

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** COHORT\_SELECTION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

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

<b>Header Text:</b> c4591001	<b>Form:</b> MAIN INFORMED CONSENT
<b>Visit:</b> COHORT_SELECTION	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1084) Clinical Trials of Texas
<b>Site No:</b> 1084	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10841266	<b>Generated Time (GMT):</b> 29-Mar-2021 10:22
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/22/2020

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001  
**Visit:** COHORT\_SELECTION **Form:** DEMOGRAPHY  
**Form Version:** 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1084 **Site Name:** (1084) Clinical Trials of Texas  
**Subject No:** 10841266 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Demography		
1.	Subject ID	[10841266]
2.	Birth Date:	(b) (6)/1943
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[eCRF Audit Trail History](#)

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
	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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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
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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

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
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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1084  
**Subject No:** 10841266  
**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1084) Clinical Trials of Texas  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Aug/22/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Levaquin allergy]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[environmental allergies]
	Start Date:	UNK/UNK/1975
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[amputation of 5 toes on right foot]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2011
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Amputation of left big toe]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2012
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Amputation of toe on left foot]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

1 f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[CORONARY ARTERIAL BYPASS GRAFTS]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1 g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Cataract Removal]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1 h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Bilateral Cataracts]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1 i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Ocular hypertension]
	Start Date:	Jun/UNK/2020
	Ongoing:	YES
1 j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Congestive Heart failure]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1 k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Hypercholesterolemia]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Type 2 Diabetes]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[atrophy to left hand]
	Start Date:	Aug/22/2020
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[gangrene on all toes on right foot]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2011
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[gangrene on left big toe]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2020
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[gangrene on toe left foot]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Subject Initials:** ---

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

1 r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[erectile dysfunction]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** VITAL SIGNS - BASELINE

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/22/2020
2.	Weight:	[79.0]
3.	Unit:	kg
4.	Height:	[166.4]
5.	Unit:	cm
6.	Body Mass Index:	[28.5]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.2]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1084  
**Subject No:** 10841266  
**Generated By:** (b) (4)

**Form:** RANDOMIZATION  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1084) Clinical Trials of Texas  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Aug/22/2020
2.	Randomization Number:	[237238]
3.	Randomization Group:	[ ]

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/22/2020
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	[BPY97P]
5.b	Sample ID	[BPY97R]
5.c	Sample ID	[BPY97S]
5.d	Sample ID	[BPFSZH]
5.e	Sample ID	[BPFSZJ]

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841266

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

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/22/2020
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	[BPY96M]
-----	-----------	----------

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/22/2020 13:51
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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> REACTOGENICITY DIARY
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, 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> 10841266	<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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/14/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** VITAL SIGNS - TEMP

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/14/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1084

**Subject No:** 10841266

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

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPC0H5]
-----	-----------	----------

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/14/2020 11:26
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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**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	Oct/12/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/12/2020
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	[BNX5G9]
5.b	Sample ID	[BNX5GB]
5.c	Sample ID	[BKSCMK]
5.d	Sample ID	[BKSCML]
5.e	Sample ID	[BKSCMM]

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1084

**Subject No:** 10841266

**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	

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001  
**Visit:** V4\_MONTH6\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1084  
**Subject No:** 10841266  
**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	[ ]
----	-----------	-----

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1084

**Subject No:** 10841266

**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:** 10841266

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1084

**Subject No:** 10841266

**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:** 10841266

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

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

**Form Status:** Not Started

**Site No:** 1084

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

**Subject No:** 10841266

**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\_ILL - New Unscheduled Visit

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **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:** 10841266      **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	[ ]
----	-----------	-----

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

**Health Care Utilization**

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

**Health Care Utilization Other**

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

**Health Care Utilization**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

**Illness Details**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

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

**Form Status:** Not Started

**Site No:** 1084

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

**Subject No:** 10841266

**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:	
----	-------------------------	--

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**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:** 10841266

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/15/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**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	Sep/15/2020
2.	Erroneous Visit	

**Header Text:** c4591001  
**Visit:** Unplanned 1 - Unscheduled Visit on Sep/15/2020  
**Form:** UNPLANNED VISIT  
**Form Version:** 22-Apr-2020 21:04  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1084  
**Site Name:** (1084) Clinical Trials of Texas  
**Subject No:** 10841266  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Unplanned Assessments	
1.	Assessments CONTACT OUTCOME

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/15/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Sep/15/2020  Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[ ]

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on  
Oct/13/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**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	Oct/13/2020
2.	Erroneous Visit	

**Header Text:** c4591001  
**Visit:** Unplanned 2 - Unscheduled Visit on Oct/13/2020  
**Form:** UNPLANNED VISIT  
**Form Version:** 22-Apr-2020 21:04  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1084  
**Site Name:** (1084) Clinical Trials of Texas  
**Subject No:** 10841266  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001  
**Visit:** Unplanned 2 - Unscheduled Visit on Oct/13/2020  
**Form:** CONTACT OUTCOME - UNPLANNED  
**Form Version:** 22-Apr-2020 21:04  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1084  
**Site Name:** (1084) Clinical Trials of Texas  
**Subject No:** 10841266  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Contact Outcome		
1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/13/2020  Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Nov/04/2020

**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:** 10841266

**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	Nov/4/2020
2.	Erroneous Visit	

**Header Text:** c4591001  
**Visit:** Unplanned 3 - Unscheduled Visit on Nov/04/2020  
**Form:** UNPLANNED VISIT  
**Form Version:** 22-Apr-2020 21:04  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1084  
**Site Name:** (1084) Clinical Trials of Texas  
**Subject No:** 10841266  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Unplanned Assessments	
1.	Assessments CONTACT OUTCOME

**Header Text:** c4591001  
**Visit:** Unplanned 3 - Unscheduled Visit on Nov/04/2020  
**Form:** CONTACT OUTCOME - UNPLANNED  
**Form Version:** 22-Apr-2020 21:04  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1084  
**Site Name:** (1084) Clinical Trials of Texas  
**Subject No:** 10841266  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Contact Outcome		
1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	NO If No, why? [Answering machine full, subject did not answer 2 calls]
3.	Comments:	[ ]

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1084

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

**Subject No:** 10841266

**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 :	Oct/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** DISPOSITION - FOLLOW-UP

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	Jan/12/2021
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	DEATH
4.	Specify Status:	[ ]

**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:** 10841266

**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:** 10841266

**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: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Acute Emphysematous Cholecystitis	Nov/3/2020 UNK:UNK	NO End Date Time:  Jan/12/2021 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Rhabdomyolysis	Nov/2/2020 UNK:UNK	NO End Date Time:  Nov/13/2020 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Atrial Fibrillation with RVR	Nov/3/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Acute Kidney Injury	Nov/3/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	Sepsis	Nov/3/2020 UNK:UNK	NO End Date Time:  Jan/12/2021 UNK:UNK	<a href="#">Repeating Pages</a>
6.	ADVERSE EVENT	6	Left lower extremity weaknesses	Oct/28/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute Emphysematous Cholecystitis]
4.	Start Date Time:	Nov/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/12/2021 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? YES  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? YES  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [bacteria]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020459195]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Rhabdomyolysis]
4.	Start Date Time:	Nov/2/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/13/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [dehydration]
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?:	RECOVERED/RESOLVED

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Atrial Fibrillation with RVR]
4.	Start Date Time:	Nov/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [CAD]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]
-----	---	-----

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute Kidney Injury]
4.	Start Date Time:	Nov/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [Dehydration]
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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]
-----	---	-----

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Sepsis]
4.	Start Date Time:	Nov/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/12/2021 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? YES  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? 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: [Klebsiella Oxytoca, Escherichia coli, Klebsiella pneumonia]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020459195]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left lower extremity weakness]
4.	Start Date Time:	Oct/28/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
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: [sepsis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]
-----	---	-----

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1084

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

**Subject No:** 10841266

**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>

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**Medication Error**

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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATION S	NO	INFLUENZA VIRUS VACCINE QUAD RIVALENT 240 MCG IM	Nov/8/2020	<a href="#">Repeating Pages</a>
2.	2	VACCINATION S	NO	Pneumococcal Polysaccharide Vaccine 0.5mL IM	Nov/8/2020	<a href="#">Repeating Pages</a>

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

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

**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](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[INFLUENZA VIRUS VACCINE QUADRIVALENT 240 MCG IM]
5.	Date:	Nov/8/2020

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

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

**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](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Concomitant Medications**

1.	What is the medication identifier?	[2]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Pneumococcal Polysaccharide Vaccine 0.5mL IM]
5.	Date:	Nov/8/2020

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001  
**Visit:** Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1084 **Site Name:** (1084) Clinical Trials of Texas  
**Subject No:** 10841266 **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>

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

**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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1084

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

**Subject No:** 10841266

**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>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**Radiation Treatment**

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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**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:** 10841266 **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>

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1084  
**Subject No:** 10841266  
**Generated By:** (b) (4)

**Form:** TRANSFUSIONS  
**Form Status:** Not Started  
**Site Name:** (1084) Clinical Trials of Texas  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**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:** 10841266

**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:** 10841266

**Subject Initials:** ---

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

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1084

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

**Subject No:** 10841266

**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?	

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME - MONTH 1
<b>Visit:</b> Unplanned Vaccination - Unscheduled	<b>Form Status:</b> Not Started
<b>Form Version:</b> 10-Oct-2020 15:57	<b>Site Name:</b> (1084) Clinical Trials of Texas
<b>Site No:</b> 1084	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10841266	<b>Generated Time (GMT):</b> 29-Mar-2021 10:22
<b>Generated By:</b> (b) (4)	

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:** 10841266      **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:	[ ]

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**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:** 10841266

**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:** 10841266

**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:** 10841266

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1084

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

**Subject No:** 10841266

**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:** 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:** 10841266

**Subject Initials:** ---

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

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

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

**Date of Visit**

1.	Date of Visit	Jan/15/2021
2.	Erroneous Visit	ERRONEOUS VISIT

**Header Text:** c4591001  
**Visit:** Potential ReVax Initial Contact - Unscheduled      **Form:** FURTHER VACCINATION CONFIRMATION  
**Form Version:** 10-Dec-2020 02:25      **Form Status:** Data Complete, Frozen  
**Site No:** 1084      **Site Name:** (1084) Clinical Trials of Texas  
**Subject No:** 10841266      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 10:22

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

Further Vaccination Confirmation			
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Not Applicable	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** TREATMENT UNBLINDED

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

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

**Subject Initials:** ---

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

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

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Not Applicable _____ //	<a href="#">Comments</a>
2.	Primary Reason for Unblinding:	Not Applicable _____ _____	<a href="#">Comments</a>

<b>Header Text:</b> c4591001		<b>Form:</b> WITHDRAWAL OF CONSENT
<b>Visit:</b> Disposition - Unscheduled		<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:03		<b>Site Name:</b> (1084) Clinical Trials of Texas
<b>Site No:</b> 1084		<b>Subject Initials:</b> ---
<b>Subject No:</b> 10841266		<b>Generated Time (GMT):</b> 29-Mar-2021 10:22
<b>Generated By:</b> (b) (4)		
<b>Withdrawal Of Consent</b>		
1.	Withdrawal of Consent Date :	//

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** DEATH DETAILS CODED

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Death Details**

1.	Date of Collection / Notification of Death:	Jan/15/2021
----	---	-------------

**Cause of Death**

2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[Sepsis]
2.b	Cause of Death Status:	SECONDARY CAUSE OF DEATH
	Cause of Death:	[Acute emphysematous cholecystitis]

<b>Header Text:</b> c4591001	
<b>Visit:</b> Subject Status - Unscheduled	<b>Form:</b> SUBJECT STATUS
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Form Status:</b> Data Complete, Verified
<b>Site No:</b> 1084	<b>Site Name:</b> (1084) Clinical Trials of Texas
<b>Subject No:</b> 10841266	<b>Subject Initials:</b> ---
<b>Generated By:</b> (b) (4)	<b>Generated Time (GMT):</b> 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Subject Status		
1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Jan/12/2021

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1084

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

**Subject No:** 10841266

**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:** Potential ReVax Initial Contact - Unscheduled

**Form:** DATE OF VISIT - Comments

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-02-2021 12:04:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not applicable

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-05-2021 08:58:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Mar-02-2021 12:04:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not applicable

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** FURTHER VACCINATION CONFIRMATION - Comments

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-05-2021 08:58:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** TREATMENT UNBLINDED - Comments

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

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-02-2021 17:18:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Mar-02-2021 12:01:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not applicable

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** TREATMENT UNBLINDED - Comments

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

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-02-2021 17:18:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** TREATMENT UNBLINDED - Comments

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

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Mar-02-2021 17:18:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Jan-26-2021 15:00:09 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

(b) (6)	Approved	Jan-22-2021 18:41:50 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------	----------	---	------	--------

**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-22-2021 15:18:30 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

(b) (6)	Approved	Jan-21-2021 16:15:28 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------	----------	---	------	--------

**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-20-2020 16:57:28 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Data Complete, Verified

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

(b) (6)	Approved	Nov-06-2020 12:08:44 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------	----------	--	------	--------

**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-05-2020 10:24:59 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

**Affidavit:**

N/A

(b) (6)	Approved	Oct-20-2020 15:31:48 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------	----------	--	------	--------

**Affidavit:**

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

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

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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: COHORT\_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-22-2020 14:46:25 (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
Aug-22-2020 14:46:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

[Back to Form](#)

**I. Consent Was:**

Date	Location	User	Value	Reason
Aug-22-2020 14:46:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/22/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-22-2020 14:46:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10841266	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-22-2020 14:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1943	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 14:47:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-22-2020 14:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Inclusion Number: Criteria: 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) Criteria met?: Criteria ID: (For Publisher use only):	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry

I.a Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criteria:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures <b>Criteria met?:</b> YES <b>Criteria ID: (For Pfizer use only):</b> IN02A00	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

**1.b Inclusion Number:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> 3 <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 <b>Criteria on met?:</b> YES	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<b>Criteria ID:</b> IN03A00 <b>For Pfizer use only):</b>
--	--	--	---

**I.c Inclusion Number:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**I.c Criterion Description:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</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	Initial Entry

**I.c Criterion met?**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN03A00	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Inclusion Number:	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<b>Criterion 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  <b>Criterion met?:</b> YES  <b>Criterion ID: (For Pfizer use only):</b> IN04A00	
--	--	--	--	--

**1.d Inclusion Number:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion 1	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<b>on Number:</b> <b>Criterion 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 <b>Criterion met?:</b> NO <b>Criterion ID:</b> EX01A00 <b>(For Pfizer use only):</b>	
--	--	--	--	--

2.a Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX01A00	Initial Entry

2.b

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion 2</b> <b>Number:</b> <b>Criterion Description:</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) <b>Criterion met?:</b> <b>Criterion ID: (For Pfizer use only):</b> EX02A00	Initial Entry

**2.b Exclusion Number:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**2.b Criterion Description:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX02A00	Initial Entry

**2.c**

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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number: <b>Criterion Description:</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) <b>Criterion met?:</b> <b>Criterion ID: (For Pfizer use only):</b> EX03A00	Initial Entry
---	-----------------	---------------------	--	---------------

2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX03A00	Initial Entry

2.d

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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 <b>For Pfizer use only):</b>	Initial Entry

2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number:	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<b>Criterion Description:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination  <b>Criterion met?:</b> NO  <b>Criterion ID: (For Pfizer use only):</b> EX08A00	
--	--	--	---	--

**2.e Exclusion Number:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 8	Initial Entry

**2.e Criterion Description:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX08A00	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number 10	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<b>ber:</b> <b>Criterion Description:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection <b>Criterion met?:</b> <b>Criterion ID: (For Pfizer use only):</b> EX10A00	
--	--	--	---	--

2.f Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	<b>Exclusion Number:</b> 11 <b>Criterion Description:</b> Women who are pregnant or breastfeeding <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX11A00
---	--	---------------------	--

2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 12 <b>Criterion Description:</b> Previous vaccination with any coronavirus vaccine <b>Criterion met?:</b> NO	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<b>Criterion ID: ( EX12A00 For Pfizer use only):</b>	
--	--	--	--	--

**2.h Exclusion Number:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous vaccination with any coronavir us vaccine	Initial Entry

**2.h Criterion met?**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion 13 Number:</b> <b>Criterion</b> Subjects who receive immu <b>Descriptio</b> nosuppressive therapy, suc <b>n:</b> h as cytotoxic agents or sys temic corticosteroids <b>Criterion</b> NO <b>met?:</b> <b>Criterion</b> EX13A01 <b>ID: (For P fizer use o nly):</b>	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number: <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: (For Pfizer use only):</b> EX14A01	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

**2.j Exclusion Number:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 15	Initial Entry

**2.j Criterion Description:**

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX14A01	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

2.k

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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 <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX16A01	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

2.l Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (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
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</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 <b>Criterion met?:</b> NO	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:50

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			Criteria ID: EX21A01 (For Pfizer use only)
--	--	--	--

2.m Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 14:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-22-2020 14:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-22-2020 14:48:05 (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
Aug-22-2020 14:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

**I.a**

Date	Location	User	Value	Reason
Aug-22-2020 14:52:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term</b> : Levaquin allerg y <b>Start Date:</b> UNK/UNK/200 0 <b>Ongoing:</b> YES	Initial Entry

**I.a Line/MH Number:**

Date	Location	User	Value	Reason
Aug-22-2020 14:52:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 14:52:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Levaquin allergy	Initial Entry

**I.a Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 14:52:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2000	Initial Entry

**I.a Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 14:52:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.b**

Date	Location	User	Value	Reason
Aug-22-2020 14:52:59 (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> environmental allergies	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<b>Start Date:</b>	UNK/UNK/1975
			<b>Ongoing:</b>	YES

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

Date	Location	User	Value	Reason
Aug-22-2020 14:52:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 14:52:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> environmental allergies	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 14:52:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1975	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 14:52:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Aug-22-2020 15:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Line/MH Num 3 <b>ber:</b> <b>Medical Histor</b> amputation of 5 toes o <b>y Term:</b> n right foot <b>Start Date:</b> UNK/UNK/2011 <b>Ongoing:</b> NO End Date: UNK/UNK/2011	Transcription Error
Aug-22-2020 15:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Num 3 <b>ber:</b>	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<b>Medical History Term:</b> amputation of 5 toes on right foot <b>Start Date:</b> UNK/UNK/2011 <b>Ongoing:</b> NO End Date: UNK/UNK/2011	
--	--	--	---	--

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-22-2020 15:05:43 (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
Aug-22-2020 15:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> amputation of 5 toes on right foot	Transcription Error
Aug-22-2020 15:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> amputation of 5 toes on right foot	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 15:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 15:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2011	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-22-2020 15:06:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number 4 :	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<b>Medical History Term:</b> Amputation of left big toe <b>Start Date:</b> UNK/UNK/2012 <b>Ongoing:</b> NO End Date: UNK/UNK/2012	
--	--	--	---	--

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

Date	Location	User	Value	Reason
Aug-22-2020 15:06:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 15:06:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Amputation of left big toe	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 15:06:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2012	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 15:06:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2012	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Aug-22-2020 15:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> Amputation of toe on left foot <b>Start Date:</b> UNK/UNK/2017	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<b>Ongoing:</b> NO End Date: UNK/UNK/2017	
--	--	--	---	--

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

Date	Location	User	Value	Reason
Aug-22-2020 15:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 15:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Amputation of toe on left foot	Initial Entry

***I.e Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 15:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

***I.e Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 15:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2017	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Aug-24-2020 11:00:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Line/MH N 6 umber: Medical His CORONARY ARTERIA tory Term: L BYPASS GRAFTS Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	Transcription Error

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

Aug-22-2020 15:09:55 (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> Bypass Graft <b>m:</b> <b>Start Date:</b> UNK/UNK/2005 <b>Ongoing:</b> NO End Date: UNK/UNK/2005	Initial Entry
---	-----------------	-------------------------	--	---------------

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

*If Line/MH Number:*

Date	Location	User	Value	Reason
Aug-22-2020 15:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

*If Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Aug-24-2020 12:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-24-2020 11:00:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-24-2020 11:00:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CORONARY ARTERIAL BYPASS GRAFTS	Transcription Error
Aug-23-2020 11:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify BYPASS GRAFT as follows...Are you reporting CORONARY ARTERIAL BYPASS GRAFTS or the term POPLITEAL ARTERY BYPASS GRAFT?Or others? If so, please edit to such. Otherwise, please edit to spell out the term. Thank you.
Aug-22-2020 15:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Bypass Graft	Initial Entry

*If Start Date:*

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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Aug-22-2020 15:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry
---	-----------------	---------------------	------------------------------------	---------------

*If Ongoing:*

Date	Location	User	Value	Reason
Aug-22-2020 15:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2005	Initial Entry

*I.g*

Date	Location	User	Value	Reason
Aug-22-2020 15:10:15 (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> Cataract Removal <b>m:</b> <b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> NO End Date:  UNK/UNK/2015	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Aug-22-2020 15:10:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 15:10:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cataract Removal	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 15:10:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 15:10:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2015	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Aug-22-2020 15:11:41 (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> Bilateral Cataracts <b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> NO End Date:  UNK/UNK/2015	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Aug-22-2020 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilateral Cataracts	Initial Entry

**I.h Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

**I.h Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2015	Initial Entry

**I.i**

Date	Location	User	Value	Reason
Aug-22-2020 15:13:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> Ocular hypertension <b>Start Date:</b> Jun/UNK/2020 <b>Ongoing:</b> YES	Transcription Error
Aug-22-2020 15:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> Ocular hypertension <b>Start Date:</b> UNK/UNK/2020 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-22-2020 15:12:11 (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
Aug-22-2020 15:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ocular hypertension	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 15:13:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-22-2020 15:13:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/UNK/2020	Transcription Error
Aug-22-2020 15:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 22/Aug/2020. Please review and update as appropriate.
Aug-22-2020 15:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 15:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.j***

Date	Location	User	Value	Reason
Aug-22-2020 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 10	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<b>Medical History Term:</b> Congestive Heart failure <b>Start Date:</b> UNK/UNK/2005 <b>Ongoing:</b> YES	
--	--	--	---	--

**I.j Line/MH Number:**

Date	Location	User	Value	Reason
Aug-22-2020 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Congestive Heart failure	Initial Entry

**I.j Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

**I.j Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 15:13:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.k**

Date	Location	User	Value	Reason
Aug-22-2020 15:14:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 11 <b>Medical History Term:</b> Hypertension <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Aug-22-2020 15:14:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 15:14:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypertension	Initial Entry

***1.k Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 15:14:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***1.k Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 15:14:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.l***

Date	Location	User	Value	Reason
Aug-22-2020 15:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 12 <b>Medical History Term:</b> Hypercholesterolemia <b>Start Date:</b> UNK/UNK/2012 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Aug-22-2020 15:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

**1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-22-2020 15:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypercholesterolemia	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 15:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2012	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 15:14:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.m**

Date	Location	User	Value	Reason
Aug-22-2020 15:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 13 <b>Medical History Term</b> Type 2 Diabetes : <b>Start Date:</b> UNK/UNK/198 0 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

***I.m Line/MH Number:***

Date	Location	User	Value	Reason
Aug-22-2020 15:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 15:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type 2 Diabetes	Initial Entry

***I.m Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 15:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1980	Initial Entry

***I.m Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 15:14:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***I.n***

Date	Location	User	Value	Reason
Aug-22-2020 15:15:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 14 <b>Medical History Term:</b> atrophy to left hand <b>Start Date:</b> Aug/22/2020 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

***I.n Line/MH Number:***

Date	Location	User	Value	Reason
Aug-22-2020 15:15:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 14	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 15:15:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> atrophy to left hand	Initial Entry

***I.n Start Date:***

Date	Location	User	Value	Reason
Aug-24-2020 06:01:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation
Aug-22-2020 15:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	finding was noted during the physical exam that occurred before the dose.
Aug-22-2020 15:15:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 22/Aug/2020. Please review and update as appropriate.
Aug-22-2020 15:15:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020	Initial Entry

***I.n Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 15:15:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***I.o***

Date	Location	User	Value	Reason
Aug-22-2020 15:16:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b>	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<b>Medical History Term:</b> gangrene on all toes on right foot <b>Start Date:</b> UNK/UNK/2011 <b>Ongoing:</b> NO End Date: UNK/UNK/2011	
--	--	--	---	--

***L.o Line/MH Number:***

Date	Location	User	Value	Reason
Aug-22-2020 15:16:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 15	Initial Entry

***L.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-22-2020 15:16:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> gangrene on all toes on right foot	Initial Entry

***L.o Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 15:16:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

***L.o Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 15:16:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2011	Initial Entry

***L.p***

Date	Location	User	Value	Reason
Aug-22-2020 15:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 16 <b>Medical History Term:</b> gangrene on left big toe <b>Start Date:</b> UNK/UNK/2012	Transcription Error

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

			<b>Ongoing:</b> NO End Date:  UNK/UNK/2020	
Aug-22-2020 15:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 16 <b>Medical History Term:</b> gangrene on left big toe <b>Start Date:</b> UNK/UNK/2020 <b>Ongoing:</b> NO End Date:  UNK/UNK/2020	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

**I.p Line/MH Number:**

Date	Location	User	Value	Reason
Aug-22-2020 15:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 16	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 15:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> gangrene on left big toe	Initial Entry

**I.p Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 15:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-22-2020 15:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2012	Transcription Error
Aug-22-2020 15:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 22/Aug/2020. Please review and update as appropriate.
Aug-22-2020 15:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

**I.p Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 15:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2020	Initial Entry

**I.q**

Date	Location	User	Value	Reason
Aug-22-2020 15:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number: 17</b>	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

			<b>Medical History Term:</b> gangrene on toe left foot	
			<b>Start Date:</b> UNK/UNK/2017	
			<b>Ongoing:</b> NO	
			<b>End Date:</b> UNK/UNK/2017	

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

**I.q Line/MH Number:**

Date	Location	User	Value	Reason
Aug-22-2020 15:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 17	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 15:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> gangrene on toe left foot	Initial Entry

**I.q Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 15:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**I.q Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 15:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2017	Initial Entry

**I.r**

Date	Location	User	Value	Reason
Aug-22-2020 15:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 18 <b>Medical History Term:</b> erectile dysfunction <b>Start Date:</b> UNK/UNK/1985 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

***L.r Line/MH Number:***

Date	Location	User	Value	Reason
Aug-22-2020 15:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 18	Initial Entry

***L.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-22-2020 15:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> erectile dysfunction	Initial Entry

***L.r Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 15:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1985	Initial Entry

***L.r Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 15:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001  
 Visit: V1\_DAY1\_VAX1\_L  
 Form Version: 21-Aug-2020 02:51  
 Site No: 1084  
 Subject No: 10841266  
 Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History  
 Form Status: Data Complete, Locked, Frozen, Verified  
 Site Name: (1084) Clinical Trials of Texas  
 Subject Initials: ---  
 Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-22-2020 14:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-22-2020 14:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 79.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-22-2020 14:50:49 (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
Aug-22-2020 14:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 166.4	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-22-2020 14:50:49 (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
Aug-22-2020 14:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28.5	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Aug-22-2020 14:50:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	<b>Record Identifier::</b> 1 <b>Temperature:</b> 36.2 <b>Temperature Unit:</b> C <b>Temperature Location::</b> ORAL CAVITY
---	--	---------------------	---

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-22-2020 14:50:49 (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
Aug-22-2020 14:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.2	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-22-2020 14:50:49 (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
Aug-22-2020 14:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-22-2020 14:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-22-2020 14:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 237238	Initial Entry

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1084

**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1084) Clinical Trials of Texas

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Aug-22-2020 15:09:31 (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
Aug-22-2020 15:09:31 (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
Aug-22-2020 15:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-22-2020 15:09:31 (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.
Aug-22-2020 15:09:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/22/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-22-2020 15:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPY97P	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-22-2020 15:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPY97P	Initial Entry

Header Text: c4591001  
 Visit: V1\_DAY1\_VAX1\_L  
 Form Version: 22-Apr-2020 21:03  
 Site No: 1084  
 Subject No: 10841266  
 Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
 Audit Trail History  
 Form Status: Data Complete, Locked, Frozen, Verified  
 Site Name: (1084) Clinical Trials of Texas  
 Subject Initials: ---  
 Generated Time (GMT): 29-Mar-2021 10:22

5.b

Date	Location	User	Value	Reason
Aug-22-2020 15:10:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPY97R	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 15:10:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPY97R	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-22-2020 15:10:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPY97S	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 15:10:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPY97S	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-22-2020 15:10:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPFZSH	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 15:10:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPFZSH	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-22-2020 15:11:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPFZSJ	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841266

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

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

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

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

**Subject Initials:** ---

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

**5.e Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-22-2020 15:11:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPFSZJ	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841266**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-22-2020 15:11:14 (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
Aug-22-2020 15:11:14 (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
Aug-22-2020 15:11:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-22-2020 15:11:14 (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.
Aug-22-2020 15:11:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/22/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-22-2020 15:11:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPY96M	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-22-2020 15:11:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPY96M	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-22-2020 14:51:36 (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
Aug-22-2020 14:51:36 (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
Aug-22-2020 14:51:36 (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
Aug-22-2020 14:51:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020 13:51	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-22-2020 14:51:36 (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
Aug-22-2020 14:51:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-22-2020 14:51:36	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-22-2020 14:51:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 14:51:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-22-2020 14:51:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJE CT	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

**I. Date of Visit**

Date	Location	User	Value	Reason
Oct-06-2020 02:48:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site confirmation-no COVID illness visit per PI
Oct-05-2020 14:48:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no COVID illness visit per PI
Oct-03-2020 02:41:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per Illness edairy records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 12SEP2020. But there is no COVID Illness visit reported in the database. Please clarify.
Sep-14-2020 12:13:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Sep-14-2020 12:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-14-2020 12:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.9 <b>Temperature Unit:</b> C <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-14-2020 12:13:38 (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
Sep-14-2020 12:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.9	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-14-2020 12:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-14-2020 12:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841266**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-14-2020 14:12:29 (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
Sep-14-2020 14:12:29 (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
Sep-14-2020 14:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-14-2020 14:12:29 (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.
Sep-14-2020 14:12:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Sep/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-14-2020 14:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPC0H5	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-14-2020 14:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPC0H5	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-14-2020 12:14:05 (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
Sep-14-2020 12:14:05 (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
Sep-14-2020 12:14:05 (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
Sep-14-2020 12:14:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020 11:26	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-14-2020 12:14:05 (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
Sep-14-2020 12:14:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-14-2020 12:14:05	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-14-2020 12:14:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 12:14:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-17-2020 12:22:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query will be moved to the SUBJECT STATUS page.
Nov-13-2020 23:08:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ1: Thank you for the response. Please consider to follow-up and confirm for reported Illness eDiary response on 10 & 31OCT2020. Please update or clarify.
Nov-13-2020 17:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unable to complete visit, subject has not answered calls nor called us back, we will continue trying
Nov-10-2020 08:55:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness eDiary: As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 10 & 31OCT2020. But there is no COVID Illness visit reported in the database.
Oct-12-2020 14:37:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/12/2020	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Oct-12-2020 16:49:40 (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
Oct-12-2020 16:49:40 (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
Oct-12-2020 16:49:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020 16:49:40 (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.
Oct-12-2020 16:49:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/12/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-12-2020 16:49:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BNX5G9	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-12-2020 16:49:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNX5G9	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Oct-12-2020 16:50:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNX5GB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:50:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNX5GB	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-12-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BKSCMK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BKSCMK	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-12-2020 16:50:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BKSCML	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:50:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BKSCML	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-12-2020 16:50:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BKSCMM	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

**5.e Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-12-2020 16:50:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BKSCMM	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/15/2020

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-24-2020 18:20:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/15/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

*I. Assessments*

Date	Location	User	Value	Reason
Sep-24-2020 18:20:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 18:20:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Sep-24-2020 18:20:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/15/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Contact Type:**

Date	Location	User	Value	Reason
Sep-24-2020 18:20:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Sep-24-2020 18:20:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact: Sep/15/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on  
Oct/13/2020

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-13-2020 16:46:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on  
Oct/13/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

*I. Assessments*

Date	Location	User	Value	Reason
Oct-13-2020 16:46:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 16:46:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-13-2020 16:46:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on  
Oct/13/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Contact Type:**

Date	Location	User	Value	Reason
Oct-13-2020 16:46:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Oct-13-2020 16:46:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact: Oct/13/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Nov/04/2020

**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:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

***I. Date of Visit***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-23-2020 03:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Event recorded in AE CRF
Nov-20-2020 04:43:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020459195 sepsis(onset date:11Nov2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Nov-05-2020 10:24:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Nov/04/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

*I. Assessments*

Date	Location	User	Value	Reason
Nov-05-2020 10:26:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 10:25:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Nov-05-2020 10:25:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Nov/04/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Contact Type:**

Date	Location	User	Value	Reason
Nov-05-2020 10:26:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Nov-05-2020 10:26:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO <i>If No, why?</i>  Answering machine full, subject did not answer 2 calls	Initial Entry

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-12-2020 14:37:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/12/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-12-2020 14:37:44 (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
Oct-12-2020 14:37:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-01-2021 20:54:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 15:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-26-2021 15:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/12/2021	Initial Entry
Jan-21-2021 13:04:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please complete Disposition Followup, as subject has died

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-26-2021 15:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-09-2021 17:51:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021 11:58:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	the field will query if you put specify status...correct as is
Feb-04-2021 11:58:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-04-2021 11:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is DEATH but "Specify Status" is Provided.
Jan-27-2021 18:20:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Disposition Follow-up status = 'Death'. Please ensure 'Specify Status' field is populated. Thank you.

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

Jan-26-2021 15:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DEATH	Initial Entry
---	-----------------	---------------------	-----------------------------	---------------

**4. Specify Status:**

Date	Location	User	Value	Reason
Feb-04-2021 11:58:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-04-2021 11:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Death	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-20-2020 16:57:28 (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:** 10841266

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-20-2020 16:59:06 (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:** 10841266

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-20-2020 17:00:16 (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:** 10841266

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-20-2020 17:01:28 (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:** 10841266

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-30-2020 09:46:33 (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:** 10841266

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Dec-03-2020 16:19:18 (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: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-20-2020 16:57:28 (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
Nov-20-2020 16:57:28 (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-01-2021 07:00:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Closed	Response satisfies query
Feb-26-2021 13:28:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Answered	It is unknown because the subject does not have family and the medical records do not indicate an autopsy- one may have been done but we will never no- unknown is more accurate
Feb-26-2021 08:11:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Reissued:Opened	Clinical Thank you; however, the 25Feb 21 SAE update still records Autopsy (in Death details section) as UNKNOWN rather than NONE
Feb-25-2021 13:16:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Answered	SAE report sent
Feb-25-2021 07:14:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Reissued:Opened	Clinical Thank you; please submit this important information to the SAE report
Feb-24-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Answered	No record of transfer for

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

08:24:13 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	wered	autopsy
Feb-10-2021 17:30:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Ope ned	Clinical Please clarify if autopsy performed; with subject discharged to SNF, is there any record of transfer to Medical Examiner or hospital pathology department for an autopsy.
Feb-10-2021 17:19:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Clos ed	no issue / clarified with med writer
Feb-04-2021 16:20:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Ans wered	please indicate which page this is documented on
Feb-02-2021 23:10:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Ope ned	Clinical Please clarify statement in SAE report which reports 'New prescriptions on discharge'
Dec-03-2020 09:09:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Clos ed	Response satisfies query
Dec-02-2020 17:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Ans wered	Per PI NSTEMI is not an SAE
Dec-01-2020 16:20:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Ope ned	CLINICAL SAE narrative reports subject experienced a NSTEMI in Hosp, documented by elevated troponin values; however not recorded on CRF. As NSTEMI occurred after Visit 3, report this event only if Serious.
Dec-01-2020 16:19:22 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clos ed	will reword to include post-visit 3 language (only SAEs are reported)

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

(US & Canada)				
Dec-01-2020 15:26:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	CLINICAL SAE narrative reports that subject experienced a NSTEMI in hospital, documented by elevated troponin values; however to AE / SAE is recorded on the AE log CRF. Please review for safety significance, and update as appropriate.
Dec-01-2020 05:54:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Nov-30-2020 11:03:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Nov-30-2020 09:42:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error
Nov-30-2020 09:42:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Nov-30-2020 09:42:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-30-2020 09:42:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute Emphysematous Cholecystitis	Transcription Error
Nov-25-2020 03:17:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON:AER#2020459195,the term in Safety database was reported separately as 'acute emphysematous cholecystitis' and 'sepsis'.Please verify and consider to split the term in AE

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

				CRF. Also, please provide additional details on sepsis in Safety database.
Nov-23-2020 18:48:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL SAE narrative reports that subject experienced a NSTEMI in hospital, documented by elevated troponin values; however to AE / SAE is recorded on the AE log CRF. Please review for safety significance, and update as appropriate.
Nov-23-2020 18:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-23-2020 15:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Emergency contact inadvertently reported this information which was incorrect, please see SAE follow up reports
Nov-21-2020 17:47:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL SAE narrative states 'Subject was admitted to Hosp for routine surgery, and then became septic). Please submit information on the condition & routine surgery which was planned & prompted admission.
Nov-21-2020 02:47:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term SEPSIS SECONDARY TO ACUTE EMPHYSEMATOUS CHOLECYSTITIS. Split the term into SEPSIS and ACUTE EMPHYSEMATOUS CHOLECYSTITIS and report as 2 separate entries. Thank you.
Nov-20-2020 16:57:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sepsis Secondary to Acute Emphysematous Cholecystitis	Initial Entry

4. Start Date Time:

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Date	Location	User	Value	Reason
Nov-23-2020 18:08:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-23-2020 15:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This has been updated in following reports
Nov-21-2020 17:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Event start date is 03Nov2020; however, SAE report has ??Nov 2020. Please review, harmonize reporting, and update in the appropriate location
Nov-20-2020 16:57:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-28-2021 10:12:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 15:00:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-26-2021 15:00:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Jan/12/2021 UNK:UNK	New Information
Jan-23-2021 15:19:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - SAE is no longer ONGOING, based on FATAL status. Please update 'Is AE still ongoing'?
Nov-20-2020 16:57:28 (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-24-2021 17:17:11 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

(US & Canada)				
Feb-24-2021 08:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-24-2021 08:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	New Information
Feb-09-2021 13:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: please clarify if the toxicity grade for Acute Emphysematous Cholecystitis should be reported as 4 (protocol 10.3.3) LIFE-THREATENING: Life-threatening consequences; urgent intervention indicated).
Nov-20-2020 16:57:28 (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
Feb-25-2021 07:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Feb-24-2021 08:25:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	updated
Feb-10-2021 17:20:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Clinical Serious criteria are HOSP, DEATH and Life-Threatening; however, SAE serious criteria are HOSP and DEATH. Please review, harmonize reporting, and update were applicable.
Feb-01-2021 20:52:31 (UTC-06:00) Central Time	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: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

(US & Canada)		(b) (4), (b) (6)		
Jan-26-2021 15:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Jan-26-2021 15:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>YES</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>YES</p> <p>Other medically important serious event</p> <p>NO</p>	New Information

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-23-2021 09:38:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	Thanks for the response, form has been unfreeze, please update as per below query
Jan-21-2021 15:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Please unfreeze
Jan-21-2021 13:03:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL SAE report states that subject died from progression of this disease condition; please review Serious criteria for DEATH option, and update as appropriate
Jan-21-2021 13:03:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Candidate	CLINICAL SAE report states that subject died from progression of this disease condition; please review Serious criteria for DEATH option, and update as appropriate
Dec-02-2020 18:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-02-2020 17:28:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Acute emphysematous cholecystitis required hospitalization and sepsis prolonged hospitalization
Nov-23-2020 18:40:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL Serious criterion is reported as required or prolonged hospitalization, and in SAE report the box for 'Prolonged Hospitalization' is

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

				checked. Please clarify which event required Hosp initially, and which event prolonged Hosp
Nov-23-2020 18:07:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-23-2020 14:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	It was reported under relevant tests
Nov-23-2020 03:40:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-21-2020 17:38:11 (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 [#2020459195] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Nov-20-2020 16:57:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Sepsis Secondary to Acute Emphysematous Cholecystitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-20-2020 16:57:28 (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 result in death?  NO  Did this serious event require or prolong hospitalization?  YES	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
--	--	--	--	--

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

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

Date	Location	User	Value	Reason
Nov-20-2020 16:57:28 (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
Nov-20-2020 16:57:28 (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  If Other, specify:  bacteria	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-20-2020 16:57:28 (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
Dec-03-2020 13:14:48 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

(US & Canada)		(b) (4), (b) (6)		
Dec-03-2020 11:22:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	These have been added
Nov-23-2020 18:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical SAE report states subject received non-study vaccinations in Hosp (Pneumococcal, Influenza); please report these on the non-study VAX log CRF
Nov-20-2020 16:57:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-09-2020 10:51:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-07-2020 14:53:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please see fup report sent today
Dec-06-2020 10:29:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - please submit a SAE safety update with the date on which the gall bladder drain was inserted; also if in ICU or not.
Nov-20-2020 16:57:28 (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
Jan-26-2021 23:25:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Jan-26-2021 15:01:52	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Ans	updated

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

(UTC-06:00) Central Time (US & Canada)			wered	
Jan-25-2021 02:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 4: Op ened	DMW6961672;The outcome of this AE is selected as FATAL, but there are no Disposition eCRFs with a 'Status' of DEATH. Please review and update as appropriate.
Jan-23-2021 15:19:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clo sed	Event was Fatal & SAE updated
Jan-23-2021 15:19:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Event was Fatal
Jan-23-2021 15:18:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Event was Fatal
Jan-22-2021 15:18:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Op ened	Response to "What was the outcome of this adverse event?" is 'Fatal' but Date of Collection / Notification of Death on the Death Details form is not completed. Please review and update as appropriate.
Jan-22-2021 15:18:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Op ened	For AE Acute Emphysematous Cholecystitis: Response to "What was the outcome of this adverse event?" is 'Fatal' but "Is the adverse event still ongoing?" is marked 'Yes'.
Jan-22-2021 15:18:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	New Information
Jan-22-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data</b>	New Information

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

15:18:30 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	<u>Entry</u> : FATA L	
Jan-22-2021 11:51:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	Page is Unfrozen.
Jan-21-2021 15:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	please unfreeze
Jan-20-2021 01:50:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Op ened	SAE RECON:AER#2020459195,outcome was reported as FATAL to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-20-2020 16:57:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : RECO VERI NG/R ESOL VING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 16:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-02-2021 16:26:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-02-2021 12:03:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	both AEs did cause subject to be discontinued

090177e196ae3f84\Final\On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1084**Subject No:** 10841266**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1084) Clinical Trials of Texas**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

Mar-02-2021 12:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'.
Mar-02-2021 12:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Mar-02-2021 12:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Changed Information
Feb-26-2021 14:59:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: 'Did the adverse event cause the subject to be discontinued from the study?' is NO, however, Outcome is recorded as FATAL. Please note: both "Sepsis" and "Acute emphysematous cholecystitis" are reported as cause of death on death details.
Feb-04-2021 22:52:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021 16:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Sepsis was the cause of death
Jan-27-2021 00:09:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM : Response to 'Did the adverse event cause the subject to be discontinued from the study?' is recorded as NO. However, Outcome is recorded as FATAL. Please review and update. Else, clarify.
Jan-26-2021 15:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Answer is no per PI
Jan-25-2021 02:51:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Outcome is reported as 'Fatal'; however, "Did the event cause the subject to be

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

				discontinued from the study" is not YES. Please review and update the CRF Appropriately.
--	--	--	--	--

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-20-2020 16:57:28 (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
Nov-23-2020 03:40:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020459195	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-20-2020 16:59:06 (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
Nov-20-2020 16:59:06 (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
Dec-06-2020 10:20:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-06-2020 10:18:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-03-2020 16:20:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	An SAE FUP has been sent today.
Dec-03-2020 16:19:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	this has been added
Nov-23-2020 18:56:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical On review of the SAE report for Sepsis, an event of Lt lower extremity weakness as the admitting complain was mentioned, yet it does not appear in the CRF. Please review for safety and update AE log CRF accordingly.
Nov-21-2020 19:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - please add clinical course of event Rhabdomyolysis to SAE, including laboratory values and

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

				basis for dehydration sufficient to cause Rhabdo
Nov-20-2020 16:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Rhabdomolysis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-18-2021 12:11:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	date clarified
Feb-18-2021 12:02:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	Clinical - Start date is 02Nov2020; please confirm this diagnosis was made 1 day prior to the start of the associated clinical events
Nov-20-2020 16:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/2/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-20-2020 16:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Nov/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-20-2020 16:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Nov-20-2020 16:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
---	-----------------	---------------------	--------------------------	---------------

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

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

Date	Location	User	Value	Reason
Nov-20-2020 16:59:06 (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
Dec-17-2020 09:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-07-2020 14:54:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please see fup report sent today
Dec-06-2020 10:23:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINICAL Thank you. SAE update does not report dehydration; it includes electrolyte imbalance / hyponatremia. Please update SAE with this condition, as the cause for rhabdomyolysis
Dec-03-2020 16:20:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	An SAE FUP has been sent today.
Nov-23-2020 18:53:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - Rhabdomyolysis reported due to dehydration; however, dehydration is not reported in the SAE narrative. Please review and submit documentation for this basis for rhabdomyolysis.
Nov-20-2020 16:59:06 (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:	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			OTHER <i>If Other, specify:</i>  dehydration	
--	--	--	---	--

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-20-2020 16:59:06 (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
Nov-20-2020 16:59:06 (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
Nov-20-2020 16:59:06 (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
Nov-20-2020 16:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 16:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1084**Subject No:** 10841266**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1084) Clinical Trials of Texas**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Nov-20-2020 17:00:16 (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
Nov-20-2020 17:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:***(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-06-2020 10:39:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-03-2020 16:20:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	An SAE FUP has been sent today.
Nov-21-2020 19:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Please submit clinical course of event Atrial Fibrillation with RVR to SAE report, including ECG reading and any imaging or other evaluation
Nov-20-2020 17:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Atrial Fibrillation with RVR	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-20-2020 17:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/3/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Feb-02-2021 23:09:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	subject died on 12Jan21
Jan-26-2021 15:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Nov-20-2020 17:00:16 (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
Nov-20-2020 17:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

Date	Location	User	Value	Reason
Nov-20-2020 17:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-20-2020 17:00:16 (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
Dec-06-2020 10:38:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-03-2020 16:20:41 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	An SAE FUP has been sent today.

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

(US & Canada)		(b) (4), (b) (6)		
Nov-21-2020 17:44:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - Event of A fib is related to CAD; however, SAE report does not include any cardiovascular Med Hx. Med Hx CRF reports HTN, CHF and s/p CABG (no details); please submit CV medical Hx as a SAE safety update
Nov-20-2020 17:00:16 (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), th is event is due to:  OTHER  If Other, specify:  CAD	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-20-2020 17:00:16 (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
Nov-20-2020 17:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-20-2020 17:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 17:00:16 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

(US & Canada)

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

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

Date	Location	User	Value	Reason
Nov-20-2020 17:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-20-2020 17:01:28 (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
Nov-20-2020 17:01:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-06-2020 10:38:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-03-2020 16:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	An SAE FUP has been sent today.
Nov-21-2020 19:11:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - please submit clinical course for event Acute kidney injury to SAE, including blood/urine laboratory values, and any imaging or other evaluation
Nov-20-2020 17:01:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute Kidney Injury	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-20-2020 17:01:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/3/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

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

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Feb-02-2021 23:09:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	subject died on 12Jan21
Jan-26-2021 15:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Nov-20-2020 17:01:28 (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
Nov-20-2020 17:01:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

Date	Location	User	Value	Reason
Nov-20-2020 17:01:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-20-2020 17:01:28 (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
Nov-20-2020 17:01:28 (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:	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			OTHER <i>If Other, specify:</i>  Dehydration	
--	--	--	---	--

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-20-2020 17:01:28 (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
Nov-20-2020 17:01:28 (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
Nov-20-2020 17:01:28 (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
Nov-20-2020 17:01:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 17:01:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-30-2020 09:46:33 (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
Nov-30-2020 09:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-01-2021 06:59:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Query closed; will follow for requested Clinical course information.
Feb-25-2021 13:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	SAE follow up sent
Feb-10-2021 17:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	Clinical Thank you, please submit to SAE
Feb-04-2021 16:45:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Do you want and SAE follow up report for this or is there somewhere in EDC you want this entered
Feb-02-2021 23:08:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical For information on intensity of required care, please submit to SAE the days receiving norepinephrine, days intubated, days on ICU and days receiving Zosyn. thank you
Dec-09-2020 10:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1084**Subject No:** 10841266**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1084) Clinical Trials of Texas**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

Dec-09-2020 10:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-09-2020 10:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-07-2020 14:55:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please see fup report sent today
Dec-07-2020 14:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	please see fup report sent today
Dec-07-2020 14:54:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	please see fup report sent today
Dec-06-2020 10:37:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL For SAE of sepsis based on cholecystitis, please update SAE with results of cultures from blood and gall bladder drainage
Dec-06-2020 10:35:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL SAE report states subject experienced Hyperglycemia; please update SAE with blood glucose results.
Dec-06-2020 10:32:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL SAE report lists medication in hospital included norepinephrine. Please update SAE with dates of pressor use; also BP values when admitted and during hospital stay
Nov-30-2020 09:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sepsis	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-30-2020 09:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/3/2020 UNK:UNK	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 17:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-24-2021 08:26:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Feb-24-2021 08:26:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Jan/12/2021 UNK:UNK	New Information
Feb-17-2021 16:52:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: please clarify if the stop date for Sepsis should be reported as 12Jan2021 to align with the date of death (12/Jan/2021) on the disposition follow up and the primary cause of death of Sepsis.
Feb-02-2021 23:08:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	subject died on 12Jan21
Jan-26-2021 15:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Nov-30-2020 09:46:33 (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-24-2021 17:23:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-24-2021 08:27:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Feb-24-2021 08:27:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	New Information
Feb-09-2021 13:46:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: please clarify if the toxicity grade for Sepsis should be reported as 4 (protocol 10.3.3 LIFE-THREATENING: Life-threatening consequences; urgent intervention indicated).
Nov-30-2020 09:46:33 (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
Feb-26-2021 14:48:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-26-2021 13:24:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	oops, sorry!
Feb-26-2021 13:24:08 (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 result in death?  YES Did this serious event require or prolong hospitalization?  YES Did this serious event result in persistent or significant disability/incapacity?	oops, sorry!

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			y? NO Is this serious event life threatening? NO Other medically important serious event NO	
Feb-25-2021 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	CLINQUERY: please clarify if 'Did this serious event result in death?' should be updated to YES for the AE of Sepsis. The response indicates "updated" but the question is still answered as NO.
Feb-25-2021 13:17:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	updated
Feb-25-2021 07:10:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-24-2021 17:28:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY: please clarify if 'Did this serious event result in death?' should be updated to YES for the AE of Sepsis.
Feb-24-2021 08:27:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated
Feb-10-2021 17:19:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Serious criterion is HOSP; however, SAE serious criteria are HOSP and DEATH. Please review, harmonize reporting, and update were applicable.
Dec-01-2020 13:42:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with	Transcription Error

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			congenital anomaly or birth defect?  NO  Did this serious event result in death ?  NO  Did this serious event require or prolonged 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	
Dec-01-2020 05:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-30-2020 09:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Sepsis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-30-2020 09:46:33 (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 result in death ?  YES  Did this serious event require or prolonged hospitalization?	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			<p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
--	--	--	---	--

**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-01-2021 01:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-26-2021 13:25:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-26-2021 13:25:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Feb-26-2021 08:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: Response to question "Is this adverse event the result of a study Medication Error" is YES, however corresponding detail on MEDICATION ERROR FORM is missing. Please update the data else clarify.
Feb-25-2021 13:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	New Information
Nov-30-2020 09:46:33 (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:**

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Jan-27-2021 03:49:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Closed	Response satisfies query

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-26-2021 15:09:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	correct as is
Jan-26-2021 08:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 3: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Oxytoca,Escherichia coli,pneumonia]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)
Jan-01-2021 14:53:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-28-2020 13:48:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Dec-28-2020 13:48:38 (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>  Klebsiella	Changed Information

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			Oxytoca, Escherichia coli, Klebsiella pneumonia	
Dec-09-2020 10:57:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL per SAE report, causative 'bacteria' identified as "Klebsiella Oxytoca, Escherichia coli, Klebsiella pneumonia". Please update the Other cause with this specific information.
Dec-02-2020 18:39:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-02-2020 17:23:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Acute emphysematous cholecystitis indicates the presence of bacteria, without the bacteria it would be acute cholecystitis
Dec-01-2020 16:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - Other cause for event SEPSIS is bacteria; however, SAE event report states Sepsis secondary to acute emphysematous cholecystitis. Please review, harmonize reporting, and update in the appropriate location.
Nov-30-2020 09:49:22 (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, sp</i>	Transcription Error

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

			ecify: bacteria	
Nov-30-2020 09:48:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATE D If Not Related to study treat ment(s), this e vent is due to:  OTHER	Transcription Error
Nov-30-2020 09:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATE D	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-30-2020 09:48:49 (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
Nov-30-2020 09:48:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-30-2020 09:48:49 (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-24-2021 14:19:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-24-2021 08:26:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Feb-24-2021 08:14:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Sepsis: Response to "What was the outcome of this adverse event?" is 'Fatal' but "Is the adverse event still ongoing?" is marked 'Yes'.
Feb-24-2021 08:14:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-24-2021 08:14:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATAL	New Information
Feb-10-2021 00:24:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020459195 ,outcome was reported as FATAL to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-30-2020 09:48:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 04:38:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-24-2021 08:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated
Feb-09-2021 10:37:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: "Did the event cause the Subject to be Discontinued from the Study" is marked as YES however AE outcome is not FATAL. Please verify and update else clarify further. Thank you.
Feb-09-2021 08:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Feb-08-2021 11:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-08-2021 11:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Transcription Error
Feb-04-2021 22:52:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM : Response to 'Did the adverse event cause the subject to be discontinued from the study?' is recorded as NO. However, Outcome is recorded as FATAL. Please review and update. Else, clarify.
Nov-30-2020 09:48:49 (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
Dec-01-2020 05:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020459195	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Dec-03-2020 16:19:18 (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
Dec-03-2020 16:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-03-2020 16:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Left lower extremity weakness	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-03-2020 16:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/28/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-02-2021 23:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	subject died on 12Jan21
Jan-26-2021 15:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Dec-03-2020 16:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

Date	Location	User	Value	Reason
Dec-03-2020 16:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-03-2020 16:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-03-2020 16:19:18 (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
Dec-09-2020 11:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-07-2020 14:55:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please see fup report sent today
Dec-06-2020 10:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - please review other etiology/etiologies for potential contribution of rhabdomyolysis
Dec-03-2020 16:19:18 (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  If Other, specify:	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

sepsis

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-03-2020 16:19:18 (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
Dec-03-2020 16:19:18 (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
Dec-03-2020 16:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-03-2020 16:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-03-2020 16:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

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

**Form Status:**

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Dec-03-2020 11:18:54 (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 21:03

**Site No:** 1084

**Subject No:** 10841266

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

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

**Form Status:**

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Dec-03-2020 11:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1084  
**Subject No:** 10841266  
**Generated By:** (b) (4)

**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. What is the medication identifier?**

Date	Location	User	Value	Reason
Dec-03-2020 11:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Dec-03-2020 11:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Dec-03-2020 11:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Dec-03-2020 20:48:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Dec-03-2020 16:21:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 16:21:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> INFLUENZA VIRUS VACCINE QUAD RIVALENT 240 MCG IM	Transcription Error
Dec-03-2020 14:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify INFLUENZA VIRUS VACCINE QUADRIVAL 240 MCG IM as

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1084  
**Subject No:** 10841266  
**Generated By:** (b) (4)

**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1084) Clinical Trials of Texas  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:22

Canada)				follows...The term appears incomplete. If reporting INFLUENZA VIRUS VACCINE QUADRIVALENT 240 MCG IM update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you.
Dec-03-2020 11:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Influenza Virus Vaccine Quadrivalent 240 mcg IM	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Dec-03-2020 11:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Dec-03-2020 11:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Dec-03-2020 11:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Dec-03-2020 11:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Dec-03-2020 11:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pneumococcal Polysaccharide Vaccine 0.5mL IM	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Dec-03-2020 11:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

[Back to Form](#)

**I. Date of Visit**

Date	Location	User	Value	Reason
Mar-09-2021 05:50:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Deleted	Query is invalid or does not apply
Mar-08-2021 04:31:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Mar-05-2021 09:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Radio button Erroneous was ticked per query
Mar-05-2021 09:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-05-2021 09:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Since the unblinding occurred after the death this data should not be within the CRF and kept in source only. Please tick the ERRONEOUS visit else clarify
Mar-05-2021 09:17:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	reword
Mar-04-2021 16:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 4: Opened	DMW7601776; 'Date of Visit' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001**Visit:** Potential ReVax Initial Contact - Unscheduled**Form:** DATE OF VISIT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1084**Site Name:** (1084) Clinical Trials of Texas**Subject No:** 10841266**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22

Mar-04-2021 14:15:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	duplicate query
Mar-04-2021 11:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Answer Auto Query
Mar-02-2021 13:37:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Form is unfroze. Please mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-02-2021 12:06:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	form level comment added, unable to remove data
Mar-01-2021 05:03:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-28-2021 23:42:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-26-2021 13:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	erroneous is ticked, unable to add form level comment-please unfreeze
Feb-26-2021 13:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.

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: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

Feb-26-2021 07:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Please tick the erroneous visit button and mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-25-2021 13:53:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	this should be deemed an erroneous visit due to the subject passing before the unblinding.
Feb-25-2021 01:09:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	The query does not ask to change the date of unblinding. This query is for the DOV for REVAX CONT, wherein the DOV cannot be after the Date of discontinuation/death. Hence, please update this date to be before or same as date of discontinuation/death.
Feb-24-2021 11:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	do you want us to inaccurately change the date of unblinding- this information is correct, changing the date would be incorrect
Feb-14-2021 23:20:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Page unfreeze kindly consider updating data as appropriate. Thank you.
Feb-12-2021 12:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	please unfreeze form
Feb-11-2021 20:15:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: If subject did not continue on the study after date at FUP, please remove post-FUP data from Inform and keep it in the source only.
Feb-09-2021 11:52:37 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	correct this is the date subject was unblinded; subject was unblinded after death- not sure how else to

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				answer this
Feb-09-2021 02:15:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM : Date of visit (15/Jan/2021) is after the Date of Completion/Discontinuation/Death (12/Jan/2021). Please review and update or clarify. Kindly contact CRA for further assistance.
Feb-08-2021 11:10:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	same date as disp not after?
Feb-05-2021 06:35:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Thank you, please note that there cannot be a date that is after the date of disposition follow-up. Please update as appropriate
Feb-04-2021 22:36:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021 11:58:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	unblinded after death; correct as is
Feb-04-2021 11:58:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unblinded after death; correct as is
Feb-03-2021 06:57:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Date of Visit (15/Jan/2021) is after the Date of Completion/Discontinuation/Death (12/Jan/2021) on the Follow-Up Disposition form. Please review and update as appropriate.
Feb-03-2021 02:48:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7129630;'Date of Visit' is after 'Date of Completion/Discontinuation/Death' on the Disposition - Follow-up eCRF. Please clarify or correct.

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

Feb-02-2021 18:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swered	Original value is correct
Feb-02-2021 18:25:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Op ened	Date of Visit is after the Date of Completion/Discontinuation /Death on the Follow-Up Disposition form. Please review and update as appropriate.
Feb-02-2021 18:25:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/15/2021	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Mar-05-2021 09:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry
Mar-04-2021 11:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 13:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Mar-08-2021 16:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Mar-05-2021 08:58:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-05-2021 08:58:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	.
Mar-05-2021 08:58:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	.
Mar-04-2021 12:12:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Per prior query responses, please replace the 'erroneous' entry on the DOV page, and using the comment (speech bubble) option, apply a Not Applicable comment at form level to this page
Mar-04-2021 11:34:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no option to mark page as NOT APPLICABLE
Mar-02-2021 14:19:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Via the form level comment section, please check the page as being NOT APPLICABLE
Mar-02-2021 12:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	form level comment added, unable to remove data
Mar-01-2021 00:27:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: DOV page has been marked as 'erroneous' but data remains on this page. To match, please add form level comment of Not Applicable to close the page

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

Feb-27-2021 15:05:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candidate	CLINQUERY: DOV page has been marked as 'erroneous' but data remains on this page. To match, please add form level comment of Not Applicable to close the page
Feb-02-2021 18:25:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1084

Subject No: 10841266

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1084) Clinical Trials of Texas

Subject Initials: ---

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

[Back to Form](#)

**I. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Mar-03-2021 02:01:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-02-2021 17:18:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-02-2021 17:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	.
Mar-02-2021 17:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	.
Mar-02-2021 14:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: If dates are confirmed to be correct, please remove all the data from this page and provide form level comment as "Not Applicable". Else clarify.
Mar-02-2021 12:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Form level comment added, unable to remove data
Feb-27-2021 11:18:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 2: Opened	P21 Review: Date Treatment Unblinded (15Jan2021) is after Disposition - Follow-Up date (12Jan2021). If dates are confirmed to be correct, please remove all the data from this page and provide form level comment as "Not Applicable". Else clarify.
Feb-04-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

23:53:25 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	sed	
Feb-04-2021 12:41:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject unblinded after death
Feb-03-2021 02:51:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7129631; 'Date Treatment Unblinded' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Feb-02-2021 18:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/15/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-03-2021 03:53:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Closed per data updated.
Mar-02-2021 17:18:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-02-2021 17:18:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	.
Mar-02-2021 12:00:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Other is correct, inform is correct, please advise on IRT change
Mar-01-2021 05:15:16 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	IVRS Reconciliation: Other is selected as the primary reason for

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001**Visit:** Disposition - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1084**Subject No:** 10841266**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

Central Time (US & Canada)				unblinding but matching blind break is not captured in IRT. Please correct primary reason in Inform or confirm as correct".
Feb-27-2021 15:06:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	P21 query raised - unblind post Disp FUP
Feb-24-2021 15:42:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_DS001_35
Feb-24-2021 11:39:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-24-2021 11:39:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-24-2021 11:39:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER <i>If other, specify:</i>  Subject passed away on 12Jan2021 per sponsor unblinding due to concerns of death.	Transcription Error
Feb-22-2021 11:19:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7349921;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.

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

**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

				Please review and update as appropriate.
Feb-15-2021 22:51:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Open ed	CLINQUERY: Subject reported as deceased 12Jan21. Please clarify if treatment unblind was performed for this subject, as reported. If so, why was treatment unblind performed on the 15Jan21?
Feb-15-2021 17:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candi date	CLINQUERY: Subject reported as deceased 12Jan21. Please clarify if treatment unblind was performed for this subject, as reported. If so, why was treatment unblind performed on the 15Jan21?
Feb-02-2021 18:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**I. Date of Collection / Notification of Death:**

Date	Location	User	Value	Reason
Feb-09-2021 18:36:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-09-2021 03:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Closed	Response satisfies query
Feb-08-2021 14:23:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated
Feb-08-2021 14:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is correct, the patient died on 12Jan21 and site was notified of death on 15Jan21
Feb-04-2021 22:29:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM : Date of Completion/Discontinuation /Death (12/Jan/2021) is prior to Date of Collection / Notification of Death (15/Jan/2021). Please review and update. Else, clarify.
Feb-04-2021 19:35:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	CRC contacted subject to unblind, emergency contact informed the CRC of the subjects death on 12JAN2021.
Jan-27-2021 19:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	ClinQuery: Kindly update cause of death information on Death Details form. Thank you.
Jan-26-2021 15:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 12/Jan/2021. Please review and update as appropriate
Jan-26-2021 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/15/2021	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

2.a

Date	Location	User	Value	Reason
Feb-08-2021 14:22:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Cause of Death</b> PRIMARY CAUSE O <b>Status:</b> F DEATH <b>Cause of Death:</b> Sepsis	Initial Entry

2.a Cause of Death Status:

Date	Location	User	Value	Reason
Feb-08-2021 14:22:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CAUSE OF DEATH	Initial Entry

2.a Cause of Death:

Date	Location	User	Value	Reason
Feb-08-2021 14:22:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sepsis	Initial Entry

2.b

Date	Location	User	Value	Reason
Feb-08-2021 14:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Cause of Death</b> SECONDARY CAUSE <b>Status:</b> OF DEATH <b>Cause of Death</b> Acute emphysematous : cholecystitis	Initial Entry

2.b Cause of Death Status:

Date	Location	User	Value	Reason
Feb-08-2021 14:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SECONDARY CAUSE OF DEATH	Initial Entry

2.b Cause of Death:

Date	Location	User	Value	Reason
Feb-08-2021 14:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute emphysematous cholecystitis	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1084

Site Name: (1084) Clinical Trials of Texas

Subject No: 10841266

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**I. Subject Status**

Date	Location	User	Value	Reason
Jan-26-2021 15:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Dec-08-2020 00:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-07-2020 14:56:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	not done due to SAE
Nov-23-2020 18:58:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-23-2020 15:03:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	it has been entered
Nov-20-2020 11:06:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL SAE report (#2020459195) for event Sepsis received; however, no entry has been made on the adverse event log CRF. Please update.
Nov-20-2020 07:10:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please consider to follow-up and confirm for reported Illness eDiary response on 10 & 31OCT2020. Please update or clarify.
Nov-17-2020 12:23:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 1: Candidate	Please consider to follow-up and confirm for reported Illness eDiary response on 10 & 31OCT2020. Please update or clarify.
Oct-12-2020 14:37:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-22-2020 14:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1084

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

**Subject No:** 10841266

**Subject Initials:** ---

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

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

Aug-22-2020 14:48:05 (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
Jan-26-2021 15:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/12/2021	Initial Entry
Oct-12-2020 14:37:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/12/2020	Initial Entry
Aug-22-2020 14:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/22/2020	Initial Entry
Aug-22-2020 14:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/22/2020	Initial Entry

090177e196ae3f84\Final\Final On: 01-Apr-2021 05:18 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1084

**Subject No:** 10841266

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

**I. Casebook Signature**

Date	Location	User	Value	Reason
Oct-20-2020 15:23:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry