

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: COHORT SELECTION

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Informed Consent

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10841470]
2.	Birth Date:	(b) (6)/1955
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 15-Sep-2020 21:52**Site No:** 1084**Subject No:** 10841470**Generated By:** (b) (4)**Form:** INCLUSION/EXCLUSION CRITERIA**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1084) Clinical Trials of Texas**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Form Comments](#)[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

1.a	Inclusion Number:	1	
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	IN01A00	
1.b	Inclusion Number:	2	
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	IN02A00	
1.c	Inclusion Number:	3	
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	IN03A00	
1.d	Inclusion Number:	4	
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	IN04A00	

Exclusion Criteria

2.a	Exclusion Number:	1	
-----	-------------------	---	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX01A00	
2.b	Exclusion Number:	2	
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX02A00	
2.c	Exclusion Number:	3	
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX03A00	
2.d	Exclusion Number:	4	
	Criterion Description:	Receipt of medications intended to prevent COVID-19	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX04A00	
2.e	Exclusion Number:	8	
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX08A00	

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

2.f	Exclusion Number:	10	
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX10A00	
2.g	Exclusion Number:	11	
	Criterion Description:	Women who are pregnant or breastfeeding	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX11A00	
2.h	Exclusion Number:	12	
	Criterion Description:	Previous vaccination with any coronavirus vaccine	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX12A00	
2.i	Exclusion Number:	13	
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX13A01	
2.j	Exclusion Number:	15	
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX14A01	

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

2.k	Exclusion Number:	16	
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX15A01	
2.l	Exclusion Number:	17	
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX16A01	
2.m	Exclusion Number:	22	
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	
	Criterion met?	Not Applicable	Comments
	Criterion ID: (For Pfizer use only)	EX21A01	

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/30/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[pulmonary fibrosis]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[gerd]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[insomnia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hyperlipidemia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/30/2020
2.	Weight:	[130.4]
3.	Unit:	kg
4.	Height:	[177.8]
5.	Unit:	cm
6.	Body Mass Index:	[41.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/30/2020
2.	Randomization Number:	[266398]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8PPG]
5.b	Sample ID	[BP8PPH]
5.c	Sample ID	[BP8PPJ]
5.d	Sample ID	[BKZ9LP]
5.e	Sample ID	[BKZ9LR]

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8PP1]
-----	-----------	----------

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/30/2020 09:54
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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/21/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/21/2020
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	[BPC0YD]
-----	-----------	----------

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/21/2020 15:53
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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BMNDLG]
5.b	Sample ID	[BMNDLH]
5.c	Sample ID	[BKSCXK]
5.d	Sample ID	[BKSCXL]
5.e	Sample ID	[BKSCXM]

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Jan/06/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/6/2021
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 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Jan/06/2021

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jan/6/2021
2.	Date of First Symptom Started:	Dec/28/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Jan/11/2021

Symptoms

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

Symptoms - Other

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Jan/06/2021

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.a	Symptoms - Other Text:	[fatigue]
5.b	Symptoms - Other Text:	[weakness]
5.c	Symptoms - Other Text:	[nausea]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Dec/31/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN

Jan/06/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Dec/31/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	POSITIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[NALT UNKNOWN]

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Jan/06/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Subject is hospitalized on ventilator]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Jan/06/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[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:	[Subject is hospitalized on ventilator]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION
Jan/06/2021

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[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:	YES Number of Visits or Contacts: [1]
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
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	YES Has the subject been in intensive care due to potential COVID-19 illness? YES
----	----------------------------------------------------------------------	-----------------------------------------------------------------------------------------

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Dec/31/2020	NO Discharge Date: Jan/11/2021	Repeating Pages

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS

Jan/06/2021

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Dec/31/2020
4.	Ongoing?	NO Discharge Date: Jan/11/2021

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	1	YES	MECHANICAL VENTILATION	MECHANICAL VENTILATION	Jan/2/2021	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT

Jan/06/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Respiratory Treatment

1.	What is the treatment Identifier?	[1]
2.	Concomitant Non-drug Treatment Pre-specified:	YES
3.	Treatment:	MECHANICAL VENTILATION
4.	Treatment:	[MECHANICAL VENTILATION]
5.	Start Date:	Jan/2/2021
6.	Ongoing?	NO End Date: Jan/11/2021

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Jan/06/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[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?	YES Respiratory Illness Diagnosis: [COVID-19] Date of Diagnosis: Dec/31/2020
3.	Toxicity Grade:	5

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	SEVERE COVID-19 ILLNESS	SIGNIFICANT ACUTE RENAL DYSFUNCTION	YES <i>Diagnosis:</i> Acute Renal Failure Start Date: Jan/4/2021 Ongoing?: NO End Date: Jan/11/2021	4	Repeating Pages

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE

Jan/06/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Illness Details

1.	Category of Clinical Event:	SEVERE COVID-19 ILLNESS
2.	Subcategory of Clinical Event:	SIGNIFICANT ACUTE RENAL DYSFUNCTION
3.	Was a diagnosis obtained?	YES Diagnosis: [Acute Renal Failure] Start Date: Jan/4/2021 Ongoing?: NO End Date: Jan/11/2021
4.	Toxicity Grade:	4

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	CLINICAL CHEMISTRY	Methodist Specialty Transplant Hospital 8026 Floyd Curl Dr San Antonio, TX 78229	Dec/31/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					329	C Reactive Protein_PX329	191.2	
					30	Alanine Aminotransferase_PX30	[]	
					28	Aspartate Aminotransferase_PX28	[]	
					35	Alkaline Phosphatase_PX35	51	
					21	Bilirubin_PX21	.8	
					47	Blood Urea Nitrogen_PX47	15	
					48	Creatinine_PX48	1.10	

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/06/2021

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Methodist Specialty Transplant Hospital 8026 Floyd Curl Dr San Antonio, TX 78229]
3.	Collection Date:	Dec/31/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[191.2]
	Not Done:	
	LNMT	Low [] High [10] Unit mg/dL
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/06/2021

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[51]
	Not Done:	
	LNMT	Low [38] High [126] Unit U/L
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[.8]
	Not Done:	
	LNMT	Low [.2] High [1.3] Unit mg/dL

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/06/2021

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5 f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[15]
	Not Done:	
	LNMT	Low [9] High [20] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[1.10]
	Not Done:	
	LNMT	Low [.4] High [1.2] Unit mg/dL

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	HEMATOLOGY	Methodist Specialty Transplant Hospital 8026 Floyd Curl Dr San Antonio, TX 78229	Dec/31/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					1	Hemoglobin_PX1	17.8	
					2	Hematocrit_PX2	53.1	
					3	Erythrocytes_PX3	[]	
					5	Platelets_PX5	176	
					7	Leukocytes_PX7	[]	
					608	Neutrophils_PX608	[]	
					609	Eosinophils_PX609	[]	
					612	Monocytes_PX612	[]	
					610	Basophils_PX610	[]	
					611	Lymphocytes_PX611	[]	

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/06/2021

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Methodist Specialty Transplant Hospital 8026 Floyd Curl Dr San Antonio, TX 78229]
3.	Collection Date:	Dec/31/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[17.8]
	Not Done:	
	LNMT	Low [13] High [17] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[53.1]
	Not Done:	
	LNMT	Low [40] High [50] Unit %

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/06/2021

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[176]
	Not Done:	
	LNMT	Low [150] High [400] Unit /uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/06/2021

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/06/2021

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 15-Sep-2020 21:52

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Date:	Vital Signs Details			Form Instance
1.	Jan/11/2021	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	90	54	

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 14-Jan-2021 02:17

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Date:	Vital Signs Details			Form Instance
2. DELETED	Dec/31/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	152	88	
3.	Dec/31/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	171	94	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Jan/06/2021

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Vital Signs

1.	Date:	Jan/11/2021
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[90]
	Diastolic:	[54]
	Respiratory Rate in respirations/minute:	[21]
	Heart Rate in beats/minute:	[132]

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Deleted, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

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

Vital Signs

1.	Date:	Dec/31/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	†
	Systolic:	[152]
	Diastolic:	[88]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[81]

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Vital Signs

1.	Date:	Dec/31/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[171]
	Diastolic:	[94]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[84]

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 15-Sep-2020 21:54

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Date:	Vital Signs Details		Form Instance
1. DELETED	Dec/31/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	92.0	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 14-Jan-2021 02:17

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Date:	Vital Signs Details		Form Instance
2. DELETED	Dec/31/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	93.0	
3.	Dec/31/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	88.0	
4.	Jan/4/2021	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	95.0	
5.	Jan/11/2021	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	96.0	

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Jan/06/2021

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Deleted, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

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

Vital Signs

1.	Date:	Dec/31/2020
----	-------	-------------

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Deleted, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

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

Vital Signs

1.	Date:	Dec/31/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	↓
	SPO2 Pulse Oximetry %	[93.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Vital Signs

1.	Date:	Dec/31/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[88.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Vital Signs

1.	Date:	Jan/4/2021
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[95.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Vital Signs

1.	Date:	Jan/11/2021
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[96.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Jan/2/2021 17:42	40	0.84	Repeating Pages
2.	Jan/11/2021 07:45	40	0.50	Repeating Pages

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS

Jan/06/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Oxygenation Parameters

1.	Date Time of Assessment:	Jan/2/2021 17:42
2.	Arterial Blood Gases PaO2 (mmHg):	[40]
3.	FiO2 (Fraction of Inhaled Oxygen):	[0.84]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS
Jan/06/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Oxygenation Parameters

1.	Date Time of Assessment:	Jan/11/2021 07:45
2.	Arterial Blood Gases PaO2 (mmHg):	[40]
3.	FiO2 (Fraction of Inhaled Oxygen):	[0.50]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Jan/06/2021

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Concomitant Medications

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Dec/31/2020	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i> bilateral multifocal viral pneumonia	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING

Jan/06/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Imaging

1.	Date of Assessment:	Dec/31/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	ABNORMAL If abnormal, specify findings: [bilateral multifocal viral pneumonia]

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Unplanned Assessments

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	COVID-19 Infection	Dec/31/2020 UNK: UNK	NO End Date Time: Jan/11/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Mutli-system organ failure	Dec/31/2020 UNK: UNK	NO End Date Time: Jan/11/2021 UNK:UNK	Repeating Pages

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[COVID-19 Infection]
4.	Start Date Time:	Dec/31/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/11/2021 UNK:UNK
6.	Toxicity Grade:	4
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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? YES Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [COVID-19]

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021011324]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Mutli-system organ failure]
4.	Start Date Time:	Dec/31/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/11/2021 UNK:UNK
6.	Toxicity Grade:	4
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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? YES Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [COVID-19]

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021011324]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Medication Error

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	MODERNA COVID 19 VACCINE	Dec/23/2020	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, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[MODERNA COVID 19 VACCINE]
5.	Date:	Dec/23/2020

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	1	IMMUNOGLOBULINS	NO	Monoclonal Antibodies	Unknown	Repeating Pages

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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

Concomitant Medications

1.	What is the medication identifier?	[1]	
2.	Category:	IMMUNOGLOBULINS	
3.	Concomitant Medications Pre-specified:	NO	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Monoclonal Antibodies]	
5.	Dose:	Unknown _____ []	Comments
6.	Dose Unit:	Unknown _____	Comments
7.	Dose Frequency:	Unknown _____	Comments
8.	Route:	Unknown _____	Comments
9.	Start Date:	Dec/31/2020	
10.	Ongoing?	NO End Date: Dec/31/2020	

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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?	

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Jan/11/2021
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	DEATH
4.	Specify Status:	[]

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit			
1.	Date of Visit	Jan/14/2021	Comments
2.	Erroneous Visit	ERRONEOUS VISIT	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Form Comments](#)

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Not Applicable <hr/>	Comments

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Form Comments](#)

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Not Applicable _____ //	Comments
2.	Primary Reason for Unblinding:	Not Applicable _____	Comments

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Death Details

1.	Date of Collection / Notification of Death:	Jan/19/2021
----	---------------------------------------------	-------------

Cause of Death

2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[Multi-system organ failure]
2.b	Cause of Death Status:	SECONDARY CAUSE OF DEATH
	Cause of Death:	[COVID-19]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Jan/11/2021

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	----------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1.a	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1.b	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1.c	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1.d	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.b	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.c	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.d	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.e	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.f	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.g	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.h	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.i	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.j	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.k	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.1	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.m	Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-21-2021 16:19:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5	Feb-22-2021 17:15:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Unknown

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
6	Feb-08-2021 14:13:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
7	Feb-22-2021 17:15:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Unknown

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
8	Feb-08-2021 14:13:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

Header Text: c4591001

Visit: Potential ReVax Initial Contact

Form: DATE OF VISIT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1	Mar-04-2021 16:53:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - Comments

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-04-2021 16:52:34 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact

Form: FURTHER VACCINATION CONFIRMATION - Comments

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1	Mar-04-2021 16:52:34 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-08-2021 16:03:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1	Mar-08-2021 16:03:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2	Mar-08-2021 16:03:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Jan-26-2021 10:22:43 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

(b) (6)	Approved	Jan-22-2021 18:18:17 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------	----------	-------------------------------------------------------------	------	--------

Affidavit:

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

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

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

(b) (6)	N/A	Nov-18-2020 15:50:02 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
---------	-----	-------------------------------------------------------------	--	-----------------------------------

Affidavit:

N/A

(b) (6)	Approved	Nov-11-2020 15:07:14 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------	----------	-------------------------------------------------------------	------	--------

Affidavit:

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

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

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jan-21-2021 16:18:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Transcription Error
Sep-30-2020 10:54:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:54:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Sep-30-2020 10:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/30/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-30-2020 10:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10841470	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-30-2020 10:54:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1955	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-30-2020 10:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-30-2020 10:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Sep-30-2020 10:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Inclusion Number:</p> <p>Criterion Description: Male or female participant between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)</p> <p>Criterion Met?:</p> <p>Criterion ID: IN01A00 (For Pfizer only):</p>	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Inclusion Number:</p> <p>Criterion Description: Male or female participant between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)</p> <p>Criterion Met?:</p>	Transcription Error

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			Criterion ID IN01A00 (For Pfizer use only):	
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: 1 Criterion Description: Male or female participant between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) Criterion Met?: YES Criterion ID IN01A00 (For Pfizer use only):	Initial Entry

1.a Inclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

1.a Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry

1.a Criterion met?

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: Criteria Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures Criteria Not Applicable ?: Criteria IN02A00 ID: (For Pfizer use only):	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number:	Transcription Error

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>mber:</p> <p>Criteria Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures</p> <p>Criteria met?:</p> <p>Criteria ID: IN02A00 (For Pfizer use only):</p>	
<p>Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry:</p> <p>Inclusion Number: 2</p> <p>Criteria Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures</p> <p>Criteria met?: YES</p> <p>Criteria ID: IN02A00 (For Pfizer use only):</p>	<p>Initial Entry</p>

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

I.b Inclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

I.b Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participants who are willing and able to comply with all scheduled visits , vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

I.b Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

I.c

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criteria on Descriptio n: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study</p> <p>Criteria on met?: Not Applicable</p> <p>Criteria on ID: (For Pfizer use only): IN03A00</p>	
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Inclusion Number: 3</p> <p>Criteria on Descriptio n: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study</p> <p>Criteria on met?: Not Applicable</p> <p>Criteria on ID: (For Pfizer use only): IN03A00</p>	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Inclusion Number: 3</p>	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criteria Description: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study</p> <p>Criteria Met: YES</p> <p>Criteria ID: IN03A00 (For Pfizer use only)</p>	
--	--	--	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

I.c Inclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

I.c Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criteria Capable of giving person on Des al signed informed conse criptio nt, which includes compli n: ance with the requirement s and restrictions listed in the ICD and in this protoc ol</p> <p>Criteria Not Applicable on met ?:</p> <p>Criteria IN04A00 on ID: (For P fizer u se only):</p>	
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Inclusi 4 on Nu mber:</p> <p>Criteria Capable of giving person on Des al signed informed conse criptio nt, which includes compli n: ance with the requirement s and restrictions listed in the ICD and in this protoc ol</p> <p>Criteria on met ?:</p> <p>Criteria IN04A00 on ID: (For P fizer u se only):</p>	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Inclusi 4 on Nu mber:</p>	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criteria Description: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol</p> <p>Criteria Met: YES</p> <p>Criteria ID: IN04A00 (For Pfizer use only)</p>	
--	--	--	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

I.d Inclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

I.d Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

I.d Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criterion Description: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior /lab abnormality that may increase the risk of study participation</p> <p>Criterion Met?: Not Applicable</p> <p>Criterion ID: EX01A00 Use on Pfizer only:</p>	
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number:</p> <p>Criterion Description: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior /lab abnormality that may increase the risk of study participation</p> <p>Criterion Met?:</p> <p>Criterion ID: EX01A00 Use on Pfizer only:</p>	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number:</p>	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criterion Description: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX01A00</p> <p>Use only: (For Pfizer only)</p>	
--	--	--	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--

2.a Exclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Time (US & Canada)				
--------------------	--	--	--	--

2.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) Criterion met?: Criterion ID: (For Pfizer use only): EX02A00	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) Criterion met?: Criterion ID: (For Pfizer use only): EX02A00	Transcription Error

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 2 Criterion Description: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) Criterion met?: NO Criterion ID: (Former Pfizer use only): EX02A00	Initial Entry
-------------------------------------------------------------------	-----------------	------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

2.b Exclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criteria on Description: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)</p> <p>Criteria met?: Not Applicable</p> <p>Criteria ID: EX03A00 (For Pfizer use only):</p>	
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 3</p> <p>Criteria on Description: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)</p> <p>Criteria met?:</p> <p>Criteria ID: EX03A00 (For Pfizer use only):</p>	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 3</p> <p>Criteria on Description: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)</p>	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			Criteria NO on met ?: Criteria EX03A00 on ID: (For Pfizer use only):	
--	--	--	------------------------------------------------------------------------------------------------------	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

2.c Exclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 4	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criterion Description: Receipt of medications intended to prevent COVID-19</p> <p>Criterion met?: Not Applicable</p> <p>Criterion ID: EX04A00 : (For Pfizer use only):</p>	
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 4</p> <p>Criterion Description: Receipt of medications intended to prevent COVID-19</p> <p>Criterion met?:</p> <p>Criterion ID: EX04A00 : (For Pfizer use only):</p>	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 4</p> <p>Criterion Description: Receipt of medications intended to prevent COVID-19</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX04A00 : (For Pfizer use only):</p>	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

2.d Exclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Receipt of medications intended to p revent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusi 8 on Nu mber:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criteria on Description: Immunocompromised in individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</p> <p>Criteria met?: Not Applicable</p> <p>Criteria ID: (For Publisher use only): EX08A00</p>	
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 8</p> <p>Criteria on Description: Immunocompromised in individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</p> <p>Criteria met?:</p> <p>Criteria ID: (For Publisher use only): EX08A00</p>	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 8</p> <p>Criteria on Description: Immunocompromised in individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</p> <p>Criteria met?: NO</p>	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Criteria ID: EX08A00 (For Pfizer use only):	
--	--	--	---------------------------------------------------	--

2.e Exclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and /or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX08A00	Initial Entry

2.f

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

<p>Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: Exclusion Number: Criterion Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection Criterion met?: Criterion ID: (For Publisher use only): EX10A00</p>	<p>Initial Entry</p>
<p>Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: Exclusion Number: Criterion Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection Criterion met?: Criterion ID: (For Publisher use only): EX10A00</p>	<p>Transcription Error</p>
<p>Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: Exclusion Number:</p>	<p>Initial Entry</p>

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criteria Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p>Criteria Met?: NO</p> <p>Criteria ID: EX10A00 (For Publisher use only)</p>	
--	--	--	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--

2.f Exclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

2.f Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding Criterion met?: Not Applicable Criterion ID: (EX11A00 For Pfizer use only):	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding Criterion met?:	Transcription Error

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			Criterion ID: (EX11A00 For Pfizer use only):	
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding Criterion met?: NO Criterion ID: (EX11A00 For Pfizer use only):	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

2.g Exclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are pregnant or breastf eeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Nu 12 mber: Criterion Des Previous vaccinati cription: on with any coron avirus vaccine	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			Criterion met?: Not Applicable Criterion ID: EX12A00 (For Pfizer use only):	
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: Criterion ID: EX12A00 (For Pfizer use only):	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: EX12A00 (For Pfizer use only):	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

2.h Exclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids</p> <p>Criterion met?: Not Applicable</p> <p>Criterion ID: (For Pfizer use only): EX13A01</p>	
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 13</p> <p>Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids</p> <p>Criterion met?:</p> <p>Criterion ID: (For Pfizer use only): EX13A01</p>	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 13</p> <p>Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids</p> <p>Criterion met?: NO</p> <p>Criterion ID: (For Pfizer use only): EX13A01</p>	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

2.i Exclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.i Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criteria Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study</p> <p>Criteria met?: Not Applicable</p> <p>Criteria ID: EX14A01 (For Pfizer use only)</p>	
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: Exclusion Number:</p> <p>Criteria Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study</p> <p>Criteria met?:</p> <p>Criteria ID: EX14A01 (For Pfizer use only)</p>	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: Exclusion Number:</p> <p>Criteria Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study</p>	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			Criteria NO on met ?: Criteria EX14A01 on ID: (For Pfizer us e only) :	
--	--	--	-----------------------------------------------------------------------------------------------------------	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

2.j Exclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.j Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

2.k

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criterion Description: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation</p> <p>Criterion met?: Not Applicable</p> <p>Criterion ID: (F or Pfizer use only): EX15A01</p>	
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: Exclusion Number: 16</p> <p>Criterion Description: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation</p> <p>Criterion met?: Not Applicable</p> <p>Criterion ID: (F or Pfizer use only): EX15A01</p>	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: Exclusion Number: 16</p> <p>Criterion Description: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation</p> <p>Criterion met?: NO</p>	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Criterion ID: (For Pfizer use only): EX15A01
--	--	--	--------------------------------------------------------

2.k Exclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.k Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry

2.l

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 17 Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles Criterion met?: Not Applicable Criterion ID: (For Pfizer use only): EX16A01	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

2.1				
Date	Location	User	Value	Reason
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 17 Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles Criterion met?: Criterion EX16A01 ID: (For Pfizer use only):	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 17 Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles Criterion met?: NO Criterion EX16A01 ID: (For Pfizer use only):	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criterion Description: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members</p> <p>Criterion ID: EX21A01</p> <p>Criterion Name: (For Pfizer use only):</p>	
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: Exclusion Number:</p> <p>Criterion Description: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members</p> <p>Criterion ID: EX21A01</p> <p>Criterion Name: (For Pfizer use only):</p>	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: Exclusion Number:</p>	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criterion Description: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members</p> <p>Criterion ID: EX21A01</p> <p>Criterion Name: (For Pfizer use only):</p>	
--	--	--	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

2.m Exclusion Number:				
Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22	Initial Entry

2.m Criterion Description:				
Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?				
Date	Location	User	Value	Reason
Jan-21-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-21-2021 16:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.m Criterion ID: (For Pfizer use only)				
Date	Location	User	Value	Reason
Sep-30-2020 10:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-30-2020 10:59:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-30-2020 10:59:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-30-2020 10:59:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Sep-30-2020 11:06:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: pulmonary fibr osis Start Date: UNK/UNK/201 4 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 11:06:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 11:06:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: pulmonary fibrosis	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 11:06:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 11:06:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Sep-30-2020 11:06:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Ter hypertension m: Start Date: UNK/UNK/20 10 Ongoing: YES	Initial Entry
-------------------------------------------------------------------	-----------------	-------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 11:06:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 11:06:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypertension	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 11:06:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 11:06:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-30-2020 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Ter gerd m:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			Start Date:	UNK/UNK/2010
			Ongoing:	YES

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: gerd	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-30-2020 11:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: insomnia Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 11:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 11:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: insomnia	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 11:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 11:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-30-2020 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: hyperlipidemia Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hyperlipidemia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-21-2021 16:19:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-30-2020 11:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-30-2020 11:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 130.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-30-2020 11:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-30-2020 11:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 177.8	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-30-2020 11:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-30-2020 11:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 41.2	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

7.a

Date	Location	User	Value	Reason
Sep-30-2020 11:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.8 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-30-2020 11:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-30-2020 11:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-30-2020 11:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-30-2020 11:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-30-2020 11:35:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-30-2020 11:35:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 266398	Initial Entry

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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-01-2020 10:29:52 (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-01-2020 10:29:52 (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-01-2020 10:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 10:29:52 (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.
Oct-01-2020 10:29:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-01-2020 10:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8PPG	Initial Entry

5.a Sample ID

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Oct-01-2020 10:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8PPG	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------	------------------------------	---------------

5.b

Date	Location	User	Value	Reason
Oct-01-2020 10:30:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8PPH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 10:30:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8PPH	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-01-2020 10:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8PPJ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 10:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8PPJ	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-01-2020 10:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BKZ9LP	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.d Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 10:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BKZ9LP	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-01-2020 10:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BKZ9LR	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 10:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BKZ9LR	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841470**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-01-2020 10:28:47 (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-01-2020 10:28:47 (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-01-2020 10:29:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 10:28:47 (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.
Oct-01-2020 10:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-01-2020 10:29:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8PP1	Initial Entry

5.a Sample ID

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

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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Oct-01-2020 10:29:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8PP1	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------	------------------------------	---------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-30-2020 11:03:39 (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-30-2020 11:03:39 (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-30-2020 11:03:39 (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
Sep-30-2020 11:03:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 09:54	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-30-2020 11:03:39 (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-30-2020 11:03:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

7. Route:

Date	Location	User	Value	Reason
Sep-30-2020 11:03:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-30-2020 11:03:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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-30-2020 11:03:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-30-2020 11:03:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-21-2020 16:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-21-2020 16:53:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-21-2020 16:53:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.6 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-21-2020 16:53:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-21-2020 16:53:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-21-2020 16:53:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Oct-21-2020 16:53:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------	-----------------------------------	---------------

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 11:00:36 (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-22-2020 11:00:36 (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-22-2020 11:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 11:00:36 (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.
Oct-22-2020 11:00:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 11:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPC0YD	Initial Entry

5.a Sample ID

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Oct-22-2020 11:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPC0YD	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------	------------------------------	---------------

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-21-2020 16:54:10 (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
Oct-21-2020 16:54:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-21-2020 16:54:10 (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
Oct-21-2020 16:54:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 15:53	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-21-2020 16:54:10 (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
Oct-21-2020 16:54:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

7. Route:

Date	Location	User	Value	Reason
Oct-21-2020 16:54:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-21-2020 16:54:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 16:54:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Nov-18-2020 15:50:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/18/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841470**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-19-2020 10:05:59 (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-19-2020 10:05:59 (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-19-2020 10:06:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-19-2020 10:05:59 (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-19-2020 10:05:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-19-2020 10:06:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMNDLG	Initial Entry

5.a Sample ID

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

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, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Nov-19-2020 10:06:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMNDLG	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------	------------------------------	---------------

5.b

Date	Location	User	Value	Reason
Nov-19-2020 10:06:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMNDLH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 10:06:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMNDLH	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-19-2020 10:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BKSCXK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 10:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BKSCXK	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-19-2020 10:07:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BKSCXL	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.d Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 10:07:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BKSCXL	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-19-2020 10:07:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BKSCXM	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 10:07:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BKSCXM	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Jan/06/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Mar-04-2021 01:35:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	This issue will put on Hold in PD tracker
Feb-15-2021 00:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Candidate	PDQ RQ1: Thank you for the response, please confirm the date scheduled in query response and requesting to respond to query once data available. Else clarify.
Feb-12-2021 10:32:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	subject is recovering from hospitalization due to Covid_19. Convalescent Visit will not take place until the subject is completely recovered.
Feb-11-2021 05:06:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	PDQ: Convalescent visit is missing and 35+ days (36) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify
Jan-25-2021 03:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Jan-22-2021 15:16:52 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	added

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Jan/06/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Time (US & Canada)				
Jan-22-2021 07:26:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as reason recorded on Swab forms
Jan-21-2021 13:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not completed due to patient hospitalization
Jan-13-2021 04:54:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	DM: Kindly review and complete 'Illness Details form' at this visit. Thank you.
Jan-13-2021 04:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Invalid query
Jan-13-2021 04:50:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Hospitalization Details, Illness Details form' at this visit. Thank you.
Jan-13-2021 01:36:38 (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-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-12-2021 16:54:38 (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.
Jan-12-2021 16:54:38 (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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Jan/06/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

				Nasal Swab are missing. Please review and update as appropriate.
Jan-12-2021 16:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-12-2021 16:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Jan/06/2021 Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/28/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-04-2021 15:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-04-2021 14:04:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Feb-04-2021 14:04:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved : Jan/11/2021	New Information
Jan-29-2021 12:34:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-23-2021 12:12:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-22-2021 14:31:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	corrected
Jan-14-2021 15:12:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021011324 that the subject presented to emergency department with symptoms of weakness, dyspnea, nausea, and diarrhea. Please review and update as appropriate this SOD CRF page
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (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-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Jan/06/2021 Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

4.b

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (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-12-2021 16:55:49 (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-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Jan/06/2021 Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNE SS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (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-12-2021 16:55:49 (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-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom YES Present:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (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-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom P NO resent:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (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-12-2021 16:55:49 (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-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREASED SORE THROAT	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Jan/06/2021 Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Symptom Present: NO	
--	--	--	---------------------	--

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-22-2021 14:30:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: DIARRHEA Symptom Present: YES	Transcription Error
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Jan/06/2021 Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-22-2021 14:30:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Transcription Error
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-12-2021 16:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-12-2021 16:56:04 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other: fatigue	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Jan/06/2021 Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(US & Canada)		(b) (4), (b) (6)		
---------------	--	------------------	--	--

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-12-2021 16:56:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fatigue	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-22-2021 14:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: weakness	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-22-2021 14:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: weakness	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-22-2021 14:31:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: nausea	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-22-2021 14:31:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: nausea	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
Jan/06/2021

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-12-2021 16:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Jan/06/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-23-2021 12:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Jan-23-2021 12:13:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Closed	Response satisfies query
Jan-21-2021 13:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	unknown
Jan-21-2021 13:10:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	unknown
Jan-14-2021 16:10:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Opened	Clin: If manufacturer/test kit name is not available, please indicate whether the test was performed by a laboratory accredited by the ISO 15189 standard by including the text 'ISO 15189 accredited lab' (ie SARS-CoV-2 test ISO 15189 accredited lab)
Jan-14-2021 16:10:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: If manufacturer/test kit name is not available, please indicate whether the test was conducted in a CLIA-certified laboratory by including the text 'CLIA-certified lab' (ie SARS-CoV-2 test CLIA-certified lab)
Jan-12-2021 16:57:39 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Jan/06/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Time (US & Canada)				
Jan-12-2021 16:57:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Transcription Error
Jan-12-2021 16:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date entered is in the future compared to today's date. Please correct.
Jan-12-2021 16:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-05-2021 03:34:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021 14:04:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-04-2021 14:04:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry
Feb-01-2021 01:08:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM 2: Thanks for the response, however please confirm when data will be available.
Jan-29-2021 10:22:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	We have not been able to gather the details
Jan-26-2021 11:04:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Jan-26-2021 10:31:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Medical records do not provide this information, only says SARS_CoV-2 (PCR)

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Jan/06/2021**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen**Site No:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841470**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22

Jan-24-2021 22:18:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM2: Please update details on field # 2 and 3. Thank you.
Jan-23-2021 12:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Please try to obtain subject medical records and completed the CRF from
Jan-22-2021 14:27:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient passed away, we don't know where test was gotten and therefore cannot gather details. Thank you.
Jan-21-2021 22:31:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Unknown is not valid comment. Kindly consider to gather and update details in eCRF or else clarify. Thank you.
Jan-21-2021 13:11:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unknown
Jan-13-2021 00:04:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for Data item#2 and 3 are missing. Kindly review and update.

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-04-2021 14:04:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4 Assay Code and Description

Date	Location	User	Value	Reason
Jan-12-2021 16:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROM E CORONAVIRUS 2	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Jan/06/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5. Device Type:

Date	Location	User	Value	Reason
Jan-12-2021 16:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-12-2021 16:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-12-2021 16:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: POSITIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-12-2021 16:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NALT UNKNOWN	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 **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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-12-2021 16:58:15 (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-12-2021 16:58:15 (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-12-2021 16:58:15 (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:

Date	Location	User	Value	Reason
Jan-12-2021 16:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject is hospitalized on ventilator	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Jan/06/2021 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-12-2021 16:58:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 16:58:25 (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-12-2021 16:58:25 (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:

Date	Location	User	Value	Reason
Jan-12-2021 16:58:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject is hospitalized on ventilator	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/06/2021

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/06/2021

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.c

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (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

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/06/2021

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(US & Canada)		(b) (4), (b) (6)	CARE	
			Occurrence of Visits or NO	
			r Contacts:	

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or NO sits or Contacts:	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/06/2021

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Co ntacts: NO	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------	-----------------------------------------------------------------------------------------------------------------	---------------

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-12-2021 16:59:13 (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-12-2021 16:59:13 (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-12-2021 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject been in intensive ca re due to potential COVID-19 illne ss? YES	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS - Audit Trail
Jan/06/2021

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-21-2021 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History
Jan/06/2021

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Hospitalization Category:

Date	Location	User	Value	Reason
Jan-21-2021 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Jan-23-2021 12:14:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-21-2021 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-21-2021 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Initial Entry
Jan-14-2021 14:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021011324 that the subject was hospitalized on 31Dec2020. Please review and update as appropriate

3. Admission Date:

Date	Location	User	Value	Reason
Jan-21-2021 13:14:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-21-2021 13:14:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Transcription Error
Jan-21-2021 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Admission Date is a future date. Please check and correct the data.

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History
Jan/06/2021

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-21-2021 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2021	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------	-----------------------------------	---------------

4. Ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 13:14:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-21-2021 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of current hospital admission is after Date of current hospital discharge. Please reconcile.
Jan-21-2021 13:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Discharge Date: Jan/11/2021	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Audit Trail
Jan/06/2021

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-21-2021 13:13:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: RESPIRATORY TREATMENT - eCRF Audit Trail History
Jan/06/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Jan-21-2021 13:13:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-21-2021 13:13:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: YES	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-23-2021 12:14:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-21-2021 13:13:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-21-2021 13:13:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MECHANICAL VENTILATION	Initial Entry
Jan-14-2021 14:34:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021011324 that on 02Jan2021, the subject was treated at bedside for acute hypoxemic respiratory failure and the subject was intubated and sedated. Please review and update as appropriate this CRF page

4. Treatment:

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
Jan/06/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Jan-21-2021 13:13:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: MECHANICAL VENTILATION	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 13:13:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/2/2021	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 13:13:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/11/2021	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - eCRF Audit Trail History
Jan/06/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-21-2021 15:12:11 (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-26-2021 11:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-26-2021 10:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-26-2021 10:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> COVID-19 Date of Diagnosis: Dec/31/2020	Transcription Error
Jan-23-2021 12:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Please consider updating the date as 31Dec2020 (date of the local SARS-CoV-2 diagnostic test). Thank you
Jan-21-2021 15:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-21-2021 15:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> COVID-19	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Jan/06/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Date of Diagnosis: Dec/28/2020	
Jan-14-2021 14:58:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please consider in response to "Was a diagnosis obtained for Potential COVID-19 Illness" entering COVID-19 ILLNESS with the date of 31Dec2020 (date of the local SARS-CoV-2 diagnostic test

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-22-2021 14:32:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 5	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Audit Trail
Jan/06/2021

Form Version: 17-Jul-2020 21:55

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-22-2021 14:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History
Jan/06/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-22-2021 14:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE COVID-19 ILLNESS	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-23-2021 12:18:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-22-2021 14:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-22-2021 14:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SIGNIFICANT ACUTE RENAL DYSFUNCTION	Initial Entry
Jan-14-2021 14:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021011324 that on 04Jan2021, subject began suffering from acute renal failure. Please review and update as appropriate this CRF page

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-22-2021 14:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Diagnosis:</i> Acute Renal Failure Start Date: Jan/4/2021 Ongoing?:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History
Jan/06/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			NO	
			End Date:	
			Jan/11/2021	

4. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-22-2021 14:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> 4	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

Form Version: 15-Sep-2020 21:51

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	New Information

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-22-2021 14:38:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Methodist Specialty Transplant Hospital 8026 Floyd Curl Dr San Antonio, TX 78229	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-23-2021 12:19:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Jan-22-2021 14:36:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-22-2021 14:36:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Transcription Error
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Collection date is updated, but result is missing. Please correct or confirm.
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Collection Date, 31/Dec/2021 is a future date relative to when it was entered on 22/Jan/2021. Please correct.

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2021	New Information
Jan-14-2021 14:43:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: SAE report #2021011324 included lab data on sample collected on 31Dec2020. Please review and update as appropriate this CRF page

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	New Information

5.a

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: C Reactive Prote in_PX329 Result:: 191.2 Not Done:: Lab Normal Range: High 10 <i>Unit</i> mg/dL	Initial Entry
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: C Reactive Prote in_PX329 Result::	New Information

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Not Done: Lab Normal Range:	
--	--	--	--------------------------------	--

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C Reactive Protein_PX329	New Information

5.a Result:

Date	Location	User	Value	Reason
Jan-26-2021 14:22:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 10:20:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Unit is provided
Jan-25-2021 09:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. Please consider to update the ranges with available unit from the CRF options. Kindly connect with your CRA for any further assistance if needed.
Jan-22-2021 14:44:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	<10 is the range given
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit)

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

				is missing. Please correct or confirm.
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 191.2	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>High</i> 10 <i>Unit</i> mg/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define d Identifier: Test:: Alanine Aminotransferase_PX30 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Define d Identifier: Test:: Alanine Aminotransferase_PX30 Result:: Not Done:: Lab Normal Range:	New Information

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen**Site No:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841470**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alanine Aminotransferase_PX30	New Information

5.b Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (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-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Aspartate Aminotransferase_PX28 Result: Not Done:: NOT DONE Lab Normal Range:	Initial Entry
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Aspartate Aminotransferase_PX28 Result: Not Done:: Lab Normal Range:	New Information

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX28	New Information

5.c Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (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-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 35 Test:: Alkaline Phosphatase_PX35 Result:: 51 Not Done:: Lab Normal Range: Low 38 High 126 Unit U/L	Initial Entry
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier:	New Information

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Test:: Alkaline Phosphatase_PX35 Result:: Not Done:: Lab Normal Range:	
--	--	--	-------------------------------------------------------------------------------------------------------------	--

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_PX35	New Information

5.d Result:

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 51	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 38 <i>High</i> 126 <i>Unit</i> U/L	Initial Entry

5.e

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Bilirubin_P X21 Result:: .8 Not Done:: Lab Normal Range: <i>Low</i> .2 <i>High</i> 1.3 <i>Unit</i> mg/dL	Initial Entry
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Bilirubin_P X21 Result:: Not Done:: Lab Normal Range:	New Information

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen**Site No:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841470**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilirubin_PX21	New Information

5.e Result:

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: .8	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> .2 <i>High</i> 1.3 <i>Unit</i> mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 47 Test:: Blood Urea Nitrogen_PX47 Result:: 15 Not Done::	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Lab Normal Range: <i>Low</i> 9 <i>High</i> 20 <i>Unit</i> mg/dL	
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Blood Urea Nitrogen_PX47 Result:: Not Done:: Lab Normal Range:	New Information

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen**Site No:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841470**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_PX47	New Information

5.f Result:

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 9 <i>High</i> 20 <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Creatinine_P X48 Result:: 1.10 Not Done::	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Lab Normal Range: <i>Low</i> .4 <i>High</i> 1.2 <i>Unit</i> mg/dL	
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Creatinine_P X48 Result:: Not Done:: Lab Normal Range:	New Information

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	New Information

5.g Result:

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.10	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-22-2021 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> .4 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 15-Sep-2020 21:55

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/06/2021

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Methodist Specialty Transplant Hospital 8026 Floyd Curl Dr San Antonio, TX 78229	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-23-2021 12:19:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-22-2021 14:49:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-22-2021 14:49:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Transcription Error
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Collection Date, 31/Dec/2021 is a future date relative to when it was entered on 22/Jan/2021. Please correct.
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2021	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-14-2021 14:43:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: SAE report #2021011324 included lab data on sample collected on 31Dec2020. Please review and update as appropriate this CRF page
-------------------------------------------------------------------	-----------------	------------------------------	-----------------	----------------------------------------------------------------------------------------------------------------------------------------

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: 17.8 Not Done:: Lab Normal Range: <i>Low</i> 13 <i>High</i> 17 <i>Unit</i> g/dL	Initial Entry
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: Not Done:: Lab Normal Range:	Initial Entry

5.a Sponsor ID:

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/06/2021 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17.8	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 13 <i>High</i> 17 <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_ PX2 Result:: 53.1 Not Done::	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/06/2021

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Lab Normal Range: <i>Low</i> 40 <i>High</i> 50 <i>Unit</i> %	
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_ PX2 Result:: Not Done:: Lab Normal Range:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/06/2021 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 53.1	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 40 <i>High</i> 50 <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 3 entifier: Test:: Erythrocytes _PX3 Result:: Not Done:: NOT DONE	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Lab Normal Range:	
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Erythrocytes _PX3 Result:: Not Done:: Lab Normal Range:	Initial Entry

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (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-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_P X5 Result:: 176 Not Done::	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/06/2021

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Lab Normal Range: <i>Low</i> 150 <i>High</i> 400 <i>Unit</i> /uL	
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_P X5 Result:: Not Done:: Lab Normal Range:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 176	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 150 <i>High</i> 400 <i>Unit</i> /uL	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_PX7 Result:: Not Done:: NOT DONE	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Lab Normal Range:	
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_PX7 Result:: Not Done:: Lab Normal Range:	Initial Entry

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (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-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_PX608 Result:: Not Done:: NOT DONE	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Lab Normal Range :	
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Neutrophils_P X608 Result:: Not Done:: Lab Normal Range :	Initial Entry

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (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-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_P X609 Result:: Not Done:: NOT DONE	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/06/2021 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Lab Normal Range :	
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Eosinophils_P X609 Result:: Not Done:: Lab Normal Range :	Initial Entry

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (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-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Monocytes_P X612 Result:: Not Done:: NOT DONE	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Lab Normal Range:	
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_P X612 Result:: Not Done:: Lab Normal Range:	Initial Entry

5.h Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Monocytes_PX612	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (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-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_P X610 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Basophils_P X610 Result:: Not Done:: Lab Normal Range:	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------

5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Basophils_PX610	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (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-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_ PX611 Result:: Not Done:: NOT DONE Lab Normal Range :	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/06/2021

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Lymphocytes_ PX611 Result:: Not Done:: Lab Normal Range :	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/06/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-22-2021 14:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 14:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Audit Trail
Jan/06/2021

Form Version: 15-Sep-2020 21:52

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-22-2021 15:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/06/2021

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date:

Date	Location	User	Value	Reason
Jan-22-2021 16:08:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-22-2021 15:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-22-2021 15:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021	Initial Entry
Jan-14-2021 14:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021011324 that on 02Jan2021, subject was treated at bedside for acute hypoxemic respiratory failure. Please review and update as appropriate this CRF page

2.a

Date	Location	User	Value	Reason
Jan-22-2021 15:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 90 Diastolic:: 54 Respiratory Rate in respiratio ns/minute: 21 Heart Rate in beats/minute: 13 2	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-22-2021 15:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/06/2021

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

2.a Systolic:

Date	Location	User	Value	Reason
Jan-22-2021 15:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 90	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-26-2021 14:16:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 10:19:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Vitals were not assessed for clinical significance at hospital
Jan-25-2021 00:39:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Please verify and confirm reported range is clinically significant or not. Thank you.
Jan-22-2021 15:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	correct as entered
Jan-22-2021 15:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 54 is outside of Normal Range 60 - 90.
Jan-22-2021 15:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 54	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-22-2021 15:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 21	Initial Entry

2.a Heart Rate in beats/minute:

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/06/2021

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-26-2021 14:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 10:19:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Vitals were not assessed for clinical significance at hospital
Jan-25-2021 02:40:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please confirm if result is clinically significant.
Jan-22-2021 15:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	correct as entered
Jan-22-2021 15:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Heart rate 132 is outside of Normal Range 0 - 120.
Jan-22-2021 15:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 132	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Audit Trail
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-01-2021 12:45:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	per query
Jan-22-2021 15:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Audit Trail
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-22-2021 15:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Deleted, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

[Back to Form](#)

I. Date:

Date	Location	User	Value	Reason
Mar-02-2021 02:11:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-01-2021 12:45:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	per query
Feb-12-2021 16:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Per completion guidelines 8.40, If multiple values were recorded on a single day, the most abnormal should be recorded. Please review.
Feb-12-2021 10:34:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	These values were completed in the hospital, we have no control over the documentation on the rec's. We are providing all values for the safety of the subject.
Feb-08-2021 07:07:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please review, If multiple values were recorded on a single day, at a minimum the most abnormal should be recorded, i.e. the lowest Diastolic & Systolic Blood Pressure and the highest Heart Rate & Respiratory rate
Feb-04-2021 14:06:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	correct as is

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Deleted, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Feb-04-2021 01:58:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Check all assessments performed on 31Dec2020. If multiple values were recorded on a single day, at a minimum the most abnormal should be recorded, i.e. the lowest Diastolic & Systolic Blood Pressure and the highest Heart Rate & Respiratory rate
Jan-22-2021 15:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-22-2021 15:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 15 2 Diastolic:: 88 Respiratory Rate in respiratio 18 ns/minute: Heart Rate in beats/minute: 81	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-22-2021 15:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-26-2021 14:23:13 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Deleted, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

(US & Canada)		(b) (4), (b) (6)		
Jan-26-2021 10:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Vitals were not assessed for clinical significance at hospital
Jan-25-2021 08:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please verify if this is clinically significant or not.
Jan-22-2021 15:08:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	correct as entered
Jan-22-2021 15:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 152 is outside of Normal Range 90 - 140.
Jan-22-2021 15:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 152	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-22-2021 15:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 88	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-22-2021 15:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 18	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-22-2021 15:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 81	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jan-22-2021 15:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-22-2021 15:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 17 1 Diastolic:: 94 Respiratory Rate in respiratio 18 ns/minute: Heart Rate in beats/minute: 84	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-22-2021 15:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-26-2021 14:34:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 10:19:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Vitals were not assessed for clinical significance at hospital.
Jan-25-2021 02:31:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please confirm if result is clinically significant.

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-22-2021 15:09:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	correct as entered
Jan-22-2021 15:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 171 is outside of Normal Range 90 - 140.
Jan-22-2021 15:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 171	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-26-2021 14:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 10:18:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Vitals were not assessed for clinical significance at hospital
Jan-25-2021 08:45:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please confirm if result is clinically significant.
Jan-22-2021 15:09:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	correct as entered
Jan-22-2021 15:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 94 is outside of Normal Range 60 - 90.
Jan-22-2021 15:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 94	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-22-2021 15:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 18	Initial Entry

2.a Heart Rate in beats/minute:

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Jan-22-2021 15:09:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 84	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
Jan/06/2021

Form Version: 15-Sep-2020 21:54

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-08-2021 14:25:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	per query request
Jan-22-2021 14:52:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Jan/06/2021

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Deleted, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

[Back to Form](#)

I. Date:

Date	Location	User	Value	Reason
Feb-09-2021 02:09:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-08-2021 14:25:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	updated
Feb-05-2021 01:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM1: Please keep the most abnormal value (i.e. the lowest Oxygen Saturation for the day) for Date 31-Dec-2020 and delete the other rows as per CCGs.
Feb-04-2021 14:06:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	correct as is
Feb-04-2021 01:58:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Opened	Per completion guidelines, If multiple values were recorded on a single day, at a minimum the most abnormal should be recorded, i.e. the lowest Oxygen Saturation for the day. Please review all data entered on 31Dec2020 and remove as applicable.
Jan-23-2021 12:20:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-22-2021 14:53:09 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
 Jan/06/2021
Form Version: 15-Sep-2020 21:54 **Form Status:** Data Complete, Deleted, Frozen
Site No: 1084 **Site Name:** (1084) Clinical Trials of Texas
Subject No: 10841470 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:22

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

Time (US & Canada)				
Jan-22-2021 14:53:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Transcription Error
Jan-22-2021 14:52:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date, 31/Dec/2021 is a future date relative to when it was entered on 22/Jan /2021. Please correct.
Jan-22-2021 14:52:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-22-2021 14:52:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2021	Initial Entry
Jan-14-2021 14:30:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021011324 that on 02Jan2021, subject was treated at bedside for acute hypoxemic respiratory failure. Please review and update as appropriate this CRF page

2.a

Date	Location	User	Value	Reason
Jan-22-2021 14:52:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 92.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-22-2021 14:52:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Jan/06/2021

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Deleted, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-22-2021 14:52:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 92.0	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-08-2021 14:26:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	per query request
Jan-22-2021 14:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-22-2021 14:55:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-22-2021 14:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-22-2021 15:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Deleted, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

[Back to Form](#)

I. Date:

Date	Location	User	Value	Reason
Jan-22-2021 14:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Dec/31/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-22-2021 14:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Oxygen Saturation: 93.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-22-2021 14:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-22-2021 14:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 93.0	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jan-22-2021 14:55:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-22-2021 14:55:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 88.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-22-2021 14:55:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-22-2021 14:55:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 88.0	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jan-22-2021 14:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-22-2021 14:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 95.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-22-2021 14:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-22-2021 14:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 95.0	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Jan/06/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jan-22-2021 15:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-22-2021 15:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 96.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-22-2021 15:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-22-2021 15:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 96.0	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Audit Trail
Jan/06/2021

Form Version: 06-Jul-2020 21:52

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-22-2021 15:02:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Audit Trail
Jan/06/2021

Form Version: 06-Jul-2020 21:52

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-22-2021 15:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: OXYGENATION PARAMETERS - eCRF Audit Trail History
Jan/06/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date Time of Assessment:

Date	Location	User	Value	Reason
Feb-12-2021 12:16:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-12-2021 11:04:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated
Feb-02-2021 09:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: The response for Data item#2 and 3 are missing. Kindly review and update.
Jan-23-2021 12:21:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-22-2021 15:02:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-22-2021 15:02:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/2/2021 17:42	Initial Entry
Jan-14-2021 14:30:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021011324 that on 02Jan2021, subject was treated at bedside for acute hypoxemic respiratory failure. Please review and update as appropriate this CRF page

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Feb-12-2021 11:04:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 40	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History
Jan/06/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Feb-12-2021 11:04:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.84	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: OXYGENATION PARAMETERS - eCRF Audit Trail History
Jan/06/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date Time of Assessment:

Date	Location	User	Value	Reason
Jan-22-2021 15:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021 07:45	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Feb-15-2021 00:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-12-2021 11:04:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-12-2021 11:04:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 40	Initial Entry
Feb-02-2021 09:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Arterial Blood Gases PaO2 (mmHg)" is missing. Kindly review and update.

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Jan-22-2021 15:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.50	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Audit Trail
Jan/06/2021

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-21-2021 14:08:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: IMAGING - eCRF Audit Trail History
Jan/06/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date of Assessment:

Date	Location	User	Value	Reason
Jan-23-2021 12:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-21-2021 14:08:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-21-2021 14:08:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Initial Entry
Jan-14-2021 14:46:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021011324 that the subject had Chest X-ray on 31Dec2020. Please document the results as appropriate in this CRF page

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-21-2021 14:08:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-21-2021 14:08:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: X-RAY	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-21-2021 14:08:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABNORMAL <i>If abnormal, specify findings:</i>	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History
Jan/06/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			bilateral multifocal viral pneumon ia	
--	--	--	------------------------------------------	--

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-12-2021 17:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-26-2021 11:10:24 (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, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jan-12-2021 17:01:19 (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
Jan-12-2021 17:01:19 (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
Mar-01-2021 08:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	information documented elsewhere
Mar-01-2021 08:01:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Closed	Autopsy section of SAE completed with 'unknown'
Feb-22-2021 21:51:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Opened	Clinical Thank you, however Safety database is separate. Would appreciate submission of the reason for unblinding after death to the SAE
Feb-22-2021 17:12:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Information concerning the unblinding is documented in our esource with the med recs
Feb-22-2021 15:49:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Opened	Clinical Thank you; please submit the information that unblinding was performed at the

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

				request of the site in a SAE safety followup
Feb-22-2021 15:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Reissued:Opened	Clinical - Thank you; please submit the information that no Autopsy was performed in a SAE safety update
Feb-22-2021 11:11:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Site was made aware of the fact that subject received Moderna vaccine on 23DEC2020
Feb-22-2021 11:10:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Answered	no
Feb-18-2021 12:57:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Opened	Clinical - please submit a SAE safety update reporting whether Autopsy was performed (Yes / No)
Feb-15-2021 20:23:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Opened	Clinical Please submit the reason the family and/or site request unblinding from the sponsor
Feb-12-2021 10:39:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Sponsor agreed to unbinding.
Feb-10-2021 17:53:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	Clinical - Please submit reason for unblinding (3 days post-mortem) to the SAE in a safety update.
Feb-02-2021 13:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Moderna vaccination confirmed 23Dec20; unblinding confirmed in SAE on 14Jan21 (3 days postmortem)
Feb-02-2021 13:52:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-29-2021 10:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	done
Jan-27-2021 11:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Clinical SAE report states subject's treatment assignment was unblinded 'after receiving Moderna vaccine' in Dec; however, CRF states date of unblinding was 14Jan2021. Please confirm date of central unblinding, and submit exact date to SAE.
Jan-27-2021 11:31:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical SAE report states subject received mRNA 1273 (MODERNA COVID 19 VACCINE) on 17Dec20; however, this pre-approval date has been clarified to be 23Dec20. Please submit a SAE update to revise this date & remove 17Dec20 everywhere
Jan-27-2021 11:31:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	rewording
Jan-27-2021 11:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical SAE report states subject received mRNA 1273 (MODERNA COVID 19 VACCINE) on 17Dec20; however, this pre-approval date has been clarified to be 23Dec20. Please submit a SAE update to revise this date
Jan-26-2021 10:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID-19 Infection	Changed Information

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-22-2021 11:19:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 2: Closed	closed based on site's response
Jan-21-2021 15:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Keeping this term per investigator
Jan-20-2021 08:35:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	duplicate query for this vaccine to be recorded
Jan-14-2021 12:25:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 2: Opened	GPD Clin: Please consider replacing "Complications due to COVID-19" with a more specific term/diagnosis, if available. Thanks.
Jan-13-2021 12:55:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL SAE report (#2021011324) states 1 dose of Moderna vaccine was administered on 17Dec20. Please record this vaccination on the vaccine log CRF.
Jan-12-2021 17:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Complications due to COVID-19	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-27-2021 11:27:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-21-2021 15:39:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The investigator does not agree with this, please reference exact place in protocol where this is stated- An SAE is not an SAE until resulting in hospitalization or death

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-20-2021 08:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - Start date is 31Dec20; however, SAE narrative reports exposure on 28Dec and symptoms started 'a day or so after'. In vaccine trial, SAE start date is day event starts; not day it meets serious criteria (item 11 in vaccine SAE instruct).
Jan-12-2021 17:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 15:37:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/11/2021 UNK:UNK	New Information
Jan-12-2021 17:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-21-2021 15:37:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	New Information
Jan-12-2021 17:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Jan-21-2021 15:37:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? YES Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO	New Information
Jan-13-2021 00:02:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-12-2021 17:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Complications due to COVID-19: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-12-2021 17:01:19	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
-------------------------------------------	--	---------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

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

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

Date	Location	User	Value	Reason
Jan-12-2021 17:01:19 (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
Jan-12-2021 17:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			OTHER If Other, specify: COVID-19	
--	--	--	-------------------------------------------------	--

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-12-2021 17:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-12-2021 17:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-23-2021 14:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Closed	Response satisfies query
Jan-21-2021 13:04:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Answered	Was non-drug treatment given is marked as yes
Jan-13-2021 12:56:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	CLINICAL Most recent SAE update (12Jan21) states subject is receiving mechanical ventilation. Please review Non-drug treatment, and update as appropriate.
Jan-12-2021 17:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

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

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Feb-01-2021 01:22:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-29-2021 10:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	done

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-27-2021 11:24:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Clinical Thank you; unblinding recorded however FUP does not have the death recorded yet
Jan-27-2021 09:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	updated
Jan-27-2021 05:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Outcome is reported as 'Fatal'; however, DISPOSITION - FOLLOW-UP CRF is not yet started. Please review and update the CRF Appropriately.
Jan-25-2021 02:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-22-2021 14:28:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Jan-22-2021 07:42:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Since "What was the outcome of this adverse event?" is 'Fatal' please record the Date of Collection / Notification of Death on the Death Details form in DISP visit.
Jan-21-2021 15:40:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	where is this form located
Jan-21-2021 15:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "What was the outcome of this adverse event?" is 'Fatal' but Date of Collection / Notification of Death

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

				on the Death Details form is not completed. Please review and update as appropriate.
Jan-21-2021 15:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-21-2021 15:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATAL	New Information
Jan-21-2021 15:37:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Complications due to COVID-19: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Jan-12-2021 17:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?				
Date	Location	User	Value	Reason
Jan-24-2021 22:45:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-22-2021 14:27:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	changed per query request
Jan-22-2021 14:27:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	changed per query request
Jan-22-2021 07:36:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Outcome is reported as 'Fatal'; however, "Did the event cause the subject to be discontinued from

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

				the study" is not YES. Please review and update the CRF Appropriately.
Jan-12-2021 17:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

<i>15. Serious Adverse Event Number: For Pfizer Use Only</i>				
Date	Location	User	Value	Reason
Jan-13-2021 03:15:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021011324	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jan-26-2021 11:10:24 (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
Jan-26-2021 11:10:24 (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
Jan-26-2021 11:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mutli-system organ failure	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-26-2021 11:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-26-2021 11:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/11/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-26-2021 11:10:24 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(US & Canada)	(b) (4), (b) (6)
---------------	------------------

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-28-2021 06:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 11:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Mutli-system organ failure: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-26-2021 11:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? YES Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			?	
			YES	
			Other medically important serious event	
			NO	

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

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

Date	Location	User	Value	Reason
Jan-26-2021 11:10:24 (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
Jan-26-2021 11:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER If Other, specify: COVID-19	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-26-2021 11:10:24 (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
Jan-26-2021 11:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

--	--	--	--	--

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Jan-26-2021 11:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-26-2021 11:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATAL	Initial Entry

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

Date	Location	User	Value	Reason
Jan-26-2021 11:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-28-2021 06:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2021011324	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-21-2021 12:53:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-21-2021 12:53:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	New Information

2. Category:

Date	Location	User	Value	Reason
Jan-21-2021 12:53:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	New Information

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-21-2021 12:53:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	New Information

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).

Date	Location	User	Value	Reason
Jan-23-2021 12:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-21-2021 12:53:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-21-2021 12:53:11 (UTC 06 00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MODERNA COVID 19 VACCINE	New Information
Jan-14-2021 14:20:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021011324 that the subject received the MODERNA COVID

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

				19 VACCINE. Please Moderna vaccine needs to be recorded as a non-study vaccine on this CRF page
--	--	--	--	-------------------------------------------------------------------------------------------------

5. Date:

Date	Location	User	Value	Reason
Jan-26-2021 10:22:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020	Transcription Error
Jan-21-2021 13:03:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Status:

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-21-2021 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-21-2021 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-21-2021 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IMMUNOGLOBULINS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-21-2021 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

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).

Date	Location	User	Value	Reason
Feb-15-2021 20:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchemo (b) (4)	Query 2: Closed	Response satisfies query
Feb-12-2021 14:35:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Med recs given to our clinic do not have a name of Monoclonal antibody.
Feb 08 2021 15 17 47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchemo (b) (4)	Query 2 Opened	GPDClin Please consider updating to include what monoclonal antibody was administered, if known. Thank you.

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-23-2021 12:22:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-21-2021 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-21-2021 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Monoclonal Antibodies	Initial Entry
Jan-14-2021 14:25:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021011324 that the subject received monoclonal antibodies. Please receipt of immunoglobulins within 60 days before enrollment through conclusion of the study needs to be recorded as a prohibited medication

5. Dose:

Date	Location	User	Value	Reason
Mar-08-2021 01:57:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Please review this query once data is updated for Dose field.
Mar-05-2021 10:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unknown, will update as more information becomes available
Feb-23-2021 05:42:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please confirm date at which information will be available for data entry.
Feb-22-2021 17:15:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Feb-22-2021 17:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	med recs do not have the dosage information.
Feb-16-2021 00:07:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Dose" is missing. Kindly review and update.
Feb-12-2021 14:34:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-12-2021 14:33:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1700	New Information
Jan-21-2021 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Feb-23-2021 06:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Please review and update data as unknown is not a valid response
Feb-22-2021 17:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	details of the medication was not provided on the med recs
Feb-14-2021 23:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Response does not satisfy query. As per your response 'mg', please update field 'Dose unit' accordingly.
Feb-12-2021 14:34:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	mg
Feb-09-2021 02:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Please update dose unit and route as appropriate. Unknown is not the valid response.

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

				Thank you.
Feb-08-2021 14:13:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry
Feb-08-2021 14:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-02-2021 09:07:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for Data item#6 and 8 are missing. Kindly review and update.

7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-23-2021 06:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query closed as per site response
Feb-22-2021 17:15:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry
Feb-22-2021 17:14:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	details of the medication were not on the med recs
Feb-16-2021 00:08:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Dose Frequency" is missing. Kindly review and update.
Feb-12-2021 14:35:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-21-2021 13:07:50 (UTC 06 00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Feb-08-2021 14:13:27	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Unknown	
-------------------------------------------	--	---------------------	---------	--

9. Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 13:07:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Dec/31/2020	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-18-2020 15:50:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-18-2020 15:50:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-18-2020 15:50:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1084**Subject No:** 10841470**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1084) Clinical Trials of Texas**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-15-2021 03:27:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Feb-12-2021 14:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-12-2021 14:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Jan/11/2021	Transcription Error
Feb-10-2021 02:07:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	SAE RECON: AER#2021011324, the date of death was reported as 11Jan2021 in Safety database but recorded as 19Jan2021 in CRF. Please confirm correct date of death. If safety update is required, please submit a follow-up form.
Jan-29-2021 10:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Jan/19/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-29-2021 10:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-29-2021 10:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: DEATH	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 06:37:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Mar-05-2021 03:16:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clo sed	Response satisfies query
Mar-04-2021 16:53:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	done
Mar-04-2021 16:53:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	done
Mar-01-2021 07:07:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Rei ssued: Opene d	DM1: Thanks for your response. Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-01-2021 06:00:39 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(US & Canada)				
Mar-01-2021 05:03:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-26-2021 13:31:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	unblinding after death-erroneous
Feb-26-2021 13:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unblinding after death-erroneous
Feb-26-2021 13:30:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-12-2021 21:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7250280;'Date of Visit' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Feb-12-2021 14:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Visit is after the Date of Completion/Discontinuation /Death on the Follow-Up Disposition form. Please review and update as

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

				appropriate.
Jan-27-2021 11:37:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Jan/14 /2021	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Feb-26-2021 13:30:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

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

Date	Location	User	Value	Reason
Mar-05-2021 06:39:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Mar-04-2021 16:52:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Mar-04-2021 16:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 16:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-27-2021 15:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: DOV page has been marked as 'erroneous' but data remains on this page. To match, please add form level comment of Not Applicable to close the page
Feb-24-2021 17:46:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated
Feb-24-2021 17:46:20 (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 and NOT confirmed to have received only placebo at Vaccination 1/2	updated
Feb-15-2021 17:00:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Subject reported to be deceased prior to this contact. If dates are correct, please do

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

				not capture this within the CRF. Data should not be reported in CRF post Disp FUP date
Jan-27-2021 09:56:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-09-2021 00:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clo sed	Response satisfies query
Mar-08-2021 16:03:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	done
Mar-08-2021 16:03:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not A pplica ble	Initial Entry
Mar-08-2021 06:18:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Rei ssued: Opene d	DM: Please go to right side upper corner icon and select Not Applicable as form level comment. Ask CRA in case any assistance if needed. Thank you.
Mar-05-2021 11:52:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Ans wered	Transcription Error
Mar-05-2021 11:52:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error
Feb-27-2021 11:20:24 (UTC-06:00)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 3: Op ened	P21 Review: Date Treatment Unblinded (14Jan2021) is after

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Central Time (US & Canada)				Disposition - Follow-Up date (11Jan2021). If dates are confirmed to be correct, please remove all the data from this page and provide form level comment as "Not Applicable". Else clarify.
Feb-25-2021 22:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-25-2021 16:01:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated
Feb-12-2021 21:20:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7250513; 'Date Treatment Unblinded' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Feb-02-2021 13:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-29-2021 10:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject unblinded post mortem
Jan-27-2021 18:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please clarify this unblinding date, as it follows the death date of 11Jan2021. Was the subject unblinded post-mortem, or please update this date.

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Jan-27-2021 09:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Jan/14 /2021	Transcription Error
Jan-27-2021 09:56:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Jan/15 /2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-09-2021 02:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	per data updated.
Mar-08-2021 16:05:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	done
Mar-08-2021 16:03:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Mar-08-2021 04:19:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued: Opened	IVRS RQ1: Data observed removed. Please consider to mark response as 'Not applicable' using field level comment option per CCG.
Mar-05-2021 11:52:28 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

(US & Canada)				
Mar-05-2021 11:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-27-2021 15:03:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	P21 query raised - unblind post Disp FUP
Feb-26-2021 10:33:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	IVRS Reconciliation: Other is selected as the primary reason for unblinding but matching blind break is not captured in IRT. Please correct primary reason in Inform or confirm as correct".
Feb-25-2021 16:01:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-25-2021 16:01:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER <i>If other, specify:</i> Subject death.	Transcription Error
Feb-24-2021 22:47:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Closed	Auto closed by Validation Check: VC_DS001_35

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Feb-24-2021 17:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	updated
Feb-22-2021 11:00:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW7349869;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Feb-15-2021 17:05:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Subject reported as deceased 11Jan21. Please clarify if treatment unblind was performed for this subject, as reported. If so, why was treatment unblind performed on the 14Jan21?
Feb-05-2021 04:39:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021 14:01:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-04-2021 14:01:41 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FO	Transcription Error

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Canada)			R ADDI TIONAL VACCIN ATION	
Jan-28-2021 01:37:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	IVRS: If Subject is un-blinded for reasons other than revaccination, the un-blinding event should be captured in Impala. Please confirm if un-blinding was performed through Impala or outside impala and update data as appropriate. Thank you.
Jan-27-2021 09:56:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SUBJECT SAFETY CONCERN	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Mar-12-2021 15:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Mar-12-2021 14:00:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Original value is correct
Mar-11-2021 14:37:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINQUERY: please confirm that the subject died on 11/Jan/2021, and the site was notified 19/Jan/2021, which is currently reported here on death details and the follow-up disposition, so therefore no changes would be needed.
Feb-22-2021 17:22:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-22-2021 10:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Sadly subject passed away after unblinding took place.
Feb-12-2021 14:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 11/Jan/2021. Please review and update as appropriate
Feb-04-2021 19:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-29-2021 15:54:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-29-2021 10:19:24 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	completed

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Time (US & Canada)				
Jan-29-2021 10:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Jan-29-2021 08:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	Please complete disposition follow up CRF.
Jan-28-2021 09:10:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Kindly update cause of death information on Death Details form. Thank you.
Jan-27-2021 19:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	ClinQuery: Kindly update cause of death information on Death Details form. Thank you.
Jan-22-2021 14:28:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-29-2021 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cause of Death PRIMARY CAUSE h Status: OF DEATH Cause of Death Multi-system organ h: failure	Initial Entry

2.a Cause of Death Status:

Date	Location	User	Value	Reason
Jan-29-2021 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CAUSE OF DEATH	Initial Entry

2.a Cause of Death:

Date	Location	User	Value	Reason
Jan-29-2021 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Multi-system organ failure	Initial Entry

2.b

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Jan-29-2021 10:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cause of Death Status: SECONDARY CAUSE OF DEATH Cause of Death: COVID-19	Initial Entry

2.b Cause of Death Status:

Date	Location	User	Value	Reason
Jan-29-2021 10:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SECONDARY CAUSE OF DEATH	Initial Entry

2.b Cause of Death:

Date	Location	User	Value	Reason
Jan-29-2021 10:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID-19	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Subject Status

Date	Location	User	Value	Reason
Jan-29-2021 10:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Jan-25-2021 00:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	query is now on SAE start date
Jan-21-2021 15:43:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	The start date of the SAE is 31Dec2020 and the first date the subject received a positive test result was 28Dec2020. Unfortunately, we do not have any information about this positive test because it was just a part of the narrative in medical records.
Jan-13-2021 12:55:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	moving query to AE which is now reported
Jan-13-2021 12:53:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Clinical Thank you. Please coordinate/harmonize everywhere the 1st DAY of SYMPTOMS with COVID illness Visit SOD which states 12/28 (exposure date), SAE Narrative which states "a day or so after" 12/28 exposure, and SAE start date of 12/31.
Jan-13-2021 12:48:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	SAE update corrected VAX 1 date to 30Sep20

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (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:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841470**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22

Jan-12-2021 17:02:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	complications began on 31Dec, no symptoms prior to 31Dec
Jan-11-2021 11:34:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical SAE (#2021011324) reports start date 31Dec; however, in narrative event starts 'day after exposure on 28Dec'. In Vaccine study, SAE start date is day event starts; not day it meets serious criteria (item 11 in vaccine SAE instruct) -please review
Jan-08-2021 13:31:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL SAE report (#2021022324) reports VAX 1 date of 20Sep20; however, visit 1 CRF reports VAX 1 date on 30Sep20. Please review, harmonize reporting, and update in the applicable location.
Jan-08-2021 13:26:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL SAE report (#2021011324) states 1 dose of Moderna vaccine was administered on 17Dec20. Please record this vaccination on the vaccine log CRF.
Nov-18-2020 15:50:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-30-2020 11:35:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-30-2020 10:59:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

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: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841470

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

2. Subject Status Date

Date	Location	User	Value	Reason
Feb-12-2021 14:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/11/2021	Transcription Error
Jan-29-2021 10:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/19/2021	Initial Entry
Jan-13-2021 12:54:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Covid Illness visit is present
Jan-04-2021 04:16:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Opened	Illness ed diary: As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 30DEC2020. But corresponding COVID Illness visit not reported. Please clarify.
Nov-18-2020 15:50:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/18/2020	Initial Entry
Sep-30-2020 11:35:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/30/2020	Initial Entry
Sep-30-2020 10:59:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/30/2020	Initial Entry

090177e196ae3f85\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1084

Subject No: 10841470

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Nov-11-2020 10:19:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry