11461152

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 - **Form:** DATE OF VISIT
Unscheduled

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

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

Subject No: 11461152 **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: 11461152

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:** 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:** 11461152**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	[]
----	-----------	-----

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: 11461152

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

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/6/2021
2.	Erroneous Visit	

Header Text: c4591001

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

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

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

Subject No: 11461152 **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: 11461152

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/6/2021
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: 11461152

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: 11461152

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: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/14/2020

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: 11461152

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
----	--------------------	----------------------

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: 11461152

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
------	----------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-28-2020 14:45:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2	Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
4	Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5	Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
6	Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
7	Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
8	Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
9	Feb-18-2021 16:05:24 (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: 11461152

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-08-2021 15:39:07 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Robert Falcone	Approved	Jan-21-2021 08:24:02 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-------------------	----------	--	------	--------

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.

(b) (6)	N/A	Dec-15-2020 10:30:26 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

N/A

(b) (6)	Approved	Nov-09-2020 19:15:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------	----------	--	------	--------

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Nov-09-2020 14:40:48 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

Affidavit:

N/A

Robert Falcone	Approved	Oct-23-2020 17:16:31 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-------------------	----------	--	------	--------

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

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.

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1146

Subject No: 11461152

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
Aug-28-2020 14:44:36 (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
Aug-28-2020 14:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

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
Aug-28-2020 14:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/28/2020	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: DEMOGRAPHY - 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. Subject ID

Date	Location	User	Value	Reason
Aug-28-2020 14:44:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11461152	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1959	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-28-2020 14:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 14:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
---	-----------------	------------------	--	---------------

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

Date	Location	User	Value	Reason
Aug-28-2020 14:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461152

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-28-2020 14:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-28-2020 14:45:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-28-2020 14:45:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-28-2020 14:45:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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:** 11461152**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Aug-28-2020 14:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Claudication Start Date: Jun/UNK/2005 Ongoing: NO End Date: Jul/UNK/2019	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 14:46:16 (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
------	----------	------	-------	--------

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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 14:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Claudication	Initial Entry
---	-----------------	------------------	------------------------------------	---------------

1.a Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/UNK/2005	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 14:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jul/UNK/2019	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-28-2020 14:46:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

			Medical History Term: Chronic cough (smokers cough)	
			Start Date: Dec/UNK/2019	
			Ongoing: YES	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 14:46:42 (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
Aug-28-2020 14:46:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic cough (smokers cough)	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:46:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/UNK/2019	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 14:46:42 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

I.c

Date	Location	User	Value	Reason
Aug-28-2020 14:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 3 Number: Medical History Term: Myocardial Infarction Start Date: Jul/10/2010 Ongoing: NO End Date: Jul/13/2010	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 14:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Myocardial Infarction	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/10/2010	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 14:47:13 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

Jul/13/2010

1.d

Date	Location	User	Value	Reason
Aug-28-2020 14:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Bradycardia Start Date: Jul/UNK/2010 Ongoing: NO End Date: Jul/13/2010	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 14:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bradycardia	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/UNK/2010	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 14:47:49 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

Jul/13/2010

I.e

Date	Location	User	Value	Reason
Aug-28-2020 14:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 5 umber: Medical His Lung Can tory Term: cer Start Date: Dec/UNK /2017 Ongoing: NO End Dat e: Dec/2 8/2017	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 14:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lung Cancer	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/UNK/2017	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 14:48:18 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US
& Canada)

Dec/28/2017

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-28-2020 14:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 144.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 14:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 14:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 69.0	Initial Entry
---	-----------------	------------------	----------------------------	---------------

5. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 14:48:56 (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
Aug-28-2020 14:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21.3	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-28-2020 14:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 97.9	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

			Temperatu F re Unit: Temperatu ORAL re Locatio CAVIT n:: Y	
--	--	--	---	--

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 14:48:56 (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
Aug-28-2020 14:48:56 (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
Aug-28-2020 14:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-28-2020 14:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461152

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-28-2020 14:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-28-2020 14:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 244831	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 14:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 14:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-28-2020 15:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 14:49:27 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				are entered. Please review and correct as appropriate.
Aug-28-2020 14:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 15:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP199 : Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP199Z	Initial Entry

5.b

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 15:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP19B : 0	Initial Entry
---	-----------------	------------------	---	---------------

5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP19B0	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 15:29:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP19B : 1	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:29:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP19B1	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.d

Date	Location	User	Value	Reason
Aug-28-2020 15:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPHCY D: B	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHCYB	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-28-2020 15:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPHCY D: C	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHCYC	Initial Entry

