

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/26/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12511060]
2.	Birth Date:	(b) (6) /1987
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/26/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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 _____
----	--	-------------------------

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/26/2020
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: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Acid Reflux]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hemorrhoids]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[sinus headaches]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[obesity]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/26/2020
2.	Weight:	[347.0]
3.	Unit:	LB
4.	Height:	[69.0]
5.	Unit:	in
6.	Body Mass Index:	[51.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/26/2020
2.	Randomization Number:	[68849]
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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/26/2020
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	[BPYNG8]
5.b	Sample ID	[BPYNG9]
5.c	Sample ID	[BPYNGB]
5.d	Sample ID	[BNWBSN]
5.e	Sample ID	[BNWBSP]

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/26/2020
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	[BPYNVC]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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/26/2020 15:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/16/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.6]
	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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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	[BM907K]
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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 08:34
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/15/2020
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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/15/2020
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	[BR90PX]
5.b	Sample ID	[BR90PY]
5.c	Sample ID	[BR90PZ]
5.d	Sample ID	[BNWBNN]
5.e	Sample ID	[BNWBNP]

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/11/2021
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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR4P2P]
5.b	Sample ID	[BR4P2R]
5.c	Sample ID	[BR4P2S]
5.d	Sample ID	[BNVKRW]
5.e	Sample ID	[BNVKRX]

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/9/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 10-Oct-2020 16:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Oct/9/2020
2.	Date of First Symptom Started:	Oct/9/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/11/2020

Symptoms

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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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:	[]

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Oct/9/2020
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	[CV29620]
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[sample collected by subject. not in our office]

Aliquot

Please enter barcode for each aliquot.

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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:	NO

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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?	NO
----	--	----

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	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 Oct/09/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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:	1

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category for Lab Test	Vendor Name	Collection Date :	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Lab Chemistry Details

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

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CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

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Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result :	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING
Hematology**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)[Form Comments](#)[eCRF Audit Trail History](#)**Laboratory Data Hematology**

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Visit: POT_COVID_ILL 1 -
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Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.h	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.i	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.j	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
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Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ []	Comments
	Diastolic:	Not Applicable _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Applicable _____ []	Comments
	Heart Rate in beats/minute:	Not Applicable _____ []	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Applicable	Not Applicable	

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	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 Oct/09/2020

Form Version: 06-Jul-2020 21:55

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Imaging

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____	Comments
4.	Assessment:	Not Applicable _____	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jan/11/2021
2.	Date of First Symptom Started:	Jan/7/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/10/2021

Symptoms

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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Sample was collected out of window]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[CV06676]
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[will use at home self swab]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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:	NO

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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?	NO
----	--	----

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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[Form Comments](#)

[eCRF Audit Trail History](#)

Respiratory Treatment

1.	What is the treatment Identifier?	Not Done _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Done _____	Comments
3.	Treatment:	Not Done _____	Comments
4.	Treatment:	Not Done _____ []	Comments
5.	Start Date:	Not Done _____ //	Comments
6.	Ongoing?	Not Done _____	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:52

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: ILLNESS DETAILS

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[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:	1

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Done _____	Comments
2.	Subcategory of Clinical Event:	Not Done _____	Comments
3.	Was a diagnosis obtained?	Not Done _____	Comments
4.	Toxicity Grade:	Not Done _____	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category f or Lab Test	Vendor Name	Collecti on Date:	Specime n Type	Lab Result			Form Instan ce
1.	Not Done	Not Do ne	Not Don e	Not Don e	Sponsor-Defi ned Identifier	Test:	Resul t:	Repeating Pages
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021**Form:** LOCAL LABORATORY DATA - REPEATING
CHEMISTRY**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)[Form Comments](#)[eCRF Audit Trail History](#)**Lab Chemistry Details**

1.	Lab Panel:	Not Done _____	Comments
2.	Laboratory Name and Address	Not Done _____ []	Comments
3.	Collection Date:	Not Done _____ //	Comments
4.	Specimen Type:	Not Done _____	Comments

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.e	Sponsor ID:	Not Done _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.f	Sponsor ID:	Not Done _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.g	Sponsor ID:	Not Done _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category f or Lab Test	Vendor Name (DERIVED)	Collection Date :	Specimen Type	Lab Result			Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Laboratory Data Hematology

1.	Lab Panel:	Not Done _____	Comments
2.	Laboratory Name and Address	Not Done _____ []	Comments
3.	Collection Date:	Not Done _____ //	Comments
4.	Specimen Type:	Not Done _____	Comments

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

	LNMT	Not Done _____ Low [] High [] Unit	Comments
5.b	Sponsor ID:	Not Done _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.c	Sponsor ID:	Not Done _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.d	Sponsor ID:	Not Done _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.e	Sponsor ID:	Not Done _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.f	Sponsor ID:	Not Done _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.g	Sponsor ID:	Not Done _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.h	Sponsor ID:	Not Done _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.i	Sponsor ID:	Not Done _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.j	Sponsor ID:	Not Done _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Done	Not Done	Not Done	

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	Systolic:	Not Done _____ []	Comments
	Diastolic:	Not Done _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Done _____ []	Comments
	Heart Rate in beats/minute:	Not Done _____ []	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Date:	Vital Signs Details		Form Instance
1.	Not Done	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Done	Not Done	

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	SPO2 Pulse Oximetry %	Not Done _____ []	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Done _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done _____ []	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:55

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Concomitant Medications

1.	What is the medication identifier?	Not Done _____ []	Comments
2.	Category:	Not Done _____	Comments
3.	Concomitant Medications Pre-specified:	Not Done _____	Comments
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).	Not Done _____ []	Comments
5.	Start Date:	Not Done _____ //	Comments
6.	Ongoing?	Not Done _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Imaging

1.	Date of Assessment:	Not Done _____ //	Comments
2.	Location of Assessment:	Not Done _____	Comments
3.	Type of Imaging Exam:	Not Done _____	Comments
4.	Assessment:	Not Done _____	Comments

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/10/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/10/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/10/2020

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/10/2020
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	[BR2K43]
5.b	Sample ID	[BR2K44]
5.c	Sample ID	[BR2K45]
5.d	Sample ID	[BSHZ1F]
5.e	Sample ID	[BSHZ1G]

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Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Feb/09/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/9/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Feb/09/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/9/2021
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	[BRJ7B7]
5.b	Sample ID	[BRJ7BP]
5.c	Sample ID	[BRJ7BR]
5.d	Sample ID	[BNVKGZ]
5.e	Sample ID	[BNVKH0]

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Header Text: c4591001

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

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

Site No: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/15/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED	ADVERSE EVENT	1	chills	Oct/6/2020 02:00	NO End Date Time: Oct/6/2020 16:00	Repeating Pages
2. DELETED	ADVERSE EVENT	2	sore throat	Oct/6/2020 02:00	NO End Date Time: Oct/8/2020 20:00	Repeating Pages
3.	ADVERSE EVENT	3	Nasal Congestion	Sep/2/2020 UNK:UNK	NO End Date Time: Sep/4/2020 UNK:UNK	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

***** THIS REPEATING FORM HAS BEEN DELETED *****

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[±]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[chills]
4.	Start Date Time:	Oct/6/2020 02:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/6/2020 16:00
6.	Toxicity Grade:	±

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

***** THIS REPEATING FORM HAS BEEN DELETED *****

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

***** THIS REPEATING FORM HAS BEEN DELETED *****

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	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

***** THIS REPEATING FORM HAS BEEN DELETED *****

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[sore throat]
4.	Start Date Time:	Oct/6/2020 02:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/8/2020 20:00
6.	Toxicity Grade:	†

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

***** THIS REPEATING FORM HAS BEEN DELETED *****

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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

***** THIS REPEATING FORM HAS BEEN DELETED *****

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	[]

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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[Form Audit Trail](#)

Adverse Event Report

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

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Medication Error

1.	Category:	Not Applicable _____	Comments
2.	Medication Error (Type of Medication Error):	Not Applicable _____ []	Comments
3.	Start Date:	Not Applicable _____ //	Comments
4.	Is the medication error still ongoing?	Not Applicable _____	Comments
5.	Latest Action Taken with Study Treatment:	Not Applicable _____	Comments
6.	Was a Concomitant Medication given?	Not Applicable _____	Comments
7.	Was a Non-Drug Treatment given?	Not Applicable _____	Comments
8.	Did the Medication Error cause the subject to be discontinued from the study?	Not Applicable _____	Comments
9.	Was this medication error associated with any adverse events?	Not Applicable _____	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

10.	Serious Adverse Event Number: For Pfizer Use Only	Not Applicable <hr/> <input type="checkbox"/>	Comments
-----	---	--	--------------------------

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Date:	Not Applicable _____ //	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____ []	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____ []	Comments
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).	Not Applicable _____ []	Comments
5.	Dose:	Not Applicable _____ []	Comments
6.	Dose Unit:	Not Applicable _____ []	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

7.	Dose Frequency:	Not Applicable _____	Comments
8.	Route:	Not Applicable _____	Comments
9.	Start Date:	Not Applicable _____ //	Comments
10.	Ongoing?	Not Applicable _____	Comments

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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[Form Comments](#)

[eCRF Audit Trail History](#)

Radiation Treatment

1.	Category:	Not Applicable _____	Comments
2.	What is the treatment Identifier?	Not Applicable _____ []	Comments
3.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Transfusion Type	Date of Transfusion	Form Instance
1.	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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[Form Comments](#)

[eCRF Audit Trail History](#)

1.	Transfusion Type:	Not Applicable _____	Comments
2.	Date of Transfusion:	Not Applicable _____ //	Comments

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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?	

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Feb/9/2021
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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

[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 per local/national recommendations and 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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/9/2021
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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/15/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Hayes Williams	Approved	Mar-12-2021 10:21:48 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Aug-27-2020 08:50:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Header Text: c4591001

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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1251

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Header Text: c4591001

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7	Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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Header Text: c4591001

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Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1251

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Form: ILLNESS DETAILS - SEVERE - Comments

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Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

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Item	Date	User	Comment
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5.f	Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

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Site No: 1251

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Header Text: c4591001

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Site No: 1251

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Item	Date	User	Comment
1	Oct-21-2020 09:47:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

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2.a	Oct-21-2020 09:47:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

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Header Text: c4591001

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Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1251

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Header Text: c4591001

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Header Text: c4591001

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Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
6	Oct-21-2020 09:48:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Oct-21-2020 09:48:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

Header Text: c4591001

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Unscheduled Visit on Oct/09/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1251

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Item	Date	User	Comment
1	Oct-21-2020 09:48:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

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Header Text: c4591001

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Form: MICROBIOLOGY SPECIMEN - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1251

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Subject Initials: ---

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Form	Jan-11-2021 13:12:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done

Header Text: c4591001

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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

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Item	Date	User	Comment
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Header Text: c4591001

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8	Jan-11-2021 13:12:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done <hr/> Not Done

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9	Jan-11-2021 13:12:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done <hr/> Not Done

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Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

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Form	Jan-11-2021 13:13:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done

Header Text: c4591001

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Form: RESPIRATORY TREATMENT - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1251

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1	Jan-11-2021 13:13:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done <hr/> Not Done

Header Text: c4591001

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Item	Date	User	Comment
2	Jan-11-2021 13:13:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done <hr/> Not Done

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

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Generated By: (b) (4)

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Item	Date	User	Comment
Form	Jan-11-2021 13:14:20 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done

Header Text: c4591001

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Form: ILLNESS DETAILS - SEVERE - Comments

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Item	Date	User	Comment
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Header Text: c4591001

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Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: LOCAL LABORATORY DATA - REPEATING
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Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

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Item	Date	User	Comment
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Header Text: c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
3	Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done <hr/> Not Done

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Header Text: c4591001

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Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Jan-11-2021 13:19:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Jan-11-2021 13:19:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form Version: 06-Jul-2020 21:52

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Site No: 1251

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Item	Date	User	Comment
3	Jan-11-2021 13:19:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form Version: 06-Jul-2020 21:55

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
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Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

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Item	Date	User	Comment
Form	Jan-11-2021 13:19:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form Version: 06-Jul-2020 21:55

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Subject No: 12511060

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Item	Date	User	Comment
1	Jan-11-2021 13:19:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done <hr/> Not Done

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Item	Date	User	Comment
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Header Text: c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
4	Jan-11-2021 13:19:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done <hr/> Not Done

Header Text: c4591001

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Form: MEDICATION ERROR - Comments

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR - Comments

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
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Header Text: c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
4	Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

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Site Name: (1251) Achieve Clinical Research

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Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
5	Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
6	Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

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Form: MEDICATION ERROR - Comments

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
7	Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

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Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
8	Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR - Comments

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
9	Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR - Comments

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
10	Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Oct-23-2020 13:07:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA _____ Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

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Item	Date	User	Comment
1	Oct-23-2020 13:07:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

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Item	Date	User	Comment
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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

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Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
9	Oct-23-2020 13:08:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
10	Oct-23-2020 13:08:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	NA
			Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
2	Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
4	Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
5	Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
6	Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-23-2020 13:08:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
1	Oct-23-2020 13:08:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
2	Oct-23-2020 13:08:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NA <hr/> Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Hayes Williams	Approved	Mar-12-2021 10:21:48 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Mar-11-2021 15:13:15 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Hayes Williams	Approved	Mar-10-2021 15:27:36 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Affidavit:

By my dated signature below, I, HayesWilliams, 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	Jan-25-2021 08:58:55 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Hayes Williams	Approved	Jan-20-2021 13:56:48 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HayesWilliams, 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.

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(b) (6)	N/A	Jan-11-2021 13:11:02 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Hayes Williams	Approved	Nov-13-2020 12:53:46 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HayesWilliams, 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-13-2020 08:12:30 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Hayes Williams	Approved	Nov-11-2020 14:12:19 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Affidavit:

By my dated signature below, I, HayesWilliams, 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-11-2020 11:10:58 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Hayes Williams	Approved	Nov-10-2020 13:51:32 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HayesWilliams, 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.

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(b) (6)	N/A	Nov-10-2020 09:54:45 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Hayes Williams	Approved	Oct-23-2020 13:10:52 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HayesWilliams, 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.

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-27-2020 08:49:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 08:49:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-27-2020 08:50:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/26/2020	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-27-2020 08:49:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12511060	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-27-2020 08:49:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1987	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-27-2020 08:50:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Aug-27-2020 08:50:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF S PANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-27-2020 08:50:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRICA N AMERICAN	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-27-2020 08:50:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020	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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-27-2020 08:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-27-2020 08:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-27-2020 08:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1.a

Date	Location	User	Value	Reason
Aug-27-2020 08:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 1 umber: Medical His Acid Ref tory Term: lux Start Date: UNK/U NK/201 6 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 08:51:31 (UTC-06:00) Central 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
Aug-27-2020 08:51:31 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acid Reflux	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

& Canada)

1.a Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 08:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 08:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-27-2020 08:52:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 2 umber: Medical His Hemorrh tory Term: oids Start Date: UNK/U NK/201 7 Ongoing: YES	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 08:52:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 08:52:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemorrhoids	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 08:52:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 08:52:17	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

I.c

Date	Location	User	Value	Reason
Aug-27-2020 08:52:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 3 Medical History Term: sinus headaches Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 08:52:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 08:52:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sinus headaches	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 08:52:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 08:52:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

1.d

Date	Location	User	Value	Reason
Feb-12-2021 08:31:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 4 Medical History Term: obesity Start Date: UNK/UNK/2011 Ongoing: YES	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

1.d Line/MH Number:

Date	Location	User	Value	Reason
Feb-12-2021 08:31:41 (UTC-06:00) Central 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
Feb-12-2021 08:31:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: obesity	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Feb-12-2021 08:31:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2011	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Feb-12-2021 08:31:41	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00) Central Time (US & Canada)				
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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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-27-2020 08:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-28-2020 03:22:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-27-2020 10:47:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	value is correct. Confirmed per source
Aug-27-2020 08:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Weight 347 is outside of Normal Range 25 - 136 for kg or 50 - 300 for lb.

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Aug-27-2020 08:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 347.0	Initial Entry
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3. Unit:

Date	Location	User	Value	Reason
Aug-27-2020 08:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-27-2020 08:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 69.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-27-2020 08:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-27-2020 08:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 51.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-27-2020 08:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 98.1 Temperature Unit: Temperature Location: ORAL CAVIT :: Y	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-27-2020 08:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

7.a Temperature:

Date	Location	User	Value	Reason
Aug-27-2020 08:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-27-2020 08:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-27-2020 08:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-27-2020 08:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-27-2020 08:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 68849	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Aug-27-2020 08:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-27-2020 08:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-27-2020 08:58:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 08:58:43 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-27-2020 08:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 08:58:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPYNG : 8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 08:58:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYNG8	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Aug-27-2020 08:59:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPYNG : 9	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 08:59:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYNG9	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-27-2020 08:59:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPYNG : B	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 08:59:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYNGB	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.d

Date	Location	User	Value	Reason
Aug-27-2020 09:02:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BNWBS D: N	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 09:02:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWBSN	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-27-2020 09:02:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BNWBS : P	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.e Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 09:02:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWBSP	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Aug-27-2020 08:59:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-27-2020 08:59:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-27-2020 09:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 08:59:55 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-27-2020 08:59:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 09:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPYNV : C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 09:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYNVC	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-27-2020 08:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-27-2020 08:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-27-2020 08:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Aug-27-2020 08:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020 15:30	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-27-2020 08:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-27-2020 08:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-27-2020 08:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-27-2020 08:55:28 (UTC-06:00) Central 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-27-2020 08:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-27-2020 08:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-25-2020 09:49:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-25-2020 06:34:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	AE Form updated
Oct-23-2020 07:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Query: Per reported PD, nasal congestion reported via phone on 02Sep was not entered into InForm. If this was a symptom of potential COVID, please record in COVID Illness Visit. If not, please record on AE CRF.

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-23-2020 03:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated per query
Oct-22-2020 07:48:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	October 9th's visit is not erroneous. Please update!
Oct-19-2020 03:20:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	RQ1: Response states 'no illness to report per investigator'. Please confirm if Illness edairy entry on 09OCT2020 was deemed erroneous and that subject had no Covid Illness symptoms.
Oct-16-2020 11:57:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no illness to report per investigator
Oct-16-2020 11:30:19 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness edairy: As per Illness edairy records,

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Header Text: c4591001

Visit: V2_VAX2_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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)				subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 09OCT2020. But corresponding COVID Illness visit not reported. Please clarify.
Sep-16-2020 09:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date:

Date	Location	User	Value	Reason
Sep-16-2020 09:54:33 (UTC-06:00) Central 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 09:54:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 97.6 Temperature Unit: F Temperature Location: ORAL CAVIT : Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 09:54:33 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-16-2020 09:54:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 09:54:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-16-2020 09:54:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 09:54:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 09:54:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 10:27:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 09:54:54 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 09:54:54 (UTC-06:00) Central 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-16-2020 10:27:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BM907 : K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 10:27:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM907K	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-16-2020 09:58:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-16-2020 09:58:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-16-2020 09:58:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Sep-16-2020 09:58:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020 08:34	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 09:58:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-16-2020 09:58:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-16-2020 09:58:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-16-2020 09:58:37 (UTC-06:00) Central 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 09:58:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 11:12:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Oct-15-2020 11:12:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-15-2020 11:12:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-15-2020 16:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 11:12:34 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251 Site Name: (1251) Achieve Clinical Research

Subject No: 12511060 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 11:12:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 16:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR90PX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 16:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR90PX	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

Oct-15-2020 16:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR90PY	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 16:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR90PY	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 16:19:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR90PZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 16:19:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR90PZ	Initial Entry

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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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

5.d

Date	Location	User	Value	Reason
Oct-15-2020 16:19:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BNWBN D: N	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 16:19:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWBNN	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-15-2020 16:19:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BNWBN D: P	Initial Entry

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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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

5.e Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 16:19:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWBNP	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 15:13:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/11/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Mar-11-2021 15:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-11-2021 15:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-12-2021 07:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-12-2021 05:57:39 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Mar-11-2021 15:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-11-2021 15:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-12-2021 07:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR4P2P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Mar-12-2021 07:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR4P2P	Initial Entry
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5.b

Date	Location	User	Value	Reason
Mar-12-2021 07:54:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR4P2R	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 07:54:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR4P2R	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-12-2021 07:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR4P2S	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.c Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 07:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR4P2S	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-12-2021 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BNVKR D: W	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNVKRW	Initial Entry

5.e

Date	Location	User	Value	Reason
Mar-12-2021 07:55:39	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BNVKR	Initial Entry

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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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	:	X	
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5.e Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 07:55:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNVKRX	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-21-2020 09:41:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-21-2020 09:39:04 (UTC-06:00) Central 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.
Oct-21-2020 09:39:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

				Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-21-2020 09:39:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-21-2020 09:39:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 10-Oct-2020 16:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Sympto m Resolved: Oct/11/2020	Initial Entry

4.a

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 10-Oct-2020 16:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEV ER Symptom Pre NO sent:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR I oms: NCREASE	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)			D COUGH Symptom Present: YES	
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4.b Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central 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
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: INCREASED SHORTNESS OF BREATH	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Symp tom P resen t:	
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4.c Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL LS Symptom Pr NO esent:	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 10-Oct-2020 16:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR IN oms: CREASED MUSCLE PA IN Sympt NO om Pr esent:	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 10-Oct-2020 16:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central 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
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 10-Oct-2020 16:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 10-Oct-2020 16:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom P present: NO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 10-Oct-2020 16:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMIT ING Symptom P NO resent:	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 10-Oct-2020 16:02

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 09:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 06-Jul-2020 21:54

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5. Device Type:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 06-Jul-2020 21:54

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Oct-21-2020 09:41:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-21-2020 09:41:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-21-2020 09:41:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 09:41:02 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-21-2020 09:41:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 09:41:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID CV2962 : 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 09:41:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV29620	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Oct-21-2020 09:41:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-21-2020 09:41:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-21-2020 09:41:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-21-2020 09:41:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sample collected by s ubject. not in our offic e	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 10-Oct-2020 15:59

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

1.b

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr EMERG actioner: ENCY ROOM Occurenc NO e of Visits o r Contacts:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00) Central 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
Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry
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1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGE NT C ARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00) Central 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
Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPH ONE CO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)			r: NSULTA TION	
			Occurren NO ce of Visit s or Cont acts:	

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONS ULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practit OT ioner: HE R	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

& Canada)			Occurrence of NO Visits or Conta cts:	
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-21-2020 09:42:47 (UTC-06:00) Central 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
Oct-21-2020 09:42:47 (UTC-06:00) Central 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
Oct-21-2020 09:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 06-Jul-2020 21:53

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: RESPIRATORY TREATMENT - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Oct-21-2020 09:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: RESPIRATORY TREATMENT - eCRF Audit Trail
History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-21-2020 09:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5. Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-21-2020 09:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 06-Jul-2020 21:52

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID- 19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 09:43:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: ILLNESS DETAILS - SEVERE - eCRF Audit
Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Oct-21-2020 09:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: ILLNESS DETAILS - SEVERE - eCRF Audit
Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-21-2020 09:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:49

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.a

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:49

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US
& Canada)

5.a Test:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:49

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Def Not Ap ined Identifi plicabl er: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:49

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

5.b LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Def Not Ap ined Identifi plicabl er: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:49

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

5.c LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Def Not Ap ined Identifi plicabl er: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:49

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

5.d LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

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CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
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Subject No: 12511060

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

5.f LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
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Header Text: c4591001

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Form Version: 21-Aug-2020 02:49

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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CHEMISTRY - eCRF Audit Trail History

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Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.g Sponsor ID:

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Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

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(UTC-06:00) Central Time (US & Canada)				
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5.g LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

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Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:51

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: LOCAL LABORATORY DATA - REPEATING
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Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.a

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Def Not Ap ined Identifi plicabl er: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Form Version: 21-Aug-2020 02:51

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Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)				
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5.a Test:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.a LNMT

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Site Name: (1251) Achieve Clinical Research

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Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

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Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.b Sponsor ID:

Date	Location	User	Value	Reason
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5.b LNMT

Date	Location	User	Value	Reason
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Site Name: (1251) Achieve Clinical Research

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Date	Location	User	Value	Reason
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Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

5.e LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Def Not Ap ined Identifi plicabl er: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:51

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Hematology - eCRF Audit Trail History

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Site No: 1251

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Generated Time (GMT): 29-Mar-2021 18:51

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Central Time (US
& Canada)

5.f LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Def Not Ap ined Identifi plicabl er: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:51

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

5.g LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Def Not Ap ined Identifi plicabl er: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:51

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

5.h LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Def Not Ap ined Identifi plicabl er: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e Lab Normal Not Ap Range: plicabl e	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.i LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Def Not Ap ined Identifi plicabl er: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:51

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

			Lab Normal Range:	Not Applicable	
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:51

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

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Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

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

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Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

5.j LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date:

Date	Location	User	Value	Reason
Oct-21-2020 09:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-21-2020 09:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in respir ations/minute : Not Applicable Heart Rate in beats/minute: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 21-Aug-2020 02:50

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-21-2020 09:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-21-2020 09:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Oct-21-2020 09:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Oct-21-2020 09:47:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Oct-21-2020 09:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date:

Date	Location	User	Value	Reason
Oct-21-2020 09:47:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-21-2020 09:47:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Not Applicable Oxygen Saturation: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-21-2020 09:47:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
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Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-21-2020 09:47:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 06-Jul-2020 21:52

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: OXYGENATION PARAMETERS - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Oct-21-2020 09:48:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Oct-21-2020 09:48:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Oct-21-2020 09:48:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 06-Jul-2020 21:55

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-21-2020 09:48:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-21-2020 09:48:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-21-2020 09:48:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

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name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-21-2020 09:48:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 09:48:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-21-2020 09:48:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form Version: 06-Jul-2020 21:53

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: IMAGING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-21-2020 09:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-21-2020 09:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-21-2020 09:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/09/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-21-2020 09:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 08:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-12-2021 03:29:30 (UTC-06:00) Central 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 Nasal Swab are missing. Please review and update as appropriate.
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-11-2021 13:11:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1251**Subject No:** 12511060**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1251) Achieve Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

				Symptoms form is missing. Please review and update as appropriate.
Jan-11-2021 13:11:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-11-2021 13:11:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-11-2021 13:11:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/7/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Sympto m Resolved: Jan/10/2021	Initial Entry

4.a

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEV ER Symptom Pre NO sent:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR I oms: NCREASE	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)			D COUGH Symptom Present: YES	
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4.b Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central 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
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: INCREASED SHORTNESS OF BREATH	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

			Symp tom P resen t:	
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4.c Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL LS Symptom Pr NO esent:	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR IN oms:CREASED MUSCLE PA IN Sympt NO om Pr esent:	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central 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
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central 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
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARR HEA Symptom P NO resent:	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMIT ING Symptom P YES resent:	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 13:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:54

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-11-2021 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-11-2021 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-11-2021 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:54

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Jan-11-2021 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5. Device Type:

Date	Location	User	Value	Reason
Jan-11-2021 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-11-2021 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-11-2021 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:54

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-11-2021 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-11-2021 13:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Jan-20-2021 08:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 08:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-26-2021 17:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-26-2021 10:00:06 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)				
Jan-22-2021 13:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued :Opened	DM2: Thank you for your response. However, please provide the reason on the CRF in field #2 instead of the query response.
Jan-22-2021 10:09:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Subject delay was due to subject not understanding the significance of timely self swab collection. Subject was educated, once again, on the importance of timely self swab collection
Jan-21-2021 00:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued :Opened	DM: Please provide reason for delay in eCRF field #4. Thank you.

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Jan-20-2021 22:35:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-20-2021 08:13:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	marken did not deliver self swab to patient on the day they were supposed to deliver. Date of collection is correct due to this.
Jan-20-2021 08:11:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-20-2021 08:10:53 (UTC-06:00) Central 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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

				appropriate.
Jan-20-2021 08:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidat e	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-20-2021 08:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-20-2021 08:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Jan/18/2021	Initial Entry
Jan-12-2021 01:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Sample Collected?" is missing. Kindly review and update.

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

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Jan-25-2021 08:58:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample was collecte d out of window	Initial Entry
Jan-20-2021 08:10:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Jan-11-2021 13:12:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: will self swab at hom e	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 08:11:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID CV0667 : 6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 08:11:13 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV06676	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

& Canada)

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Jan-11-2021 13:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-11-2021 13:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-11-2021 13:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Jan-11-2021 13:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: will use at home self s wab	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:26

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1.a

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

1.b

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr EMERG actioner: ENCY ROOM Occurenc NO e of Visits o r Contacts:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00) Central 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
Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry
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1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGE NT C ARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00) Central 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
Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPH ONE CO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)			r: NSULTA TION	
			Occurren ce of Visit s or Cont acts:	

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONS ULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practit OT ioner: HE R	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

& Canada)			Occurrence of NO Visits or Conta cts:	
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 13:13:23 (UTC-06:00) Central 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
Jan-11-2021 13:13:23 (UTC-06:00) Central 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
Jan-11-2021 13:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:53

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: RESPIRATORY TREATMENT - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Jan-11-2021 13:13:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-11-2021 13:13:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-11-2021 13:13:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:53

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: RESPIRATORY TREATMENT - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Jan-11-2021 13:13:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5. Start Date:

Date	Location	User	Value	Reason
Jan-11-2021 13:13:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-11-2021 13:13:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:52

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID- 19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 13:14:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: ILLNESS DETAILS - SEVERE - eCRF Audit
Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-11-2021 13:14:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 17-Jul-2020 21:55

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: ILLNESS DETAILS - SEVERE - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Jan-11-2021 13:14:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 21-Aug-2020 02:49

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.a

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Not Range: Done	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 21-Aug-2020 02:49

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

& Canada)

5.b

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
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& Canada)

5.b LNMT

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Not Range: Done	Initial Entry

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Date	Location	User	Value	Reason
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Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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5.c LNMT

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Not Range: Done	Initial Entry

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5.d Sponsor ID:

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5.d Test:

Date	Location	User	Value	Reason
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5.d Result:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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5.d LNMT

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Not Range: Done	Initial Entry

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Site No: 1251

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& Canada)

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Date	Location	User	Value	Reason
Jan-11-2021 13:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
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Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Site No: 1251

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5.a

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Not Range: Done	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.c Test:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

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

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

5.c LNMT

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Not Range: Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 21-Aug-2020 02:51

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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5.d LNMT

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Not Range: Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

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Form Version: 21-Aug-2020 02:51

Site No: 1251

Subject No: 12511060

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Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

5.e LNMT

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Not Range: Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

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Visit: POT_COVID_ILL 2 -
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Form Version: 21-Aug-2020 02:51

Site No: 1251

Subject No: 12511060

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Generated Time (GMT): 29-Mar-2021 18:51

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

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& Canada)

5.f LNMT

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Not Range: Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form Version: 21-Aug-2020 02:51

Site No: 1251

Subject No: 12511060

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Hematology - eCRF Audit Trail History

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Subject No: 12511060

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Generated Time (GMT): 29-Mar-2021 18:51

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Central Time (US
& Canada)

5.g LNMT

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Not Range: Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

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Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

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5.h Sponsor ID:

Date	Location	User	Value	Reason
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5.h Test:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Form Version: 21-Aug-2020 02:51

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Site No: 1251

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00)
Central Time (US
& Canada)

5.h LNMT

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
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Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

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Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.i LNMT

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j

Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin Not ed Identifier: Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Not Range: Done	Initial Entry

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Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
Jan-11-2021 13:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Visit: POT_COVID_ILL 2 -
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Form Version: 21-Aug-2020 02:50

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

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1. Date:

Date	Location	User	Value	Reason
Jan-11-2021 13:15:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-11-2021 13:15:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Systolic:: Not Done Diastolic:: Not Done Respiratory Rate in respiratory rate in respiratory ns/minute: Not Done Heart Rate in beats/minute: Not Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

Generated By: (b) (4)

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2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-11-2021 13:15:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-11-2021 13:15:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-11-2021 13:15:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-11-2021 13:15:16	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

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(UTC-06:00)
Central Time (US
& Canada)

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-11-2021 13:15:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

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1. Date:

Date	Location	User	Value	Reason
Jan-11-2021 13:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-11-2021 13:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Ident Not D ifier:: one Oxygen Satu Not D ration: one	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-11-2021 13:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a SPO2 Pulse Oximetry %

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Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Jan-11-2021 13:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:52

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: OXYGENATION PARAMETERS - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Jan-11-2021 13:19:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Jan-11-2021 13:19:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Jan-11-2021 13:19:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:55

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-11-2021 13:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-11-2021 13:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-11-2021 13:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:55

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-11-2021 13:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-11-2021 13:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-11-2021 13:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:53

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: IMAGING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-11-2021 13:19:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-11-2021 13:19:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-11-2021 13:19:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/11/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Jan-11-2021 13:19:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/10/2020

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-13-2020 16:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Cl osed	Response satisfies query
Nov-13-2020 08:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: A nswered	updated
Nov-13-2020 01:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: O pened	DM: Convalescent Visit (COVID_B1)is entered, however there is no corresponding Covid Illness Visit(COVID_B)exist. Kindly review and update data as appropriate. Else explain.
Nov-10-2020 09:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: Nov/10/20 20	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/10/2020

Form Version: 22-Apr-2020 21:04

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-13-2020 08:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Transcription Error
Nov-11-2020 16:07:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 11:07:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	COVID visit is entered??
Nov-11-2020 05:06:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: Subject has completed Convalescent visit, however corresponding COVID illness visit is not recorded. Please review and update the details as appropriate. Thank you.

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/10/2020

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Nov-10-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_B1	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/10/2020

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Nov-10-2020 10:00:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-10-2020 10:00:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-11-2020 11:10:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-11-2020 10:19:21 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: 'Sample Collected?' is Yes, however

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/10/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1251**Subject No:** 12511060**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1251) Achieve Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Nov-10-2020 10:00:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-10-2020 10:00:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Nov/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-11-2020 11:10:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR2K43	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/10/2020

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Nov-11-2020 11:10:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR2K43	Initial Entry
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5.b

Date	Location	User	Value	Reason
Nov-11-2020 11:11:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR2K44	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 11:11:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR2K44	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-11-2020 11:11:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR2K45	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/10/2020

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.c Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 11:11:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR2K45	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-11-2020 11:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHZ1F	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 11:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHZ1F	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-11-2020 11:12:05	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BSHZ1	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/10/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	:	G	
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5.e Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 11:12:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHZ1G	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Feb/09/2021

Form Version: 22-Apr-2020 21:04

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-10-2021 12:22:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-10-2021 12:22:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_B1	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Feb/09/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Feb-10-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-10-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-10-2021 12:31:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 12:22:25 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Feb/09/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-10-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-10-2021 12:31:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ7B7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 12:31:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ7B7	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Feb/09/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Feb-10-2021 12:31:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ7BP	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 12:31:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ7BP	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-10-2021 12:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRJ7B : R	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 12:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ7BR	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Feb/09/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.d

Date	Location	User	Value	Reason
Feb-10-2021 12:32:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BNVKG : Z	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 12:32:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNVKGZ	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-10-2021 12:32:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BNVKH : 0	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Feb/09/2021

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.e Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 12:32:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNVKH0	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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-15-2020 11:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-15-2020 11:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-15-2020 11:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

***** THIS REPEATING FORM HAS BEEN DELETED *****

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Date	Location	User	Value	Reason
Oct-22-2020 08:00:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	entered in error
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

***** THIS REPEATING FORM HAS BEEN DELETED *****

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Date	Location	User	Value	Reason
Oct-22-2020 08:01:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Oct-22-2020 07:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Oct-23-2020 13:06:01 (UTC-06:00) Central 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, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Category:

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: chills	Initial Entry

4. Start Date Time:

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020 02:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/6/2020 16:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

*** THIS REPEATING FORM HAS BEEN DELETED ***

(UTC-06:00)
Central Time (US
& Canada)

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

Date	Location	User	Value	Reason
Oct-22-2020 07:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Category:

Date	Location	User	Value	Reason
Oct-22-2020 07:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-22-2020 07:57:08 (UTC-06:00) Central 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-22-2020 07:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sore throat	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

***** THIS REPEATING FORM HAS BEEN DELETED *****

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-22-2020 07:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020 02:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-22-2020 07:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/8/2020 20:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-22-2020 07:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

***** THIS REPEATING FORM HAS BEEN DELETED *****

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-22-2020 07:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-22-2020 07:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-22-2020 07:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

*** THIS REPEATING FORM HAS BEEN DELETED ***

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-22-2020 07:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-22-2020 07:57:08 (UTC-06:00) Central 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-22-2020 07:57:08 (UTC-06:00) Central 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
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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, Deleted, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

*** THIS REPEATING FORM HAS BEEN DELETED ***

Oct-22-2020 07:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-22-2020 07:57:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

Date	Location	User	Value	Reason
Oct-23-2020 13:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-23-2020 13:06:01 (UTC-06:00) Central 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
Oct-23-2020 13:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nasal Congestion	Initial Entry

4. Start Date Time:

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-23-2020 13:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/2/2020 UNK:UN K	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-23-2020 13:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/4/2020 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-23-2020 13:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-23-2020 13:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-23-2020 13:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-23-2020 13:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-23-2020 13:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-23-2020 13:06:01 (UTC-06:00) Central 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-23-2020 13:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-23-2020 13:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESO LVED	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Oct-23-2020 13:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

Date	Location	User	Value	Reason
Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Medication Error (Type of Medication Error):

Date	Location	User	Value	Reason
Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Start Date:

Date	Location	User	Value	Reason
Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Is the medication error still ongoing?

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

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Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

8. Did the Medication Error cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Was this medication error associated with any adverse events?

Date	Location	User	Value	Reason
Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-23-2020 13:07:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-23-2020 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-23-2020 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-23-2020 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-23-2020 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-23-2020 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-23-2020 13:08:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-23-2020 13:08:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-23-2020 13:08:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-23-2020 13:08:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Oct-23-2020 13:08:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Oct-23-2020 13:08:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-23-2020 13:08:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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8. Route:

Date	Location	User	Value	Reason
Oct-23-2020 13:08:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Oct-23-2020 13:08:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Oct-23-2020 13:08:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

Date	Location	User	Value	Reason
Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. What is the treatment Identifier?

Date	Location	User	Value	Reason
Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
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090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5. Start Date:

Date	Location	User	Value	Reason
Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-23-2020 13:08:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: TRANSFUSIONS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Transfusion Type:

Date	Location	User	Value	Reason
Oct-23-2020 13:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Date of Transfusion:

Date	Location	User	Value	Reason
Oct-23-2020 13:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 14:03:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251 **Site Name:** (1251) Achieve Clinical Research

Subject No: 12511060 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Feb-23-2021 14:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/n ational recommend ations and confirm ed to have received only placebo at Va ccination 1/2	Initial Entry

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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-12-2021 13:09:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-24-2021 11:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 14:03:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answer ed	Changed data per query
Feb-23-2021 00:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Puig (b) (4)	Query 1: Opened	DM: Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

				VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Feb-12-2021 13:09:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Subject Status

Date	Location	User	Value	Reason
Oct-15-2020 11:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-27-2020 08:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-27-2020 08:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-15-2020 11:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/15/2020	Initial Entry
Aug-27-2020 08:55:05	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/26/2020	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (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: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00) Central Time (US & Canada)				
Aug-27-2020 08:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/26/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1251

Subject No: 12511060

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 11:14:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3d08\Final\Final On: 01-Apr-2021 04:23 (GMT)