

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 10-Oct-2020 16:01

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

**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	06 OCT 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** MAIN INFORMED CONSENT

**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](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Nov/6/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** DEMOGRAPHY

**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](#)

**Demography**

1.	Subject ID	[10841538]
2.	Birth Date:	(b) (6)/2004
3.	Sex:	FEMALE
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:** 10841538

**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/6/2020
2.	Erroneous Visit	

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Oct-2020 15:59**Site No:** 1084**Subject No:** 10841538**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[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?	YES
	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?	YES
	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?	YES
	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?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

**Exclusion Criteria**

2.a	Exclusion Number:	1
	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

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1084

**Subject No:** 10841538

**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 met?	NO
	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?	NO
	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?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	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?	NO
	Criterion ID: (For Pfizer use only)	EX08A00
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?	NO
	Criterion ID: (For Pfizer use only)	EX10A00

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**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1084

**Subject No:** 10841538

**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.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	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?	NO
	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?	NO
	Criterion ID: (For Pfizer use only)	EX14A01
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?	NO
	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?	NO
	Criterion ID: (For Pfizer use only)	EX16A01

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**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1084

**Subject No:** 10841538

**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.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?	NO
	Criterion ID: (For Pfizer use only)	EX21A01



**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1084

**Subject No:** 10841538

**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 _____
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**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
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**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** DISPOSITION - SCREENING

**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 - Screening**

1.	Date of Completion/Discontinuation/Death	Nov/6/2020
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: 10841538

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

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](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[seasonal allergies]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[insomnia]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[post-traumatic stress disorder]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[depression]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1084) Clinical Trials of Texas

**Subject Initials:** ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[kidney infection]
	Start Date:	Aug/UNK/2010
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillectomy]
	Start Date:	UNK/UNK/2006
	Ongoing:	NO End Date: UNK/UNK/2006
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillitis]
	Start Date:	UNK/UNK/2004
	Ongoing:	NO End Date: Nov/UNK/2006
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anxiety]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1084) Clinical Trials of Texas

**Subject Initials:** ---

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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[urinary tract infection]
	Start Date:	Sep/UNK/2010
	Ongoing:	YES

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<b>Header Text:</b> c4591001	<b>Form:</b> HIV STATUS
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 15-Sep-2020 21:57	<b>Site Name:</b> (1084) Clinical Trials of Texas
<b>Site No:</b> 1084	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10841538	<b>Generated Time (GMT):</b> 29-Mar-2021 10:22
<b>Generated By:</b> (b) (4)	

[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
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**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** VITAL SIGNS - BASELINE

**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](#)

**Vital Signs**

1.	Date:	Nov/6/2020
2.	Weight:	[79.6]
3.	Unit:	kg
4.	Height:	[165.5]
5.	Unit:	cm
6.	Body Mass Index:	[29.1]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Nov/6/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

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**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** RANDOMIZATION

**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**

1.	Randomization Date :	Nov/6/2020
2.	Randomization Number:	[114554]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841538

**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/6/2020
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	[BNX58R]
5.b	Sample ID	[BNX58S]
5.c	Sample ID	[BR037C]
5.d	Sample ID	[BR037D]
5.e	Sample ID	[BR037F]

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**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841538

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

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

**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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/6/2020
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	[BKSCRY]
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**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** VACCINATION

**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](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/6/2020 10:57
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

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<b>Header Text:</b> c4591001	<b>Form:</b> REACTOGENICITY DIARY
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 06-Jul-2020 21:53	<b>Site Name:</b> (1084) Clinical Trials of Texas
<b>Site No:</b> 1084	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10841538	<b>Generated Time (GMT):</b> 29-Mar-2021 10:22
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1084

**Subject No:** 10841538

**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/30/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 14-Jan-2021 02:28

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 14-Jan-2021 02:28

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** VITAL SIGNS - TEMP

**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](#)

**Vital Signs**

1.	Date:	Nov/30/2020
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**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:** 10-Oct-2020 15:58

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Nov/30/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1084

**Subject No:** 10841538

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

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

**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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/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	[BPC22R]
-----	-----------	----------

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** VACCINATION

**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](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/30/2020 09:56
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

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**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:** 10841538

**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	Dec/30/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 14-Jan-2021 02:28

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 14-Jan-2021 02:28

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1084

**Subject No:** 10841538

**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: Dec/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	[BPC1W5]
5.b	Sample ID	[BPC1W6]
5.c	Sample ID	[BPC1W7]
5.d	Sample ID	[BMNDT7]
5.e	Sample ID	[BMNDT8]

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**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1084

**Subject No:** 10841538

**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:** 10841538

**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	[ ]
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**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1084

**Subject No:** 10841538

**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:** 10841538

**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	[ ]
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**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1084

**Subject No:** 10841538

**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:** 10841538

**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	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on 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:** 10841538

**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
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Jan/06/2021

**Form Version:** 14-Jan-2021 02:23

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**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:	Jan/2/2021
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Jan/9/2021

**Symptoms**

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

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Jan/06/2021

**Form Version:** 14-Jan-2021 02:23

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

**Symptoms - Other**

5.a	Symptoms - Other Text:	[Nasal congestion]
5.b	Symptoms - Other Text:	[Chest congestion]

**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:** 10841538

**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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

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

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**Microbiology Specimen**

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

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on 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:** 10841538

**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 swabbed at another facility]

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on 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:** 10841538

**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:	[Swab collected at another facility]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Jan/06/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841538**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:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
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?	NO
----	--	----

**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:** 10841538

**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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**Respiratory Treatment**

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

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)



**Header Text:** c4591001

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

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**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?	NO
3.	Toxicity Grade:	2

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Jan/06/2021

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**Illness Details**

1.	Category of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
2.	Subcategory of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
3.	Was a diagnosis obtained?	Not Applicable _____	<a href="#">Comments</a>
4.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Jan/06/2021

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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**Lab Chemistry Details**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Jan/06/2021

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

5.b	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.c	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Jan/06/2021

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

5.d	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.e	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Jan/06/2021

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

5.f	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.g	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Jan/06/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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**Laboratory Data Hematology**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Jan/06/2021

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

5.b	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.c	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Jan/06/2021

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

5.d	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Platelets_PX5	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.e	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Jan/06/2021

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

5.f	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	

5.g	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
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**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

5.h	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.i	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Basophils_PX610	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
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**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

5.j	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	Not Applicable	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Jan/06/2021

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
----	-------	-------------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Diastolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Respiratory Rate in respirations/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Heart Rate in beats/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** c4591001

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

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Jan/06/2021

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
----	-------	-------------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ [ ]	<a href="#">Comments</a>

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**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:** 10841538

**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.	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

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

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**Oxygenation Parameters**

1.	Date Time of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**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:** 10841538

**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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Jan/06/2021

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**Concomitant Medications**

1.	What is the medication identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

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**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:** 10841538

**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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

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

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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**Imaging**

1.	Date of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Location of Assessment:	Not Applicable _____	<a href="#">Comments</a>
3.	Type of Imaging Exam:	Not Applicable _____	<a href="#">Comments</a>
4.	Assessment:	Not Applicable _____	<a href="#">Comments</a>

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**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:** 10841538

**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 Visit

**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:** 10841538

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

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**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:** 10841538

**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:** 10841538

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

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**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:** 10841538

**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 On going	Form Instance
1.	ADVERSE EVENT	1	Bipolar I	Jan/31/2021 UNK:UNK	YES	<a href="#">Repeating Pages</a>
2.						<a href="#">Repeating Pages</a>

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Bipolar I]
4.	Start Date Time:	Jan/31/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
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? 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.	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: [Depression]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Answered Queries

**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?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021145100]



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Incomplete

**Site Name:** (1084) Clinical Trials of Texas

**Subject Initials:** ---

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

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

**Adverse Event Report**

1.	Category:		
2.	AE ID:	[ ]	<a href="#">Comments</a>
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ ]	
4.	Start Date Time:	//	
5.	Is the adverse event still ongoing?		
6.	Toxicity Grade:		
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).		
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.		
9.	Is this event related to study treatment:		
10.	Latest Action Taken with Study Treatment:		
11.	Was a Concomitant Medication given?		
12.	Was a Non-Drug Treatment given?		

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Incomplete

**Site Name:** (1084) Clinical Trials of Texas

**Subject Initials:** ---

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

13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021145100]

**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:** 10841538

**Subject Initials:** ---

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

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

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

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

**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

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**Medication Error**

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

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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:** 10841538

**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.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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:** 10841538

**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.						<a href="#">Repeating Pages</a>

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1084) Clinical Trials of Texas

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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:** 10841538

**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.						<a href="#">Repeating Pages</a>

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

**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

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**Radiation Treatment**

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

**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:** 10841538

**Subject Initials:** ---

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

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

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

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

**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

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

**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:** 10841538

**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:** 10841538

**Subject Initials:** ---

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

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

**Unplanned Assessments**

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

**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:** 10841538

**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:** 10841538

**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:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**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:** 10841538

**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?	

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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:** 10841538

**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:** 10841538

**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:** 10841538

**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:** 10841538

**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:** 10841538

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

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**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:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Dec/30/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
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:** 10841538

**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/20/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1084) Clinical Trials of Texas

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

**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:** 10841538

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/20/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1084) Clinical Trials of Texas

**Subject Initials:** ---

**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:** 10841538

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1084) Clinical Trials of Texas

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/30/2020



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Not Started

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

**Casebook Signature Form**

1.	Casebook Signature	
----	--------------------	--

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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Not Started

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**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:** 10-Oct-2020 16:00

**Site No:** 1084

**Subject No:** 10841538

**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

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Item	Date	User	Comment
Form	Dec-04-2020 12:23:32 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Jan/06/2021

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Feb-22-2021 15:59:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Jan/06/2021

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
1	Feb-22-2021 15:59:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Jan/06/2021

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2	Feb-22-2021 15:59:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Jan/06/2021

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

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**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5	Mar-12-2021 10:25:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
Comments

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
6	Mar-12-2021 10:25:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Mar-12-2021 10:23:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
1	Mar-12-2021 10:23:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2	Mar-12-2021 10:23:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
3	Mar-12-2021 10:23:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
4	Mar-12-2021 10:23:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** ADVERSE EVENT REPORT - Comments

**Form Status:** Data Complete, Answered Queries

**Site Name:** (1084) Clinical Trials of Texas

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Mar-12-2021 10:20:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Mar-12-2021 10:19:30 (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:** Not Started

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: COHORT\_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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***1. Select appropriate response - Protocol version***

Date	Location	User	Value	Reason
Dec-03-2020 00:42:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Closed	Response satisfies query
Dec-02-2020 11:35:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 06 OCT 2020	Subject consented under Amendment 8 version 15OCT2020 but this is not an option to choose from. (b) (6)
Dec-02-2020 11:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Subject consented under Amendment 6
Dec-02-2020 11:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 08 SEP 2020	Subject consented under Amendment 6
Dec-01-2020 00:58:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM : Thanks for response. Please confirm whether this subject consented under protocol amendment 4 dated 30Jun2020. If not, please update the correct protocol version date. Thank you.
Nov-30-2020 12:34:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Nov-25-2020 01:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Subject's age is 16 years at the time of Informed consent collection. Please confirm whether this subject

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:01

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

				consented under protocol amendment 4 dated 30Jun2020. If not, please update the correct protocol version date. Thank you.
Nov-06-2020 11:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** MAIN INFORMED CONSENT - 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

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**I. Consent Was:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Nov/6/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: DEMOGRAPHY - 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

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**1. Subject ID**

Date	Location	User	Value	Reason
Nov-06-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10841538	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Nov-06-2020 11:55:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/2004	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LATINO(A) OR O F SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841538

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Dec-07-2020 00:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-04-2020 12:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Dec-03-2020 05:27:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'HIV and Inclusion and Exclusion form' at this visit. Thank you.
Nov-06-2020 11:56:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/6/2020	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**I.a**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Inclus 1 ion N umbe r: <b>Criterion Description:</b> Male or female participant s between the ages of 18 a scripti nd 55 years, inclusive, 65 <b>on:</b> and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (depende nt upon study stage)  <b>Criterion m et?:</b> <b>Criterion ID : (For Pfizer use on ly):</b>	Initial Entry

**I.a Inclusion Number:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**I.a Criterion Description:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Male or female participants between n the ages of 18 and 55 years, inclu sive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at rando mization (dependent upon study sta	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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**1.a Criterion met?**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN01A00	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusi 2</b> <b>on Nu</b> <b>mber:</b> <b>Criteri</b> Participants who are willi <b>on Des</b> ng and able to comply wit <b>criptio</b> h all scheduled visits, vac <b>n:</b> cination plan, laboratory t ests, lifestyle consideratio ns, and other study proced ures <b>Criteri</b> YES <b>on met</b> <b>?:</b> <b>Criteri</b> IN02A00 <b>on ID:</b> <b>(For P</b> <b>fizer u</b> <b>se only</b> <b>):</b>	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

**1.b Inclusion Number:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**1.b Criterion Description:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

**1.b Criterion met?**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN02A00	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Inclusion Number:	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1084

**Subject No:** 10841538

**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><b>Criteria on Description:</b> 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><b>Criteria on met?:</b> YES</p> <p><b>Criteria on ID:</b> IN03A00 (For Pfizer use only)</p>	
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090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

**I.c Inclusion Number:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

**I.c Criterion Description:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> IN03A00	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Inclusion Number:	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1084

**Subject No:** 10841538

**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><b>Criteria Description:</b> 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><b>Criteria Met:</b> YES</p> <p><b>Criteria ID:</b> IN04A00</p> <p><b>(For Pfizer use only):</b></p>	
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090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

**1.d Inclusion Number:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

**1.d Criterion Description:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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

**1.d Criterion met?**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.d Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN04A00	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclus 1 ion Nu mber:	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

			<p><b>Criteria Description:</b> 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><b>Criteria Met?:</b> NO</p> <p><b>Criteria ID:</b> EX01A00 (For Pfizer use only)</p>	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX01A00	Initial Entry
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**2.b**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusio 2</b> <b>n Numb</b> <b>er:</b> <b>Criteria</b> Known infection with h <b>n Descri</b> uman immunodeficiency <b>ption:</b> virus (HIV), hepatitis C virus (HCV), or hepatiti s B virus (HBV)  <b>Criteria</b> NO <b>n met?:</b> <b>Criteria</b> EX02A00 <b>n ID: (F</b> <b>or Pfize</b> <b>r use onl</b> <b>y):</b>	Initial Entry

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Header Text: c4591001

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Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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2.b Exclusion Number:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusion Number: 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)	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

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			<b>Criteria NO on met ?:</b> <b>Criteria EX03A00 on ID:</b> <b>(For Pfizer use only):</b>
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2.c Exclusion Number:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX03A00	Initial Entry

2.d

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Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number: 4 <b>Criterion Description:</b> Receipt of medications intended to prevent COVID-19 <b>Criterion met?:</b> NO <b>Criterion ID:</b> EX04A00 (For Pfizer use only):	Initial Entry

2.d Exclusion Number:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX04A00	Initial Entry

2.e

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion Description:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination <b>Criterion met?:</b> <b>Criterion ID:</b> EX08A00 <b>(For Publisher use only):</b>	Initial Entry

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Site Name: (1084) Clinical Trials of Texas

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Subject Initials: ---

Generated By: (b) (4)

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2.e Exclusion Number:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusion Number:	Initial Entry

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**Site No:** 1084

**Subject No:** 10841538

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

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**Subject Initials:** ---

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

Generated By: (b) (4)

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2.f Exclusion Number:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding Criterion met? NO	Initial Entry

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			<b>Criterion ID:</b> ( EX11A00 <b>For Pfizer use only):</b>	
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**2.g Exclusion Number:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 11	Initial Entry

**2.g Criterion Description:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Women who are pregnant or breast feeding	Initial Entry

**2.g Criterion met?**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX11A00	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Nu</b> 12 <b>mber:</b> <b>Criterion Des</b> Previous vaccinati <b>cription:</b> on with any corona virus vaccine	Initial Entry



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Subject Initials: ---

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			<b>Criterion met NO</b> <b>?:</b> <b>Criterion ID: EX12A00</b> <b>(For Pfizer use only):</b>
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**2.h Exclusion Number:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 12	Initial Entry

**2.h Criterion Description:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous vaccination with any coronavirus vaccine	Initial Entry

**2.h Criterion met?**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX12A00	Initial Entry

**2.i**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number:	Initial Entry

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			<b>Criterion Description:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX13A01	
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2.i Exclusion Number:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX13A01	Initial Entry

2.j

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**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 15 <b>Criterion Description:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study <b>Criterion Met?:</b> NO <b>Criterion ID:</b> EX14A01 <b>(For Printer use only):</b>	Initial Entry

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2.j Exclusion Number:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX14A01	Initial Entry

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

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2.k				
Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 16 <b>Criterion Description:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX15A01	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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2.k Exclusion Number:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 17 <b>Criterion Description:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

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Subject Initials: ---

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			<b>Criterion NO met?:</b> <b>Criterion EX16A01 ID: (For Pfizer use only):</b>
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2.l Exclusion Number:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 17	Initial Entry

2.l Criterion Description:

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.l Criterion met?

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclus 22	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1084

**Subject No:** 10841538

**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><b>ion Nu mber:</b></p> <p><b>Criterion Description:</b> 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><b>Criterion met?:</b></p> <p><b>Criterion ID:</b> EX21A01</p> <p><b>Use only:</b> (For Pfizer use only):</p>	
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090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

**2.m Exclusion Number:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 22	Initial Entry

**2.m Criterion Description:**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.m Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Nov-06-2020 11:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX21A01	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:52

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - 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

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Nov-06-2020 11:57:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/6/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-06-2020 11:57:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-06-2020 11:57:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

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*1.a*

Date	Location	User	Value	Reason
Nov-06-2020 11:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 1 Medical History Term: seasonal allergies Start Date: UNK/UNK/2009 Ongoing: YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Nov-06-2020 11:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> seasonal allergies	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Nov-06-2020 11:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2009	Initial Entry

*1.a Ongoing:*

Date	Location	User	Value	Reason
Nov-06-2020 11:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*1.b*

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Date	Location	User	Value	Reason
Nov-06-2020 11:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> insomnia <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> YES	Initial Entry

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Nov-06-2020 11:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> insomnia	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Nov-06-2020 11:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Nov-06-2020 11:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Nov-06-2020 11:58:29 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 3	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Time (US & Canada)			ber: Medical Histo ry Term: Start Date: Ongoing:	post-traumatic stre ss disorder UNK/UNK/2015 YES
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**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Nov-06-2020 11:58:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:58:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> post-traumatic stress disorder	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Nov-06-2020 11:58:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Nov-06-2020 11:58:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Nov-06-2020 11:58:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History T</b> depression <b>erm:</b>	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			<b>Start Date:</b>	UNK/UNK/2018
			<b>Ongoing:</b>	YES

**1.d Line/MH Number:**

Date	Location	User	Value	Reason
Nov-06-2020 11:58:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 11:58:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> depression	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Nov-06-2020 11:58:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Nov-06-2020 11:58:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.e**

Date	Location	User	Value	Reason
Nov-06-2020 12:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Te</b> kidney infecti <b>rm:</b> on <b>Start Date:</b> Aug/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

***1.e Line/MH Number:***

Date	Location	User	Value	Reason
Nov-06-2020 12:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 12:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kidney infection	Initial Entry

***1.e Start Date:***

Date	Location	User	Value	Reason
Nov-06-2020 12:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/UNK/2010	Initial Entry

***1.e Ongoing:***

Date	Location	User	Value	Reason
Nov-06-2020 12:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Nov-06-2020 12:07:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> tonsillectomy <b>Start Date:</b> UNK/UNK/2006 <b>Ongoing:</b> NO End Date: UNK/UNK/ 2006	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

**1.f Line/MH Number:**

Date	Location	User	Value	Reason
Nov-06-2020 12:07:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Nov-06-2020 12:07:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> tonsillectomy	Initial Entry

**1.f Start Date:**

Date	Location	User	Value	Reason
Nov-06-2020 12:07:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2006	Initial Entry

**1.f Ongoing:**

Date	Location	User	Value	Reason
Nov-06-2020 12:07:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2006	Initial Entry

**1.g**

Date	Location	User	Value	Reason
Nov-06-2020 12:08:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> tonsillitis <b>Start Date:</b> UNK/UNK/2004	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			<b>Ongoing:</b>	NO	
				End Date:	
				Nov/UNK/2006	

***1.g Line/MH Number:***

Date	Location	User	Value	Reason
Nov-06-2020 12:08:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

***1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Nov-06-2020 12:08:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> tonsillitis	Initial Entry

***1.g Start Date:***

Date	Location	User	Value	Reason
Nov-06-2020 12:08:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2004	Initial Entry

***1.g Ongoing:***

Date	Location	User	Value	Reason
Nov-06-2020 12:08:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Nov/UNK/2006	Initial Entry

***1.h***

Date	Location	User	Value	Reason
Nov-06-2020 12:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8 <b>Medical History Term:</b> anxiety	Initial Entry

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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1084**Subject No:** 10841538**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - 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

			<b>Start Date:</b>	UNK/UNK/2018	
			<b>Ongoing:</b>	YES	

***1.h Line/MH Number:***

Date	Location	User	Value	Reason
Nov-06-2020 12:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

***1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Nov-06-2020 12:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> anxiety	Initial Entry

***1.h Start Date:***

Date	Location	User	Value	Reason
Nov-06-2020 12:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***1.h Ongoing:***

Date	Location	User	Value	Reason
Nov-06-2020 12:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.i***

Date	Location	User	Value	Reason
Nov-06-2020 12:09:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> <b>Medical History</b> urinary tract infection <b>Term:</b> <b>Start Date:</b> Sep/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

***1.i Line/MH Number:***

Date	Location	User	Value	Reason
Nov-06-2020 12:09:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

***1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Nov-06-2020 12:09:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> urinary tract infection	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Nov-06-2020 12:09:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/UNK/2010	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Nov-06-2020 12:09:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1084

**Subject No:** 10841538

**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

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

Date	Location	User	Value	Reason
Dec-04-2020 12:22:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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

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**1. Date:**

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

**2. Weight:**

Date	Location	User	Value	Reason
Nov-06-2020 12:11:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 79.6	Initial Entry

**3. Unit:**

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

**4. Height:**

Date	Location	User	Value	Reason
Nov-06-2020 12:11:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 165.5	Initial Entry

**5. Unit:**

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

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Nov-06-2020 12:11:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 29.1	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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

7.a

Date	Location	User	Value	Reason
Nov-06-2020 12:11:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.3 <b>Temperature Unit:</b> C <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Nov-06-2020 12:11:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Nov-06-2020 12:11:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.3	Initial Entry

7.a Unit:

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

7.a Temperature Location:

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

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-06-2020 12:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Nov-06-2020 12:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-06-2020 12:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/6/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Nov-06-2020 12:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Nov-06-2020 12:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Nov-06-2020 12:11:36 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>
--------------------	--	--	--

6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-06-2020 12:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Nov-06-2020 12:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Nov-06-2020 12:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** RANDOMIZATION - 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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Nov-06-2020 12:11:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/6/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Nov-06-2020 12:11:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 114554	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-09-2020 12:16:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-09-2020 12:16:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-09-2020 12:16:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-09-2020 12:16:19 (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-09-2020 12:16:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/6/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-09-2020 12:16:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNX58R	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 12:16:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNX58R	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-09-2020 12:16:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BNX58S	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 12:16:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNX58S	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-09-2020 12:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR037C	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 12:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR037C	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-09-2020 12:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR037D	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 12:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR037D	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-09-2020 12:17:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR037F	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 12:17:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR037F	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-09-2020 11:47:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-09-2020 11:47:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-09-2020 11:47:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-09-2020 11:47:07 (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-09-2020 11:47:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/6/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-09-2020 11:47:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BKSCRY	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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, Frozen, Verified

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-09-2020 11:47:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BKSCRY	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: VACCINATION - 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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Nov-06-2020 12:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-06-2020 12:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-06-2020 12:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-06-2020 12:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/6/2020 10:57	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-06-2020 12:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Nov-06-2020 12:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: VACCINATION - 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

7. Route:

Date	Location	User	Value	Reason
Nov-06-2020 12:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-06-2020 12:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION 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
Nov-06-2020 12:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 06-Jul-2020 21:53

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - 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

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**1. Select appropriate response - Reactogenicity diary collection**