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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 14:49:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 14:49:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-28-2020 15:29:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 14:49:39 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				are entered. Please review and correct as appropriate.
Aug-28-2020 14:49:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 15:29:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP199 : W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:29:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP199W	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461152

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-28-2020 14:49:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-28-2020 14:49:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-28-2020 14:49:56 (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
------	----------	------	-------	--------

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461152

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

Aug-28-2020 14:49:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020 13:05	Initial Entry
---	-----------------	------------------	---	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-28-2020 14:49:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-28-2020 14:49:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-28-2020 14:49:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461152

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

Date	Location	User	Value	Reason
Aug-28-2020 14:49:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:49:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-28-2020 14:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461152

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-16-2020 12:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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. Date:

Date	Location	User	Value	Reason
Sep-16-2020 12:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-16-2020 12:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 97.7 Temperature Unit: Temperature Location: ORAL Temperature Unit: CAVIT Temperature Unit: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 12:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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

2.a Temperature:

Date	Location	User	Value	Reason
Sep-16-2020 12:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 12:56:52 (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-16-2020 12:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 12:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 12:57:01 (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-17-2020 08:49:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-17-2020 04:28:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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:** 11461152**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

& Canada)				are entered. Please review and correct as appropriate.
Sep-16-2020 12:57:01 (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-16-2020 12:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 08:49:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP9C88	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

08:49:25
(UTC-05:00)
Eastern Time (US
& Canada)

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

BP9C88

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461152

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-16-2020 12:57:20 (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-16-2020 12:57:20 (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-16-2020 12:57:20 (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
------	----------	------	-------	--------

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Sep-16-2020 12:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020 12:00	Initial Entry
---	-----------------	------------------	---	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 12:57:20 (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-16-2020 12:57:20 (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-16-2020 12:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1146

Subject No: 11461152

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

Date	Location	User	Value	Reason
Sep-16-2020 12:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 12:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-14-2020 12:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152 **Subject Initials:** ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-14-2020 12:05:04 (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-14-2020 12:05:04 (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-15-2020 10:39:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020 04:33:14 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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:** 11461152**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

& Canada)				are entered. Please review and correct as appropriate.
Oct-14-2020 12:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 12:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 10:39:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRTWW : S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

10:39:16 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	BRTWWS	
--	--	------------------	--------	--

5.b

Date	Location	User	Value	Reason
Oct-15-2020 10:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRTWW : T	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 10:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRTWWT	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 10:40:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPW22F	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 10:40:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW22F	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: DATE OF VISIT - 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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 13:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-10-2021 14:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-10-2021 14:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-10-2021 14:30:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-10-2021 14:29:46 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				entered. Please review and correct as appropriate.
Mar-10-2021 14:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-10-2021 14:30:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR49S6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 14:30:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR49S6	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-10-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

14:30:35 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Sample ID BS1YH : V	
--	--	---------------------	----------------------------------	--

5.b Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 14:30:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS1YHV	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-10-2021 14:30:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS1YHR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 14:30:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS1YHR	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-19-2021 00:19:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 23:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-18-2021 16:05:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	documented
Feb-18-2021 16:05:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	documented.
Feb-09-2021 15:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

				Nasal Swab are missing. Please review and update as appropriate.
Feb-09-2021 10:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Microbiology Specimen and Hospitalization form' at this visit. Thank you.
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-08-2021 15:39:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-08-2021 15:39:05 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-08-2021 15:39:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/8/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-08-2021 15:39:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 14-Jan-2021 02:23

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/8/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Mar-10-2021 07:28:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/6/2021	Transcription Error
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/7/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 14:20:07 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symp tom Resolved:	New Information

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)			Feb/12/2021	
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEV ER Symptom Pr NO esent:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US
& Canada)

4.b

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 14-Jan-2021 02:23

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

4.c

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR IN toms: CREASD S HORTNESS OF BREATH Symp YES tom Prese nt:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED SHORTNESS O F BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.d

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL LS Symptom Pr NO esent:	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR IN oms: CREASED	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)			MUSCLE PAIN	
			Symptom Present:	

4.e Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

			Sympt NO on Pr esent:	
--	--	--	--------------------------------------	--

4.f Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TAS TE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR IN toms: CREASED SORE THR OAT	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

			Symp NO tom P resent :	
--	--	--	---	--

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms DIARR : HEA Symptom NO Present:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

4.h Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms VOMI : TING Symptom NO Present:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

4.i Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 06-Jul-2020 21:54

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail
History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
---	-----------------	---------------------	--------------------------------------	---------------

5. Device Type:

Date	Location	User	Value	Reason
Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail
History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Feb-18-2021 16:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-09-2021 19:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-09-2021 19:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-10-2021 11:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-09-2021 19:54:45 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - 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:** 11461152**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

& Canada)				sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Feb-09-2021 19:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 08:05:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-18-2021 15:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	every effort will be made to have the patient self swab if released from

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - 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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				the hospital and able to swab within 4 days of symptom resolution.
Feb-15-2021 11:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: Please make every effort to collect swab which may be collected at the latest 4 days after symptom resolution as per Protocol Section 8.13.
Feb-12-2021 11:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-12-2021 11:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Patient was in the hospital at time of telehealth call.	Changed Information
Feb-10-2021 11:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

				the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Feb-10-2021 11:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Patient was in the hos pital at time of telehe alth call.	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-12-2021 11:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-12-2021 11:25:06 (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
Mar-11-2021 11:24:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	data updated
Mar-11-2021 07:45:53 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				
Mar-10-2021 10:44:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued :Opened	please record this reason in #4 on this form.
Mar-10-2021 07:24:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	subject was in the hospital so date of collection was beyond 4 day window
Mar-08-2021 23:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued :Opened	DM:Date of Collection is more than 4 days after Date of Last Symptom Resolved on the SOD form in the same visit. Thus, Please review and provide the reason for delay in "If no sample was collected or sample was not collected ..." field. Else, clarify.
Mar-08-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	subject was in

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

20:40:24 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	d	the hospital so date of collection was beyond 4 day window
Mar-05-2021 14:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Mar-04-2021 11:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 11:21:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Mar-04-2021 11:20:57 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	swab performed on patient following

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				hospitalization on site so date of collection is different from date telephone visit was performed.
Mar-04-2021 08:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-04-2021 08:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection 25/Feb/2021 is different from Date of Visit 08/Feb/2021. Please review and update as appropriate, else clarify.
Mar-04-2021 08:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/25/2021	New Information
Feb-12-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

11:25:06 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	NO	
--	--	------------------	----	--

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

Date	Location	User	Value	Reason
Mar-11-2021 07:44:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject was in hospital so was not able to self swab	Initial Entry
Mar-04-2021 11:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Feb-12-2021 11:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: subject hospitalized.	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-04-2021 11:21:58 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRR4W : 5	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

5.a Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 11:21:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRR4W5	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 14-Jan-2021 02:24

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Feb-08-2021 15:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPEC IALI ST Occurrence of Visits or Contacts: NO	Initial Entry
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPEC IALI ST Occurrence of Visits or Contacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-08-2021 15:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Feb-08-2021 15:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr EMER actioner: GENC Y ROO M Occurenc NO e of Visits or Contact s:	Initial Entry
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr EMER actioner: GENC Y ROO M Occurenc e of Visits or Contact s:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROO M	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-08-2021 15:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Feb-08-2021 15:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P PRIMAR ractitione Y CARE r: PHYSICI AN Occurren NO ce of Visi ts or Con tacts:	Initial Entry
Feb-08-2021 15:49:24	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P PRIMAR	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Practitioner: Y CARE PHYSICIAN	
			Occurrence of Visits or Contacts:	

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE P HYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-08-2021 15:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Feb-08-2021 15:50:21 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGE NT C	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021**Form:** HEALTH CARE UTILIZATION - eCRF Audit
Trail History**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1146**Site Name:** (1146) Amici Clinical Research**Subject No:** 11461152**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

Eastern Time (US & Canada)			ARE Occurrence of Visits or Contacts: NO	
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGE NT C ARE Occurrence of Visits or Contacts:	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-08-2021 15:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

I.f

Date	Location	User	Value	Reason
Feb-08-2021 15:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OT HE R Occurrence of Visits or Contacts: NO	Initial Entry
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OT HE R Occurrence of Visits or Contacts:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-08-2021 15:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 15:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-12-2021 10:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Mar-12-2021 09:09:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	Clin: Please complete LAB CHEM and VITALS COV CRFs.
Mar-11-2021 07:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Mar-10-2021 09:22:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	Clin: Please complete LAB CHEM, VITALS COV, PULSE OX, OXYGEN, VASOPRESS, and IMAGING CRFs, as applicable.
Mar-10-2021 07:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-10-2021 07:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject b een in intensive c are due to potenti al COVID-19 illn ess?	Transcription Error

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

			NO	
Mar-03-2021 17:03:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: As subject was hospitalized, please complete RESP TX, ILL SEVERE, LAB CHEM, LAB HEM, VITALS COV, PULSE OX, OXYGEN, VASOPRESS, and IMAGING CRFs, as applicable.
Feb-19-2021 08:04:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 15:41:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	will update once medical records are received.
Feb-15-2021 11:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: As subject was hospitalized, please complete HOSP, RESP TX, ILL

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 14-Jan-2021 02:24

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

				SEVERE, LAB CHEM, LAB HEM, VITALS COV, PULSE OX, OXYGEN, VASOPRESS, and IMAGING CRFs, as applicable.
Feb-08-2021 15:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? YES	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HOSPITALIZATION DETAILS - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-09-2021 19:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail
History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Hospitalization Category:

Date	Location	User	Value	Reason
Feb-09-2021 19:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION S TATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Mar-10-2021 09:19:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-10-2021 07:21:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject was not in ICU, Transcription error
Mar-03-2021 17:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: Please enter separate record for ICU as per CRF CRs Section 8.36.1.
Feb-19-2021 08:04:37 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail
History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)		(b) (4), (b) (6)		
Feb-18-2021 15:42:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Will enter ICU information once records are obtained.
Feb-18-2021 14:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Clin: Please enter 2 separate records, 1 for hospital and 1 for ICU. Please refer to CRF CRs Section 8.36.1 for details.
Feb-18-2021 11:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-18-2021 11:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Transcription Error
Feb-15-2021 11:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Per CRF CRs Section 8.36.1, please click New to report the

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021**Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail
History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1146**Site Name:** (1146) Amici Clinical Research**Subject No:** 11461152**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

				duration of hospitalization by selecting HOSPITAL (should be the total hospital stay including ICU).
Feb-09-2021 19:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ICU	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Mar-10-2021 07:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/6/2021	Transcription Error
Feb-09-2021 19:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/7/2021	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Mar-09-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail
History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

12:03:15 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		satisfies query
Mar-09-2021 10:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-09-2021 10:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Discharge Date: Feb/12/2021	New Information
Mar-03-2021 17:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Please record end date.
Feb-09-2021 19:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: RESPIRATORY TREATMENT - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-09-2021 10:38:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: RESPIRATORY TREATMENT - eCRF Audit Trail
History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Mar-09-2021 10:38:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Mar-09-2021 10:38:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: YES	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Mar-09-2021 10:38:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HIGH FLOW OXYG EN THERAPY	Initial Entry

4. Treatment:

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: RESPIRATORY TREATMENT - eCRF Audit Trail
History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Mar-09-2021 10:38:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HIGH FLOW OXYGE N THERAPY	Initial Entry
---	-----------------	-------------------------	--	---------------

5. Start Date:

Date	Location	User	Value	Reason
Mar-09-2021 10:38:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Mar-09-2021 10:38:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Feb/9/2021	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-08-2021 15:47:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-1 9 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Feb-08-2021 15:47:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-08-2021 15:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-08-2021 15:50:01 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Transcription Error

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				
Feb-08-2021 15:47:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on Signs and Symptoms CRF. Please review and update as appropriate.
Feb-08-2021 15:47:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 0	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - Audit Trail

Form Version: 21-Aug-2020 02:49

Form Status:

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMIST RY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021**Form:** LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete**Site No:** 1146**Site Name:** (1146) Amici Clinical Research**Subject No:** 11461152**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor- Defined I dentifier: Test:: C Reactiv e Protein_ PX329 Result:: Not Done: : Lab Norm al Range:	Initial Entry
---	-----------------	---------------------	---	---------------

5.a Test:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C Reactive Protein_P X329	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor- Defined I dentifier:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

			Test:: Alanine A minotransf erase_PX3 0 Result:: Not Done :: Lab Nor mal Ran ge:	
--	--	--	--	--

5.b Test:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alanine Aminotranse rase_PX30	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor- Defined I dentifier: Test:: Aspartate Aminotran sferase_PX 28 Result::	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				Not Done: Lab Normal Range:

5.c Test:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX28	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Alkaline Phosphatase_PX35 Result:: Not Done: : Lab Normal Range:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.d Test:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_ PX35	Initial Entry

5.e

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Def ined Identifi er: Test:: Bilirubi n_PX2 1 Result:: Not Done:: Lab Normal Range:	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilirubin_PX21	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.f

Date	Location	User	Value	Reason
Mar-12-2021 10:19:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor- 47 Defined Identifie r: Test:: Blood Ur ea Nitrog en_PX47 Result:: 19 Not Don e:: Lab Nor <i>Low</i> mal Ran 7 ge: <i>High</i> 20 <i>Unit</i> mg/dL	Transcription Error
Mar-12-2021 10:18:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor- 47 Defined Identifie r: Test:: Blood Ur ea Nitrog en_PX47 Result:: 19	Transcription Error

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 21-Aug-2020 02:49

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

			Not Done: Lab Normal Range: <i>Low</i> .9 <i>High</i> 1.3 <i>Unit</i> mg/L	
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 47 Test: Blood Urea Nitrogen_PX47 Result: 19 Not Done: Lab Normal Range: <i>Unit</i> mg/L	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_ PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Mar-12-2021 10:18:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing.

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				Please correct or confirm.
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 19	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Mar-12-2021 10:19:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 7 <i>High</i> 20 <i>Unit</i> mg/dL	Transcription Error
Mar-12-2021 10:18:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> .9 <i>High</i> 1.3 <i>Unit</i> mg/L	Transcription Error
Mar-12-2021 10:16:34 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Unit</i> mg/L	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US
& Canada)

5.g

Date	Location	User	Value	Reason
Mar-12-2021 10:18:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-D 48 efined Identifier: Test:: Creatinine_PX48 Result:: .62 Not Done:: Lab Normal Range: Low .9 High 1.3 Unit mg/dL	Transcription Error
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-D 48 efined Identifier: Test:: Creatinine_PX48 Result:: .62 Not Done::	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

			Lab Norm	<i>Unit</i>	
			al Range:	mg/dL	

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Mar-12-2021 10:18:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing.

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				Please correct or confirm.
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: .62	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Mar-12-2021 10:18:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> .9 <i>High</i> 1.3 <i>Unit</i> mg/dL	Transcription Error
Mar-12-2021 10:16:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Unit</i> mg/dL	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - Audit Trail

Form Version: 21-Aug-2020 02:51

Form Status:

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Mar-09-2021 10:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematology general	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-10-2021 07:28:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-10-2021 07:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Mar-09-2021 10:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Collection Date is before Date of First Symptom Started on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Mar-09-2021 10:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Collection date is updated, but both results and NOT DONE is marked. Please clarify.
Mar-09-2021 10:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/6/2021	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-De 1 fined Identi fier: Test:: Hemogl obin_PX 1 Result:: 13.3 Not Done:: Lab Norma <i>Low</i> l Range: 13 <i>High</i> 18 <i>Unit</i> g/dL	Initial Entry
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-De 1 fined Identi fier: Test:: Hemogl obin_P X1 Result:: 13.3 Not Done:: Lab Norma l Range:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing.

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				Please correct or confirm.
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13.3	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 13 <i>High</i> 18 <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Hemato crit_PX 2 Result:: 39	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 21-Aug-2020 02:51

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

			Not Done:: Lab Normal Range: <i>Low</i> 45 <i>High</i> 62 <i>Unit</i> %	
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_PX 2 Result:: 39 Not Done:: Lab Normal Range:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing.

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				Please correct or confirm.
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 39	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 45 <i>High</i> 62 <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 3 Test:: Erythrocytes_P X3 Result::	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 21-Aug-2020 02:51

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

			Not Done:: NOT D ONE Lab Norma l Range:	
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-De fined Identi fier: Test:: Erythro cytes_P X3 Result:: Not Done:: Lab Norma l Range:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Def 5	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 21-Aug-2020 02:51

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

Eastern Time (US & Canada)			Identified Identifier: Test:: Platelets_PX5 Result:: 153 Not Done:: Lab Normal Range: <i>Low</i> 150 <i>High</i> 350 <i>Unit</i> g/dL	
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_PX5 Result:: 153 Not Done:: Lab Normal Range:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing.

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				Please correct or confirm.
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 153	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 150 <i>High</i> 350 <i>Unit</i> g/dL	Initial Entry

5.e

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defi 7 ned Identifie r: Test:: Leukoc ytes_PX 7 Result::	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done:: NOT D ONE	
			Lab Normal Range:	

5.e Sponsor ID:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.f

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-De 608 defined Identi fier: Test:: Neutrop hils_PX 608 Result:: Not Done:: NOT D ONE Lab Norma I Range:	Initial Entry
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-De defined Identi fier: Test:: Neutrop hils_PX 608 Result:: Not Done:: Lab Norma I Range:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.g

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-D 609	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 21-Aug-2020 02:51

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

Eastern Time (US & Canada)			efined Identifier: Test:: Eosinophils_PX609 Result:: 0.2 Not Done:: Lab Normal Range: Low 1 High 6 Unit %	
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_PX609 Result:: 0.2 Not Done:: Lab Normal Range:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing.

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				Please correct or confirm.
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.2	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1 <i>High</i> 6 <i>Unit</i> %	Initial Entry

5.h

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Monocytes_PX61 2 Result:: 0.7	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 21-Aug-2020 02:51

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

			Not Done:: Lab Normal Range: <i>Low</i> .2 <i>High</i> 1 <i>Unit</i> g/L	
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Monocytes_PX6 12 Result:: 0.7 Not Done:: Lab Normal Range:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Monocytes_PX612	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

5.h Result:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.7	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> .2 <i>High</i>	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

			1	
			<i>Unit</i>	
			<i>g/L</i>	

5.i

Date	Location	User	Value	Reason
Mar-10-2021 07:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-D 610 efined Ide ntifier: Test:: Basophi ls_PX6 10 Result:: 0.2 Not Done:: Lab Norm <i>Low</i> al Range: 0 <i>High</i> 300 <i>Unit</i> /uL	Transcription Error
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-D 610 efined Ide ntifier: Test:: Basophi ls_PX6 10	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 21-Aug-2020 02:51

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

			Result:: 0.2 Not Done:: NOT D ONE Lab Normal Range: <i>Low</i> 0 <i>High</i> 300 <i>Unit</i> /uL	
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basoph ils_PX 610 Result:: 0.2 Not Done:: NOT D ONE Lab Normal Range:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.i Sponsor ID:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing.

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				Please correct or confirm.
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.2	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Mar-10-2021 07:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 300	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

			<i>Unit</i> /uL	
--	--	--	--------------------	--

5.j

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_PX611 Result:: 1.3 Not Done:: Lab Normal Range: <i>Low</i> 1 <i>High</i> 4.8 <i>Unit</i> 10 ³ /uL	Initial Entry
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_PX611 Result:: 1.3	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form Version: 21-Aug-2020 02:51

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1146) Amici Clinical Research

Subject Initials: ---

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

			Not Done::	
			Lab Norm	
			al Range:	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing.

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				Please correct or confirm.
Mar-09-2021 10:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.3	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Mar-09-2021 10:50:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1 <i>High</i> 4.8 <i>Unit</i> 10 ³ /uL	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: VITAL SIGNS - COVID - Audit Trail

Form Version: 21-Aug-2020 02:50

Form Status:

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-12-2021 09:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Mar-12-2021 09:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/6/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-12-2021 09:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 : Systolic:: 1 3 5 Diastolic:: 9 0 Respiratory Rate 2 in respirations/mi 4 nute: Heart Rate in bea 8 ts/minute: 2	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Mar-12-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

09:33:03 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	1	
--	--	------------------	---	--

2.a Systolic:

Date	Location	User	Value	Reason
Mar-12-2021 09:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 135	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Mar-12-2021 09:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 90	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Mar-12-2021 09:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24	Initial Entry

2.a Heart Rate in beats/minute:

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-12-2021 09:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 82	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit
Trail

Form Version: 21-Aug-2020 02:51

Form Status:

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-11-2021 07:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Mar-11-2021 07:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/6/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-11-2021 07:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Oxygen Saturation: 92.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Mar-11-2021 07:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Mar-11-2021 07:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 92.0	Initial Entry
---	-----------------	---------------------	----------------------------	---------------

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-11-2021 07:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-11-2021 07:37:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Mar-11-2021 07:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/6/2021	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Mar-11-2021 07:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Mar-11-2021 07:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: X-RAY	Initial Entry

4. Assessment:

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

<p>Mar-11-2021 07:36:03 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><u>Data Entry:</u> ABNORMAL <i>If abnormal, specify findings:</i></p> <p>Worsening opacific ation in the right up per lung with histor y of right upper lob ectomy. Findings ar e concerning for pn eumonia.No acute osseous abnormalit y.</p>	<p>Initial Entry</p>
--	------------------------	-----------------------------	--	----------------------

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Mar-11-2021 07:37:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/6/2021	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Mar-11-2021 07:37:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Mar-11-2021 07:37:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CT SCAN	Initial Entry

4. Assessment:

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/08/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

<p>Mar-11-2021 07:37:02 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><u>Data Entry:</u> ABNORMAL <i>If abnormal, specify findings:</i></p> <p>Consolidation with air bronchograms, within the right middle lobe which is suggestive of atelectasis versus pneumonia. Few peripheral areas of groundglass within the left upper lobe. No Effusion</p>	<p>Initial Entry</p>
--	------------------------	-----------------------------	---	----------------------

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/10/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 13:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Mar-10-2021 13:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/10/2021

Form Version: 22-Apr-2020 21:03

Site No: 1146

Subject No: 11461152

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-10-2021 14:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-10-2021 14:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-10-2021 14:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-10-2021 14:33:21 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/10/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				entered. Please review and correct as appropriate.
Mar-10-2021 14:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-10-2021 14:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR49S7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 14:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR49S7	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-10-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 -
Unscheduled Visit on Mar/10/2021**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Verified**Site No:** 1146**Site Name:** (1146) Amici Clinical Research**Subject No:** 11461152**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

14:33:59 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Sample ID BS1YH : W	
--	--	---------------------	----------------------------------	--

5.b Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 14:33:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS1YHW	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-10-2021 14:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS1YHS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 14:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS1YHS	Initial Entry

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: 11461152 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-14-2020 12:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-14-2020 12:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-14-2020 12:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-16-2020 13:45:00 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-10-2021 07:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-19-2020 11:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-16-2020 13:46:01 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Fall date of completion corrected and bruised ribs

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, Locked, Frozen**Site No:** 1146**Site Name:** (1146) Amici Clinical Research**Subject No:** 11461152**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

& Canada)				entered. Subject contacted for update but still pending.
Oct-15-2020 17:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Fall off Ladder is noted. When a fall results in an injury, both the fall & injury should be recorded as AEs. Please confirm if an injury resulted and add as a separate AE.
Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fall off ladder	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020 UNK:U NK	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

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
Oct-21-2020 09:13:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-20-2020 17:15:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/7/2020 UNK:UNK	Correction. Fall single day occurrence
Oct-20-2020 17:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No resolution-subject to have CT scan 11/3- no diagnosis provided to date.
Oct-20-2020 16:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery3: Thanks for responding. However the CRF still reflects Ongoing and Not Recovered for the Outcome. Please confirm the END DATE of 07Oct2020 and OUTCOME of Recovered/Resolved, then update each

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				field within the CRF
Oct-19-2020 17:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Corrected to reflect 1 day event
Oct-19-2020 11:08:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	ClinQuery2: Thanks for responding. However the CRF still reflects Ongoing and Not Recovered for the Outcome. Please confirm the END DATE and OUTCOME, then update the CRF as appropriate
Oct-16-2020 13:19:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Oct-15-2020 17:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Fall off Ladder is noted as ongoing. However, this is a traumatic event and should only be 1 day in duration. Please confirm the END DATE and OUTCOME, then

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				update the CRF as appropriate
Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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.

Date	Location	User	Value	Reason
Oct-14-2020 13:31:04 (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-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to st udy treatment(s), th is event is due to: OTHER <i>If Other, specify:</i> fall	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 16:06:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2 : Closed	Response satisfies query
Nov-09-2020 14:40:48 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	auto query (autoquery)	Query 2 : Answered	Changed Information

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				
Nov-09-2020 14:40:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/ RESOLVED	Changed Information
Nov-09-2020 02:55:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2 : Reissued:Opened	Thanks for the response, form has been unfreeze, please update as per below query
Nov-08-2020 18:15:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2 : Reissued:Candidate	GPDClin: Please unfreeze, so the site can make change.
Nov-08-2020 12:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2 : Answered	please unlock the line so we can respond
Nov-06-2020 19:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2 : Opened	GPDClin: Please clarify what sequelae is present. If not, please change it to "RECOVERED/RESOLVED".

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Locked, Frozen**Site No:** 1146**Site Name:** (1146) Amici Clinical Research**Subject No:** 11461152**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

Oct-20-2020 17:17:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Closed	Close Auto Query
Oct-20-2020 17:17:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/ RESOLVED WITH SEQUELAE	Subject bruised ribs
Oct-20-2020 17:15:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Opened	For AE Fall off ladder: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/ NOT RESOLVED	Initial Entry

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

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

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, Locked, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Oct-14-2020 13:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
---	-----------------	------------------	--------------------------	---------------

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-16-2020 13:45:00 (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
Oct-16-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bruised ribs	Initial Entry

4. Start Date Time:

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Oct-16-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020 UNK:UN K	Initial Entry
---	-----------------	---------------------	--	---------------

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-15-2020 11:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-15-2020 10:30:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	update
Dec-15-2020 10:30:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/21/2020 UN K:UNK	update
Dec-14-2020 18:29:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please verify if Bruised Ribs is ongoing, then update the END DATE and

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				OUTCOME as appropriate.
Oct-16-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-16-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-16-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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.

Date	Location	User	Value	Reason
Oct-16-2020 13:45:00 (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-16-2020 13:45:00 (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: accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 13:45:00 (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
Dec-15-2020 10:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-15-2020 10:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RE SOLVED	update

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Dec-15-2020 10:30:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Bruised ribs: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-16-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERE D/NOT RESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-10-2021 07:30:30 (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
Mar-10-2021 07:30:30 (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
Mar-12-2021 12:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answe red	FU SAE Report submitted stating new AE term Chronic Obstructive Pulmonary Disease with acute exacerbation

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Mar-12-2021 11:30:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021139031, the term was reported as Pneumonia in Safety database while recorded as Chronic Obstructive Pulmonary Disease with acute exacerbation in AE CRF. Please confirm correct term. If safety update is required, please submit a ffup form
Mar-11-2021 07:47:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic Obstructive Pulmonary Disease with acute exacerbation	Hospital records obtained. Diagnosis updated as per hospital records. Follow up SAE form submitted with new AE term.
Mar-10-2021 07:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pneumonia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-12-2021 10:46:31	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	Pending SDB update

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, Answered Queries

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Mar-11-2021 07:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Date of onset confirmed as 6-feb-2021 and recovery 12-feb-2021. SAE follow up form submitted.
Mar-10-2021 14:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021139031 onset date was recorded as 07Feb2021 in Safety database however, recorded as 06Feb2021 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Mar-10-2021 07:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/6/2021 UNK: UNK	Initial Entry

5. Is the adverse event still ongoing?

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-10-2021 07:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/12/2021 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-10-2021 07:30:30 (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
Mar-10-2021 14:54:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Mar-10-2021 07:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-10-2021 07:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening?	Transcription Error

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

			NO Other medically important serious event NO	
Mar-10-2021 07:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Mar-10-2021 07:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Pneumonia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-10-2021 07:30:30 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Did this serious event require or prolon	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)			g hospitalization?	
			YES	

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

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

Date	Location	User	Value	Reason
Mar-10-2021 07:30:30 (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
Mar-10-2021 07:30:30 (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> Pneumonia	Initial Entry

10. Latest Action Taken with Study Treatment:

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

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Mar-10-2021 07:30:30 (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
Mar-10-2021 07:30:30 (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
Mar-10-2021 07:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 10:47:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Candi date	Pending SDB update

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Answered Queries
Site No: 1146 **Site Name:** (1146) Amici Clinical Research
Subject No: 11461152 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

Mar-11-2021 07:10:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Onset and recovery confirmed via hospital record and follow-up SAE submitted
Mar-10-2021 15:03:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Op ened	SAE RECON:AER#2021139031,outcome is reported as RECOVERED/RESOLVED on AE CRF while reported as Not Recovered/Not Resolved in Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Mar-10-2021 07:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : REC OVE RED/ RESO LVE D	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 07:30:30 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-10-2021 14:54:09 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021139031	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-14-2021 12:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

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

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

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

Subject No: 11461152 **Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-15-2021 10:15:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-15-2021 00:53:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-14-2021 12:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

				complete this date.
Feb-14-2021 12:28:43 (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 confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (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: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-15-2021 10:15:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-15-2021 10:15:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-14-2020 12:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-28-2020 14:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-28-2020 14:45:29 (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
Mar-10-2021 15:04:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Entered in AE CRF
Mar-10-2021 08:25:23 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				
Mar-10-2021 04:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Op ened	SAE RECON:AER#2021139031 Pneumonia(onset date:07Feb2021)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.
Oct-14-2020 12:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry
Aug-28-2020 14:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/28/202 0	Initial Entry
Aug-28-2020 14:45:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/28/202 0	Initial Entry

090177e196ae3ec6\Final\Final On: 01-Apr-2021 05:01 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1146

Site Name: (1146) Amici Clinical Research

Subject No: 11461152

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 17:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Robert Falcone (b) (4)	Data Entry: Click Here to Enable	Initial Entry