Date	Location	User	Value	Reason
Feb-26-2021 15:12:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	I confirm that subject was enrolled under Amendment 8 and this should answered as NO.
Feb-24-2021 00:49:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-23-2021 10:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-23-2021 10:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Transcription Error
Feb-17-2021 01:45:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	PDQ: This question is answered NO. As per protocol amendment 9 and onwards, all subjects aged 16 - 17 years should be part of reactogenicity subset. Please confirm whether or not this subject consented under PA9. Else clarify.
Feb-12-2021 14:44:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Subject was not entered into Reactogenicity in error by site.
Feb-04-2021 00:43:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** REACTOGENICITY DIARY - 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

Feb-03-2021 14:57:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-03-2021 14:57:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E- DIARY COLLECTED FOR T HIS SUBJECT	Transcription Error
Jan-15-2021 07:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: This question is answered NO. As per protocol amendment 9 and onwards, all subjects aged 16 - 17 years should be part of reactogenicity subset. Please confirm whether or not this subject consented under PA9. Else clarify.
Nov-06-2020 12:13:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841538

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Feb-11-2021 22:54:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-11-2021 13:56:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	updated
Feb-05-2021 03:24:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly consider to update missing SYMPRDATE form or else clarify. Thank you.
Dec-07-2020 01:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per SITE response, added to PD tracker for Clinical Review
Dec-07-2020 00:37:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-04-2020 12:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject was unavailable during window for V2

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1084

**Subject No:** 10841538

**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

Dec-04-2020 12:22:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	updated
Dec-02-2020 06:12:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ope ned	DM: Kindly review and complete 'Nasal Swab' form at this visit. Thank you.
Dec-01-2020 02:17:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Ope ned	PDQ: Date of visit at V2_VAX2_L is out of window for 1 days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Nov-30-2020 10:43:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data E</b> <b>ntry:</b> Nov/3 0/2020	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:28

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

			GU E	
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	

2.b Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS <b>Were fever or systemic sy</b> NO <b>mptoms present on the la</b> <b>st day the Subject Diary</b> <b>was completed?:</b>	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic s ymptoms present on the last day the Subject Diar y was completed?:</b> NO	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic s ymptoms present on the last day the Subject Diar y was completed?:</b> NO	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSC LE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ENED JOINT PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE ENED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reacti</b> NO <b>ons present on the last da</b> <b>y the Subject Diary was c</b> <b>ompleted?:</b>	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SW ELL ING  <b>Were injection site react</b> NO <b>ions present on the last</b> <b>day the Subject Diary w</b> <b>as completed?:</b>	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction: PAIN AT INJECTION SITE  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-11-2021 13:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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

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**1. Date:**

Date	Location	User	Value	Reason
Nov-30-2020 10:51:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/30/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-30-2020 10:51:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.6 <b>Temperature Unit:</b> C <b>Temperature Locat</b> ORAL CAVI <b>ion::</b> TY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-30-2020 10:51:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-30-2020 10:51:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.6	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-30-2020 10:51:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** VITAL SIGNS - TEMP - 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

Date	Location	User	Value	Reason
Nov-30-2020 10:51:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/30/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:17 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-02-2020 11:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-02-2020 11:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-02-2020 11:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-02-2020 11:32:40 (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.
Dec-02-2020 11:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-02-2020 11:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPC22R	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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, Frozen, Verified

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-02-2020 11:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPC22R	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: VACCINATION - 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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Nov-30-2020 10:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-30-2020 10:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-30-2020 10:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-30-2020 10:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/30/2020 09:56	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-30-2020 10:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Nov-30-2020 10:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: VACCINATION - 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

7. Route:

Date	Location	User	Value	Reason
Nov-30-2020 10:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-30-2020 10:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION 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
Nov-30-2020 10:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841538

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-26-2021 04:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-25-2021 15:57:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated
Feb-24-2021 02:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Please update SYMPRDATE form. Thank you.
Feb-23-2021 10:06:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	has now been updated
Feb-05-2021 03:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Kindly consider to update missing SYMPRDATE form or else clarify. Thank you.
Jan-29-2021 01:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-28-2021 11:42:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Jan-05-2021 03:43:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

Jan-04-2021 11:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Initial Entry
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**2. Erroneous Visit**

Date	Location	User	Value	Reason
Feb-23-2021 15:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 10:05:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	sae has now been completed
Feb-21-2021 10:43:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	please complete the SAE

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:28

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4), (b) (6)
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2.b

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TIG UE  Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?: NO	Initial Entry
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TIG UE  Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?:	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)



**Header Text:** c4591001  
**Visit:** V3\_MONTH1\_POSTVAX2\_L  
**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History  
**Form Version:** 14-Jan-2021 02:28  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1084  
**Site Name:** (1084) Clinical Trials of Texas  
**Subject No:** 10841538  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:22

			AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

**2.c Symptom:**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

**2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  CH IL LS  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry
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2.d Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  VO MIT ING  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  VO MIT ING  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSEN ED MUS CLE PAI N  <b>Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?:</b> NO	Initial Entry
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSEN ED MUS CLE PAI N  <b>Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?:</b>	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED JOI NT PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?:</b> NO	Initial Entry
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?:</b>	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOINT P AIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS <b>Were injection site reactio ns present on the last day t he Subject Diary was comp leted?:</b> NO	Initial Entry
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

			DN ESS	
Were injection site reactions present on the last day the Subject Diary was completed?:				

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLI NG  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLI NG  Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction</b> PAIN A :: T INJE CTION SITE  <b>Were injection site reac</b> NO <b>tions present on the las</b> <b>t day the Subject Diary</b> <b>was completed?:</b>	Initial Entry
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction</b> PAIN A :: T INJE CTION SITE  <b>Were injection site reac</b> <b>tions present on the las</b> <b>t day the Subject Diary</b> <b>was completed?:</b>	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:28

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-25-2021 15:56:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	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: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-04-2021 11:17:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-04-2021 11:17:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-04-2021 11:17:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-04-2021 11:17:39 (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.
Jan-04-2021 11:17:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-04-2021 11:17:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPC1W5	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 11:17:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPC1W5	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-04-2021 11:18:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPC1W6	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 11:18:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPC1W6	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-04-2021 11:18:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPC1W7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 11:18:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPC1W7	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-04-2021 11:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BMNDT7	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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:** 10841538

**Subject Initials:** ---

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

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

**5.d Sample ID**

Date	Location	User	Value	Reason
Jan-04-2021 11:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BMNDT7	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Jan-04-2021 11:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BMNDT8	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Jan-04-2021 11:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BMNDT8	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

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

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-04-2021 03:15:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	This issue will put on Hold in PD tracker
Mar-03-2021 15:30:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Subject is still hospitalized
Mar-03-2021 03:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	PDQ RQ1:Thank you for the response, however Please confirm whether subject was contacted and accordingly, enter corresponding CONVA visit else provide planned CONVA visit date.
Feb-24-2021 01:19:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: 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-23-2021 14:43:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	data updated
Feb-23-2021 10:04:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Subject is unable to come into the clinic for a convalescent visit at this time. she is currently being treated for

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

				psychological issues as stated in the ae
Feb-23-2021 10:03:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	both nasal swab self and nasal swab are missing due to the subject not doing this with the swab our site gave to her. this is missed
Feb-23-2021 02:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-23-2021 00:50:46 (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.
Feb-22-2021 16:02:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	updated
Feb-22-2021 16:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-11-2021 05:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: 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

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on 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:** 10841538**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22

				visit even if OOW and obtain the CONVA sample else clarify.
Feb-01-2021 21:48:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Microbiology Specimen form' at this visit. Thank you.
Feb-01-2021 01:48:00 (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-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-29-2021 13:42:05 (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-29-2021 13:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-29-2021 13:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on 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:** 10841538

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Jan-29-2021 13:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Jan/06/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1084**Subject No:** 10841538**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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 Assessment:**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/2/2021	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolv ed:  Jan/9/2021	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

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: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCRE : ASSED COUGH <b>Symptom</b> YES <b>Present:</b>	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUG H	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympto</b> NEW OR INCREAS <b>ms:</b> ED SHORTNESS OF BREATH <b>Sympto</b> YES <b>m Prese</b> <b>nt:</b>	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841538**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22**4.c Symptoms:**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHOR TNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> YES	Initial Entry

**4.d Symptoms:**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREA <b>s:</b> SED MUSCLE PAI N	Initial Entry

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: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

			Symptom YES Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom NEW LOSS OF TASTE OR SMELL Symptom NO <b>Present:</b>	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

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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: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: DIARRHEA Symptom Present YES :	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/06/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1084**Subject No:** 10841538**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.h Symptoms:**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITIN G <b>Symptom Present</b> NO :	Initial Entry

**4.i Symptoms:**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:24 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Ot</b> Nasal congest	Initial Entry

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: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4), (b) (6)	her:	ion
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5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-29-2021 13:43:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nasal congestion	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-29-2021 13:43:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> Chest congestion	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-29-2021 13:43:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Chest congestion	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

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

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Feb-22-2021 15:59:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Feb-22-2021 15:59:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Feb-22-2021 15:59:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Feb-22-2021 15:59:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Feb-22-2021 15:59:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Feb-22-2021 15:59:31 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Jan/06/2021

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

Time (US & Canada)	(b) (4), (b) (6)
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**7. Test Result:**

Date	Location	User	Value	Reason
Feb-22-2021 15:59:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Feb-22-2021 15:59:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Feb-22-2021 15:59:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841538

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

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-22-2021 16:00:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-22-2021 16:00:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-22-2021 16:00:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 16:00:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> subject swabbed at another facility	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-22-2021 16:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-22-2021 16:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-22-2021 16:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 16:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Swab collected at another facility	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/06/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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**1.a**

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner</b> SPECIA : LIST <b>Occurrence of Visits</b> NO <b>or Contacts:</b>	Initial Entry

**1.a Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

**1.a Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGEN CY ROOM <b>Occurrence of Vi</b> NO <b>sits or Contacts:</b>	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/06/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841538**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/06/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry
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*1.d Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

*1.d Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

*1.e*

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/06/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841538**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATIO N	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH ER <b>Occurrence of Visits or NO Contacts:</b>	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 13:44:41 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Jan/06/2021

**Form Version:** 14-Jan-2021 02:24

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

Time (US & Canada)	(b) (4), (b) (6)
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Jan/06/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Mar-12-2021 11:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Mar-12-2021 11:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Mar-12-2021 11:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Mar-12-2021 11:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Mar-12-2021 11:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Mar-12-2021 11:17:06 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History  
on Jan/06/2021

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

Time (US & Canada)	(b) (4), (b) (6)
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090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Jan/06/2021

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 13:43:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-29-2021 13:43:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Jan/06/2021

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Mar-12-2021 11:14:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Mar-12-2021 11:14:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Mar-12-2021 11:14:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-12-2021 11:14:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Not Done:</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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

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Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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5.b Test:

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

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**Header Text:** c4591001

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			<b>Result::</b>	Not Applicable	
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			<b>Lab Normal Range:</b>	Not Applicable	

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Date	Location	User	Value	Reason
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5.c Test:

Date	Location	User	Value	Reason
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5.c Result:

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5.c Not Done:

Date	Location	User	Value	Reason
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5.c LNMT

Date	Location	User	Value	Reason
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5.d

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

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			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

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Date	Location	User	Value	Reason
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5.d Test:

Date	Location	User	Value	Reason
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5.d Result:

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5.d Not Done:

Date	Location	User	Value	Reason
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5.d LNMT

Date	Location	User	Value	Reason
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5.e

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

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			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

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

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Date	Location	User	Value	Reason
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5.e Test:

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
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5.e Not Done:

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

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**Header Text:** c4591001

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**Subject No:** 10841538

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			<b>Lab Normal Range:</b>	Not Applicable	

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
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5.g Not Done:

Date	Location	User	Value	Reason
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5.g LNMT

Date	Location	User	Value	Reason
Mar-12-2021 11:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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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: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

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

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Form Version: 10-Oct-2020 16:02

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Site No: 1084

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			<b>Not Done:</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
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5.c

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

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**Header Text:** c4591001

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

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

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**Header Text:** c4591001

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**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

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

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

			<b>Test::</b>	Not Applicable	
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			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

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

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

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

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

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Site Name: (1084) Clinical Trials of Texas

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

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**Header Text:** c4591001

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**Site No:** 1084

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**Subject No:** 10841538

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

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

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Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

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**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:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

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

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Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

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**Site No:** 1084

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**Subject Initials:** ---

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

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

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
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			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined I Not Appli	Initial Entry

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**Header Text:** c4591001

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**Subject No:** 10841538

**Subject Initials:** ---

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

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

			<b>dentifier:</b>	cable	
			<b>Test::</b>	Not Appli cable	
			<b>Result::</b>	Not Appli cable	
			<b>Not Done::</b>	Not Appli cable	
			<b>Lab Normal Range:</b>	Not Appli cable	

Header Text: c4591001

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

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j Not Done:**

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Mar-12-2021 11:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Jan/06/2021

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Mar-12-2021 11:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-12-2021 11:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Applicable <b>Systolic::</b> Not Applicable <b>Diastolic::</b> Not Applicable <b>Respiratory Rate in respirations/minute:</b> Not Applicable <b>Heart Rate in beats/minute:</b> Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Mar-12-2021 11:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Mar-12-2021 11:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
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090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Jan/06/2021

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**Form Status:** Data Complete

**Site No:** 1084

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Mar-12-2021 11:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Mar-12-2021 11:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Mar-12-2021 11:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)



Header Text: c4591001

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

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Mar-12-2021 10:26:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-12-2021 10:26:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> Not Applicable <b>Oxygen Saturation:</b> Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Mar-12-2021 10:26:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Mar-12-2021 10:26:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Jan/06/2021

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Mar-12-2021 10:26:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Mar-12-2021 10:26:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Mar-12-2021 10:26:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

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

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Mar-12-2021 10:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Mar-12-2021 10:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Mar-12-2021 10:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	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
Mar-12-2021 10:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Mar-12-2021 10:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6. Ongoing?

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**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Mar-12-2021 10:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Jan/06/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841538

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Mar-12-2021 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Mar-12-2021 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Mar-12-2021 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Mar-12-2021 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

**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

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Date	Location	User	Value	Reason
Feb-23-2021 09:55:29 (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:** 10841538

**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

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Date	Location	User	Value	Reason
Mar-12-2021 10:15:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Mar-10-2021 11:49:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	SAE update, duplicate deleted.
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-12-2021 14:28:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Query closed; will follow for deletion for 2nd incorrect SAE on attempt to self harm.
Mar-12-2021 10:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	updated
Mar-12-2021 10:22:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	updated
Mar-12-2021 07:31:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	SAE RECON:aER#2021145100 Per previous query reponse 'Patient did not attempt to self harm'. Please submit a follow up SAE form to clarify that event 'attempt to self harm' is no longer an SAE.
Mar-11-2021 16:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query

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Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

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Form Status: Data Complete, Answered Queries

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Mar-11-2021 16:10:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Opened	Clinical Thank you; that is the update being referred to - there are 2 EVENTS still, with the 2nd tab being Self-Harm.
Mar-11-2021 13:16:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	New SAE faxed on 3-9-2021.
Mar-11-2021 13:12:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Mar-11-2021 12:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Clinical - thank you for clarification about Self-Harm. Please send a SAE update to REMOVE this term from the SAE report
Mar-11-2021 12:16:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Mar-11-2021 09:12:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Patient did not attempt to self harm
Mar-10-2021 19:25:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical - Event Attempt to Inflict Self-Harm was deleted. Please review if this would be an AE by itself (w/ or w/o Bipolar); if so please report it again. Event can be serious or non-serious; if serious add as 2nd Event tab in SAE report (2021145100)
Mar-10-2021 19:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical - Unfortunately, the wrong duplicate was removed (the SAE version) - subject had hospitalization so must have SAE. Please update this remaining Bipolar I event to SAE, onset 31Jan21 (while still

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1084**Subject No:** 10841538**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries**Site Name:** (1084) Clinical Trials of Texas**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

				non-serious), with all serious criteria
Mar-05-2021 13:34:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-05-2021 13:03:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject does not have history of bipolar disease, subject was diagnosed after joining study- subject has history of depression, anxiety, PTSD, and insomnia
Mar-05-2021 10:14:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	clinical: pls confirm subject does not have prior history of bipolar disease, just depression and anxiety. Thanks
Mar-04-2021 07:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-25-2021 15:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Bipolar 1 is AE, attempt to inflict self-harm is SAE will be corrected
Feb-23-2021 16:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Event is Bipolar I; however, SAE report has the original term of Attempted to Inflict Self-harm. Please review, harmonize reporting, and update event term where appropriate
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bipolar I	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-04-2021 07:08:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Feb-25-2021 15:27:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	corrected
Feb-23-2021 16:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - Event start date is 31Jan21; however, SAE report start date is 07Feb21. Please review, harmonize reporting, and update start date where applicable.
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/31/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-12-2021 07:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Deleted	Close Auto Query

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1084**Subject No:** 10841538**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries**Site Name:** (1084) Clinical Trials of Texas**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

Mar-11-2021 13:10:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Candidate	For AE Bipolar I: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-11-2021 13:10:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associat ed with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO  Did this serious event requir e or prolong hospitalization?  YES  Did this serious event result in persistent or significant di sability/incapacity?  NO  Is this serious event life thre atening?  NO  Other medically important s erious event  NO	Transcription Error
Mar-04-2021 07:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	moving query to SAE
Mar-04-2021 07:09:35 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Answered Queries

**Site Name:** (1084) Clinical Trials of Texas

**Subject Initials:** ---

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

Time (US & Canada)				
Mar-03-2021 15:29:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Adverse event of attempt to self injure has been added
Mar-01-2021 11:05:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021145100] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Mar-01-2021 11:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical A SAE report (#2021145100) was submitted for Attempt to Inflict Self-Harm (update pending to Bipolar I), with serious criterion of HOSPITALIZATION; however, AE log states event is non-serious. Please review and update where appropriate
Mar-01-2021 04:42:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Feb-25-2021 15:26:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE Bipolar I: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Feb-25-2021 15:26:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Feb-23-2021 23:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 10:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-23-2021 10:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associat ed with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO  Did this serious event requir e or prolong hospitalization?  YES  Did this serious event result in persistent or significant di sability/incapacity?  NO  Is this serious event life thre atening?  NO  Other medically important s erious event  YES	Transcription Error
Feb-23-2021 09:59:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associat ed with congenital anomaly or birth defect?	Transcription Error

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1084**Subject No:** 10841538**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries**Site Name:** (1084) Clinical Trials of Texas**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

			<p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Bipolar I: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO Did this serious event require	Initial Entry

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841538

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

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			e 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
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-04-2021 17:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-04-2021 17:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 15:56:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE follow up sent today

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Subject No: 10841538

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-04-2021 15:55:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE follow up sent today
Mar-03-2021 16:11:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Please update SAE narrative to include parent report of recent social stressors as precipitating factor to event.
Mar-03-2021 16:10:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Thank you. Please amend SAE narrative to include prior hospitalization for depression.
Mar-03-2021 14:29:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was hospitalized for a week in 2015
Mar-03-2021 14:28:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	per parent, social stressors were present
Feb-25-2021 10:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	GPD Clin: please confirm if participant had recent precipitating events to hospitalization such as school/social stressors or changes in family circumstances.
Feb-25-2021 10:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please confirm if patient was found to have medhx of any of the following - prior hospitalization for

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Subject No: 10841538

Generated By: (b) (4)

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				mental health, past or recent substance abuse
Feb-23-2021 09:58:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Depression	Transcription Error
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 09:55:29	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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(UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	RECOVERING/RESOLVING
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-23-2021 09:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-12-2021 07:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021145100	Initial Entry
Mar-01-2021 04:42:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	downgraded to non serious
Feb-23-2021 23:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021145100	Initial Entry

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Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Mar-12-2021 10:15:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-12-2021 10:20:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Mar-12-2021 10:19:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-12-2021 10:15:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-12-2021 10:15:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-10-2021 19:31:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	removing query from a deleted AE
Mar-10-2021 10:05:07 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	AE log was corrected the

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Subject No: 10841538

Generated By: (b) (4)

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Time (US & Canada)		(b) (4), (b) (6)		Attempt to self injure was incorrectly logged.
Mar-10-2021 08:46:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - SAE report (#2021145100) has 2 serious events [Bipolar I, Attempt to Self Injure]; however, only 1 SAE is reported on the AE CRF. Please add the 2nd SAE on a separate line on the AE CRF.
Mar-09-2021 21:47:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-09-2021 15:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-09-2021 15:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bipolar I	Transcription Error
Mar-05-2021 20:17:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical - thank you; however 04Mar21 update did not include Bipolar I in the SAE Med History section; please update
Mar-04-2021 15:56:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE follow up sent today
Mar-04-2021 07:14:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - As Bipolar I event start date is 31Jan21, prior to Self Harm SAE on 07Feb21, please submit a SAE update reporting Bipolar I condition

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Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Attempt to self injure	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-10-2021 19:31:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	removing query from a deleted AE
Mar-10-2021 11:49:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	SAE update, duplicate deleted.
Mar-10-2021 08:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - event 'Bipolar I' began 31Jan21, with HOSP on 07Feb21. In Vaccine study, SAE start date is day event starts; not day it meets serious criteria (item 11 in vaccine SAE instructs). Please update Start to 31Jan21 and remove extra Bipolar I AE
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/7/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-12-2021 10:16:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-05-2021 20:11:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		query
Mar-04-2021 15:56:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject is still hospitalized due to SAE
Mar-04-2021 07:15:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - Event end date is NONE; please review for possible end date for event 'attempt to inflict self-harm'
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-12-2021 10:16:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-12-2021 10:16:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-05-2021 20:18:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for requested COVID test information.

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Mar-04-2021 15:57:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE follow up sent today
Mar-04-2021 07:13:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021145100] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Mar-04-2021 04:25:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Attempt to self injure: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associate d with congenital anomaly or birth defect?  NO  Did this serious event result i n death?  NO  Did this serious event require or prolong hospitalization?  YES	Initial Entry

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			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>
--	--	--	---

**8. Is this adverse event the result of a study Medication Error?**  
**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Mar-12-2021 10:16:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-12-2021 10:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p><i>If Other, specify:</i></p> <p>Bipolar 1</p>	Initial Entry

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Generated By: (b) (4)

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-12-2021 10:17:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-12-2021 10:17:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-12-2021 10:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Mar-03-2021 15:27:59 (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
Mar-12-2021 10:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

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

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**Site No:** 1084

**Subject No:** 10841538

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Incomplete

**Site Name:** (1084) Clinical Trials of Texas

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Mar-12-2021 10:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 15:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001

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**Site No:** 1084

**Subject No:** 10841538

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Incomplete

**Site Name:** (1084) Clinical Trials of Texas

**Subject Initials:** ---

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

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**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Mar-04-2021 04:25:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021145100	Initial Entry

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

**Site No:** 1084

**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841538

**Subject Initials:** ---

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

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

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-28-2021 11:42:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-28-2021 11:42:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-28-2021 11:42:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (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:** 10841538

**Subject Initials:** ---

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

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-03-2021 12:48:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1084

**Subject No:** 10841538

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

**Form:** FURTHER VACCINATION CONFIRMATION - 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

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

Date	Location	User	Value	Reason
Feb-23-2021 10:14:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return f or Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placeb o at Vaccination 1/2	Transcription Error
Jan-25-2021 16:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is NOT willing to re turn for Vaccination 3 OR other wise not eligible	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841538

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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-25-2021 16:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-23-2021 15:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Closed	Response satisfies query
Feb-23-2021 10:15:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Feb-22-2021 12:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7350105;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.
Jan-25-2021 16:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS EL	Initial Entry

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

**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

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090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841538

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

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**I. Subject Status**

Date	Location	User	Value	Reason
Jan-28-2021 11:42:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Nov-06-2020 12:11:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Nov-06-2020 11:57:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Mar-08-2021 00:20:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-04-2021 15:52:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	CRF updated, SAE follow up will be sent today
Mar-01-2021 04:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2021145100 attempted to inflict self harm(onset date:07Feb2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Feb-23-2021 23:36:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-23-2021 10:08:04 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	ae is now entered

090177e196ae3f82\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1084**Subject No:** 10841538**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

Time (US & Canada)		(b) (4), (b) (6)		
Feb-15-2021 04:47:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021145100 attempted to inflict self harm(onset date:07Feb2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Feb-12-2021 00:31:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 15:07:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	symptom on 08JAN2021 was reported along with the symptoms in Covid illness that was assessed on 06JAN2021.
Jan-28-2021 11:42:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/30/2020	Initial Entry
Jan-21-2021 08:32:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Opened	Illness edary: As per Illness edary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 08JAN2021. But corresponding COVID Illness visit not reported. Please clarify.
Nov-06-2020 12:11:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/6/2020	Initial Entry
Nov-06-2020 11:57:02 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/6/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841538

**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

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