

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: C4591001
Visit: COHORT_SELECTION **Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1174 **Site Name:** (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject No: 11741042 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/9/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11741042]
2.	Birth Date:	(b) (6)/1949
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Sep/16/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
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Exclusion Criteria Met

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

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/9/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypothyroidism]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypercholesterolaemia]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[left inguinal Hernia repair]
	Start Date:	Aug/UNK/2019
	Ongoing:	NO End Date: Aug/UNK/2019

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hemorrhoidectomy]
	Start Date:	Jul/UNK/2020
	Ongoing:	NO End Date: Jul/UNK/2020
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Microdiscectomy Lumbar spine]
	Start Date:	UNK/UNK/1980
	Ongoing:	NO End Date: UNK/UNK/1980
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Microdiscectomy Lumbar spine]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hemorrhoid]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: Jul/UNK/2020

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Herniated disc L4-L5]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Lumbar radiculopathy]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[nephrolithiasis]
	Start Date:	UNK/UNK/2008
	Ongoing:	NO End Date: UNK/UNK/2008

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/16/2020	
2.	Weight:	Not Done _____	Comments
		[]	
3.	Unit:	Not Done _____	Comments
4.	Height:	Not Done _____	Comments
		[]	
5.	Unit:	Not Done _____	Comments
6.	Body Mass Index:	[]	

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.4]
	Unit:	F
	Temperature Location:	EAR

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: RANDOMIZATION
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Sep/16/2020
2.	Randomization Number:	[256899]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYGR3]
5.b	Sample ID	[BL9WLD]
5.c	Sample ID	[BL9WLF]
5.d	Sample ID	[BL9WLG]

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYGR4]
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090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Sep/9/2020 Reason(s) for Temporary Delay of Vaccination RECENT NON-STUDY VACCINATION
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/16/2020 08:53
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001	Form: REACTOGENICITY DIARY
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 06-Jul-2020 21:53	Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Site No: 1174	Subject Initials: ---
Subject No: 11741042	Generated Time (GMT): 29-Mar-2021 12:55
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/6/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/6/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	EAR

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/6/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYGTP]
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090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/6/2020 09:57
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/5/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/5/2020
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	[BPYGX7]
5.b	Sample ID	[BSGGD3]
5.c	Sample ID	[BSGGD4]
5.d	Sample ID	[BSGGD5]

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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:	[]
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090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/16/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit

	Date of Visit		Comments
1.	Date of Visit	Sep/16/2020	
2.	Erroneous Visit	ERRONEOUS VISIT	

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[Form Comments](#)

[eCRF Audit Trail History](#)

Unplanned Assessments

Unplanned Assessments			
1.	Assessments	Not Applicable	Comments

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Contact Outcome

1.	Contact Type:	Not Applicable _____	Comments
2.	Was contact made?	Not Applicable _____	Comments
3.	Comments:	Not Applicable _____ []	Comments

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/16/2020

Form: VITAL SIGNS - TEMP

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Vital Signs

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

2.a	Record Identifier:	Not Applicable _____ 1	
	Temperature:	Not Applicable _____ []	Comments
	Unit:	Not Applicable _____	Comments
	Temperature Location:	Not Applicable _____	Comments

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form Version: 15-Sep-2020 21:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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

Unplanned Assessment Of Local Reaction

1.	Date of Assessment:	Not Applicable //	Comments
2.	Injection Site Location	Not Applicable	Comments
3.	Injection Site Body Side:	Not Applicable	Comments

Reaction

4.a	Reaction:	REDNESS	
	Reaction Present:	Not Applicable	Comments
4.b	Reaction:	SWELLING	
	Reaction Present:	Not Applicable	Comments

Symptom

5.a	Symptom:	PAIN AT INJECTION SITE	
	Symptom Present:	Not Applicable	Comments
5.b	Symptom:	FATIGUE/TIREDNESS	
	Symptom Present:	Not Applicable	Comments
5.c	Symptom:	HEADACHE	
	Symptom Present:	Not Applicable	Comments
5.d	Symptom:	VOMITING	
	Symptom Present:	Not Applicable	Comments

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form Version: 15-Sep-2020 21:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

5.e	Symptom:	DIARRHEA	
	Symptom Present:	Not Applicable	Comments
5.f	Symptom:	NEW OR WORSENERD MUSCLE PAIN	
	Symptom Present:	Not Applicable	Comments
5.g	Symptom:	NEW OR WORSENERD JOINT PAIN	
	Symptom Present:	Not Applicable	Comments
5.h	Symptom:	CHILLS	
	Symptom Present:	Not Applicable	Comments

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/5/2020
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: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Disposition - Follow-Up

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	nephrolithiasis	Oct/2/2020 UNK:UNK	NO End Date Time: Oct/6/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Hydronephrosis	Oct/2/2020 UNK:UNK	NO End Date Time: Oct/6/2020 UNK:UNK	Repeating Pages

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Adverse Event Report

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

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020389747]

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Hydronephrosis]
4.	Start Date Time:	Oct/2/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/6/2020 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: [Nephrolithiasis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[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	[]

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	influenza vaccine	Sep/2/2020	Repeating Pages

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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[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 vaccine]
5.	Date:	Sep/2/2020

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Concomitant Medications

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

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Radiation Treatment

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

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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: 1174 **Site Name:** (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject No: 11741042 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 12:55

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?	

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Contact Outcome

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

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/6/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/6/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Withdrawal Of Consent

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/5/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Donald Poretz	Approved	Jan-27-2021 19:11:36 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, Donald Poretz, 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.

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Sep-09-2020 16:06:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:51
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Sep-29-2020 14:16:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:51
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
3	Sep-29-2020 14:17:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:51
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
4	Sep-29-2020 14:19:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:51
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5	Sep-29-2020 14:19:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: C4591001
Visit: Unplanned 1
Form Version: 22-Apr-2020 21:02
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: DATE OF VISIT - Comments
Form Status: Data Complete, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Sep-30-2020 16:53:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Date cannot be deleted

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/16/2020

Form: UNPLANNED VISIT - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Dec-14-2020 09:15:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001
Visit: Unplanned 1
Form Version: 22-Apr-2020 21:04
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: UNPLANNED VISIT - Comments
Form Status: Data Complete, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Dec-14-2020 09:15:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Dec-14-2020 09:16:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Dec-14-2020 09:16:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Dec-14-2020 09:16:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
3	Dec-14-2020 09:16:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/16/2020

Form: VITAL SIGNS - TEMP - Comments

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Dec-14-2020 09:16:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001
Visit: Unplanned 1
Form Version: 15-Sep-2020 21:54
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments
Form Status: Data Complete, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Dec-14-2020 09:16:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001
Visit: Unplanned 1
Form Version: 15-Sep-2020 21:54
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments
Form Status: Data Complete, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
2.a	Dec-14-2020 09:16:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001
Visit: Unplanned 1
Form Version: 15-Sep-2020 21:54
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments
Form Status: Data Complete, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
2.a	Dec-14-2020 09:16:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001
Visit: Unplanned 1
Form Version: 15-Sep-2020 21:54
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments
Form Status: Data Complete, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
2.a	Dec-14-2020 09:16:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form Version: 15-Sep-2020 21:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
Form	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
1	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
3	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
4.a	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
4.b	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.a	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.b	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
5.c	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.d	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.e	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.f	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.g	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Item	Date	User	Comment
5.h	Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Donald Poretz	Approved	Jan-27-2021 19:11:36 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Dec-14-2020 09:15:49 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Donald Poretz	Approved	Nov-13-2020 17:55:35 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, DonaldPoretz, 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.

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-09-2020 16:03:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:03:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-30-2020 02:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-29-2020 14:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	consent date is correct, but there were a temporary delay due to proper vaccine
Sep-29-2020 14:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Sep-09-2020 16:03:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/9/2020	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Subject ID

Date	Location	User	Value	Reason
Sep-09-2020 16:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 11741042	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-09-2020 16:03:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6)/1949	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-12-2020 01:02:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated.
Sep-11-2020 15:17:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-11-2020 15:17:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> MALE	Transcription Error
Sep-11-2020 12:11:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	As per Impala, Sex is recorded as Male. Please review and update as appropriate. (b) (4)

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Sep-09-2020 16:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry
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4. Ethnicity:

Date	Location	User	Value	Reason
Sep-09-2020 16:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 16:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-29-2020 14:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Transcription Error
Sep-29-2020 14:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Transcription Error
Sep-17-2020 02:56:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-16-2020 09:02:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-15-2020 10:13:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly complete the VACIN TRT form to avoid yellow traffic light. Thank you.
Sep-09-2020 16:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-09-2020 16:07:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-09-2020 16:07:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-09-2020 16:07:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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I.a

Date	Location	User	Value	Reason
Sep-16-2020 09:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: hypertension Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 09:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 09:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypertension	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 09:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 09:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
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090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Sep-16-2020 09:15:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Ter hypothyroidis m: m Start Date: UNK/UNK/20 05 Ongoing: YES	Initial Entry
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I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 09:15:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 09:15:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypothyroidism	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 09:15:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 09:15:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-16-2020 11:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Num 3 er: Medical History hypercholester Term: laemia	Transcription Error

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

			Start Date: UNK/UNK/2005 Ongoing: YES	
Sep-16-2020 09:17:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: hypercholesterol aemia Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 09:17:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 12:26:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-16-2020 11:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-16-2020 11:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: : hypercholesterolemia	Transcription Error
Sep-16-2020 10:56:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify HYPERCHOLESTROLAEMIA as follows...Should the spelling be HYPERCHOLESTEROLAEMIA? If so, edit. Otherwise clarify. Thank you.
Sep-16-2020 09:17:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: : hypercholesterolemia	Initial Entry

I.c Start Date:

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Sep-16-2020 09:17:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 09:17:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-16-2020 09:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History: left inguinal Hernia repair Term: a repair Start Date: Aug/UNK/2019 Ongoing: NO End Date: Aug/UNK/2019	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 09:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 09:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: left inguinal Hernia repair	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 09:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/UNK/2019	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 09:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Aug/UNK/2019	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-16-2020 09:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Hemorrhoidectomy Start Date: Jul/UNK/2020 Ongoing: NO End Date: Jul/UNK/2020	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 09:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-30-2020 09:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The medical history CRF was updated to include The condition or diagnosis that led to this recent surgery/procedure.
Sep-21-2020 14:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Per CRF completion requirements (8.7), please document the condition or diagnosis that led to this recent surgery/procedure as a separate MH entry.
Sep-21-2020 10:40:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	ClinQuery: Per CRF completion requirements (8.7), please document the condition or diagnosis that led to this recent surgery/procedure as a separate MH entry.
Sep-16-2020 09:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemorrhoidectomy	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 09:20:09 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/UNK/2020	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

(US & Canada)	(b) (4), (b) (6)
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I.e Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 09:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jul/UNK/2020	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-07-2020 15:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Nu 6 mber: Medical Hist Microdiscectomy L ory Term: umbar spine Start Date: UNK/UNK/1980 Ongoing: NO End Date: UNK/UNK/1980	Transcription Error
Sep-16-2020 09:21:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 6 mber: Medical Hist Microdiscectomy L ory Term: umber spine Start Date: UNK/UNK/1980 Ongoing: NO End Date: UNK/UNK/1980	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1174

Subject No: 11741042

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

I.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 09:21:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 15:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Microdiscectomy Lumbar spine	Transcription Error
Sep-16-2020 09:21:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Microdiscectomy Lumber spine	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 09:21:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 09:21:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1980	Initial Entry

I.g

Date	Location	User	Value	Reason
Oct-07-2020 15:40:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 7 Medical History Term: Microdiscectomy Lumbar spine Start Date: UNK/UNK/2005	Transcription Error

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

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Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

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Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

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			Ongoing: NO End Date: UNK/UNK/2005	
Sep-16-2020 09:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Microdiscectomy Lumbar spine Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

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Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 09:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 15:40:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Microdiscectomy Lumbar spine	Transcription Error
Oct-06-2020 13:04:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-06-2020 10:52:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The condition or diagnosis that led to the surgery/procedure was documented. herniated disc L4-L5.
Oct-02-2020 15:33:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Per CRF completion requirements (8.7), please document the condition or diagnosis that led to the surgery/procedure as a separate MH entry.
Oct-02-2020 12:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	ClinQuery: Per CRF completion requirements (8.7), please document the condition or diagnosis that led to the surgery/procedure as a separate MH entry.
Sep-16-2020 09:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Microdiscectomy Lumber spine	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

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I.g Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 09:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 09:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-30-2020 09:36:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number 8 : Medical History T Hemorrhoid erm: Start Date: UNK/UNK/2015 Ongoing: NO End Date: Jul/UNK/2020	Transcription Error
Sep-30-2020 09:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number 8 : Medical History T Hemorrhoid erm: Start Date: Jul/UNK/2020 Ongoing: NO End Date: Jul/UNK/2020	Transcription Error

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

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Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Sep-30-2020 09:18:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 8 : Medical History T Hemorrhoid erm: Start Date: UNK/UNK/20 20 Ongoing: NO End Date: Jul/UNK/2 020	Initial Entry
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090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

I.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 09:18:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 09:18:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemorrhoid	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 09:36:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Transcription Error
Sep-30-2020 09:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-30-2020 09:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/UNK/2020	Transcription Error
Sep-30-2020 09:18:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 16/Sep/2020. Please review and update as appropriate.
Sep-30-2020 09:18:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2020	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 09:18:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

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Subject No: 11741042

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Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

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Jul/UNK/2020

Li

Date	Location	User	Value	Reason
Oct-06-2020 10:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 9 r: Medical History T Herniated disc L erm: 4-L5 Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2 005	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

I.i Line/MH Number:

Date	Location	User	Value	Reason
Oct-06-2020 10:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 10:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Herniated disc L4-L5	Initial Entry

I.i Start Date:

Date	Location	User	Value	Reason
Oct-06-2020 10:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.i Ongoing:

Date	Location	User	Value	Reason
Oct-06-2020 10:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

I.j

Date	Location	User	Value	Reason
Oct-07-2020 15:38:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 10 Medical History Term: Lumbar radiculopathy Start Date: UNK/UNK/2019 Ongoing: YES	Transcription Error
Oct-06-2020 10:53:23 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 10	Initial Entry

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Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

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Time (US & Canada)			umber: Medical Hi story Term : Start Date: Ongoing:	Lower back pain with left sided radiculopat hy UNK/UNK/2019 YES
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I.j Line/MH Number:

Date	Location	User	Value	Reason
Oct-06-2020 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 15:38:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lumbar radiculopathy	Transcription Error
Oct-06-2020 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lower back pain with left sided rad iculopathy	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Oct-06-2020 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Oct-06-2020 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.k

Date	Location	User	Value	Reason
Oct-12-2020 11:32:39 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 11	Initial Entry

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Subject No: 11741042

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(US & Canada)			:	
			Medical History Term:	nephrolithiasis
			Start Date:	UNK/UNK/2008
			Ongoing:	NO
			End Date:	UNK/UNK/2008

I.k Line/MH Number:

Date	Location	User	Value	Reason
Oct-12-2020 11:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 11:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: nephrolithiasis	Initial Entry

I.k Start Date:

Date	Location	User	Value	Reason
Oct-12-2020 11:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2008	Initial Entry

I.k Ongoing:

Date	Location	User	Value	Reason
Oct-12-2020 11:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2008	Initial Entry

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Header Text: C4591001

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Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

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I. Date:

Date	Location	User	Value	Reason
Sep-29-2020 14:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-29-2020 14:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Transcription Error
Sep-29-2020 14:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Vital signs Date 11/Sep/2020 is not same as Date of Visit 16/Sep/2020. Please review and update as appropriate or clarify.
Sep-29-2020 14:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-29-2020 14:01:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital signs Date 11/Sep/2020 is not same as Date of Visit 09/Sep/2020. Please review and update as appropriate or clarify.
Sep-29-2020 14:01:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Transcription Error
Sep-09-2020 16:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-05-2020 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-05-2020 09:14:58 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject height was 68.3 in, and the

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Header Text: C4591001

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Form Version: 21-Aug-2020 02:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

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Time (US & Canada)		(b) (4), (b) (6)		weight was 154.8 lb collected on 9/9/2020. the height and weight were not collected when the subject was dosed on 9/16/2020
Oct-02-2020 18:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Not Done is entered for several vital signs. Even though a temp delay was done, the Vitals should reflect the data from when the subject was dosed on 16Sep2020. Please review and update the Vitals as appropriate.
Sep-29-2020 14:16:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	WEIGHT WAS COOLECTED ON 9/9/2020. THE WEIGHT WAS 154.8 LB
Sep-09-2020 16:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 154.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-29-2020 14:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-09-2020 16:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

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4. Height:

Date	Location	User	Value	Reason
Sep-29-2020 14:19:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Sep-29-2020 14:12:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	HIGHT WAS COLLECTED ON 9/9/2020. THE HIGHT WAS 68.25 IN. Hight was collected on 9/9/2020. the height was 68.25 IN. The was not collected on 9/16/2020.
Sep-09-2020 16:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 68.25	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-29-2020 14:19:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Sep-29-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Sep-09-2020 16:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-29-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Sep-29-2020 14:12:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	HIGHT WAS COLLECTED ON 9/9/2020. THE HIGHT WAS 68.25

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

				IN. Hight was collected on 9/9/2020. the height was 68.25 IN. The was not collected on 9/16/2020.
Sep-29-2020 14:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Sep-29-2020 14:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	WEIGHT WAS COOLECTED ON 9/9/2020. THE WEIGHT WAS 154.8 LB
Sep-09-2020 16:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23.4	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-29-2020 14:04:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.4 Temperature Unit: F Temperature Location:: EAR	Transcription Error
Sep-09-2020 16:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.2 Temperature Unit: F Temperature Location:: EAR	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-09-2020 16:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
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090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Sep-29-2020 14:04:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.4	Transcription Error
Sep-09-2020 16:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-09-2020 16:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-09-2020 16:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EAR	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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I. Randomization Date :

Date	Location	User	Value	Reason
Sep-29-2020 14:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-29-2020 14:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Randomization Date 16/Sep/2020 is before or more than 1 day after corresponding Date of Visit 11/Sep /2020. Please review and update as appropriate.
Sep-24-2020 01:02:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 14:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The data was entered in the unplanned visit.
Sep-18-2020 02:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM 2: Thank you for the response. However, Please review and update the new data on Vitals sign form. Else, clarify.
Sep-17-2020 08:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Vital sign was repeated on Sep/16 /2020: Weight: 154.8 lb Height: 68.3 in Temp: 97.4 f
Sep-17-2020 02:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: VACIN TRT is done on 16/Sep/2020. However, VITAL TEMP is done on 9/Sep/20. Please review and explain why Vitals signs is not repeated on the vaccination day. If

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

				repeated, please review and update the repeated Vital signs data with date. Else, clarify
Sep-16-2020 09:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	there was a temperately delay because of prior vaccination with influenza vaccine
Sep-16-2020 09:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Randomization Date 16/Sep/2020 is before or more than 1 day after corresponding Date of Visit 09/Sep/2020. Please review and update as appropriate.
Sep-16-2020 09:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-16-2020 09:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 256899	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 10:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 10:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-17-2020 02:56:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-16-2020 15:28:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	There was a temporary delay due to prior influenza vaccine
Sep-16-2020 14:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4722423;Date of Collection is earlier or more than 1 day after Date of Visit. Please clarify or correct.
Sep-16-2020 10:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/16/ 2020	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.a

Date	Location	User	Value	Reason
Sep-16-2020 10:17:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYGR3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 10:17:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYGR3	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-16-2020 10:17:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9WLD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 10:17:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9WLD	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-16-2020 10:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9WLF	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 10:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9WLF	Initial Entry

5.d

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Sep-16-2020 10:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9WLG	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 10:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9WLG	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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 10:15:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 10:15:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-29-2020 14:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Sep-29-2020 14:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Date of Collection 16/Sep/2020 is more than 1 day after Date of Visit 11/Sep/2020. Please review and update as appropriate, else clarify.
Sep-17-2020 02:55:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-16-2020 10:16:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	there was a temperately delay because of prior influenza vaccine
Sep-16-2020 10:15:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-16-2020 10:15:02	ACV0PFEINFP6000	auto query	Query 2: Candidate	'Sample Collected?'

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1174**Site Name:** (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID**Subject No:** 11741042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55

(UTC-05:00) Eastern Time (US & Canada)		(autoquery)		is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 10:15:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection 16/Sep/2020 is more than 1 day after Date of Visit 09/Sep/2020. Please review and update as appropriate, else clarify.
Sep-16-2020 10:15:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 10:15:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYGR4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 10:15:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYGR4	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-09-2020 16:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-09-2020 16:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First Delay: Sep/9/2020 Reason(s) for Temporary Delay of Vaccination RECENT NON-STUDY VACCINATION	Transcription Error
Sep-09-2020 16:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Was there a temporary delay of vaccination?' is marked as Yes and 'Date of First Delay' is not entered. Please review and update as appropriate.
Sep-09-2020 16:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Reason(s) for Temporary Delay of Vaccination RECENT NON-STUDY VACCINATION	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-16-2020 09:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Sep-16-2020 09:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-29-2020 14:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-29-2020 14:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Dose Date is before or more than 1 day after Date of Visit 11/Sep/2020 of the corresponding Visit. Please review and update as appropriate.
Sep-17-2020 02:55:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-16-2020 09:05:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	there was a temperately delay because of prior vaccination with influenza vaccine
Sep-16-2020 09:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Dose Date is before or more than 1 day after Date of Visit 09/Sep/2020 of the corresponding Visit. Please review and update as appropriate.
Sep-16-2020 09:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020 08:53	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
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090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Sep-16-2020 09:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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6. Body Side:

Date	Location	User	Value	Reason
Sep-16-2020 09:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-16-2020 09:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-16-2020 09:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 09:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 06-Jul-2020 21:53
Site No: 1174
Subject No: 11741042
Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 12:55

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-16-2020 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-06-2020 11:59:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date:

Date	Location	User	Value	Reason
Oct-06-2020 12:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-06-2020 12:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.9 Temperature Unit: F Temperature Location:: EAR	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-06-2020 12:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-06-2020 12:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-06-2020 12:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Oct-06-2020 12:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EAR	Initial Entry
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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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Data Origin

Date	Location	User	Value	Reason
Oct-06-2020 12:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-06-2020 12:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-06-2020 12:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-06-2020 12:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-06-2020 12:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/6/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-06-2020 12:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYGTP	Initial Entry

5.a Sample ID

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (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: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Oct-06-2020 12:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYGTP	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-06-2020 12:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-06-2020 12:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-06-2020 12:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-06-2020 12:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020 09:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-06-2020 12:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-06-2020 12:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

7. Route:

Date	Location	User	Value	Reason
Oct-06-2020 12:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-06-2020 12:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 12:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-05-2020 11:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Data Origin

Date	Location	User	Value	Reason
Nov-05-2020 11:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-05-2020 11:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-05-2020 11:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 11:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-05-2020 11:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-05-2020 11:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYGX7	Initial Entry

5.a Sample ID

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Nov-05-2020 11:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYGX7	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-05-2020 11:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSGGD3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 11:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGGD3	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-05-2020 11:45:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSGGD4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 11:45:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGGD4	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-05-2020 11:45:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSGGD5	Initial Entry

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.d Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 11:45:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSGGD5	Initial Entry

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-14-2020 23:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Per database update.
Dec-14-2020 09:18:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	all data cleared and the form marked not applicable
Dec-11-2020 11:59:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	DM: As this is erroneous visit, any forms within the visit which were started in error should be cleared of all data entered and marked Not Applicable at the form level, not the item level. Please update all forms in this visit.
Oct-01-2020 09:35:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	ok as is
Sep-30-2020 19:58:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-30-2020 16:52:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Sep-30-2020 16:51:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-30-2020 02:38:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Erroneous Visit is marked, but date of

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001**Visit:** Unplanned 1 - Unscheduled Visit on Sep/16/2020**Form Version:** 22-Apr-2020 21:02**Site No:** 1174**Subject No:** 11741042**Generated By:** (b) (4)**Form:** DATE OF VISIT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55

Time (US & Canada)		(b) (4), (b) (6)		visit is entered. Please check whether other assessments are performed at this visit.
Sep-29-2020 14:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	the subject didn't have UNPL visit
Sep-29-2020 13:52:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Sep-26-2020 20:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Subject is listed to have a UNPL visit. Subject is not part of the reactogenicity subset. Please update the AE log to indicate why the subject had an UNPL visit. Thanks
Sep-23-2020 10:28:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Sep-30-2020 16:52:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry
Sep-30-2020 16:51:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-29-2020 13:52:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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I. Assessments

Date	Location	User	Value	Reason
Dec-14-2020 09:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:55:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 10:41:34 (UTC-05:00) Eastern 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-23-2020 10:41:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

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Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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I. Contact Type:

Date	Location	User	Value	Reason
Dec-14-2020 09:16:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Sep-23-2020 10:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Dec-14-2020 09:16:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 10:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Sep-23-2020 10:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact:	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001
Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020
Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Frozen, Verified
Site No: 1174
Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID
Subject No: 11741042
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 12:55

			Sep/16/2020	
			Contact Outcome:	
			VISIT ARRANGED	

3. Comments:

Date	Location	User	Value	Reason
Dec-14-2020 09:16:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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I. Date:

Date	Location	User	Value	Reason
Dec-14-2020 09:16:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 14:13:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-14-2020 09:16:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: Not Applicable Temperature Unit: Not Applicable Temperature Location:: Not Applicable	Initial Entry
Sep-29-2020 14:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: Temperature Unit: Temperature Location::	Transcription Error
Sep-29-2020 14:13:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: Temperature Unit: Temperature Location:: EAR	Transcription Error
Sep-29-2020 13:56:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature:	Transcription Error

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Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

			Temperature Unit: F Temperature Location:: EAR	
Sep-23-2020 10:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.4 Temperature Unit: F Temperature Location:: EAR	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-23-2020 10:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Dec-14-2020 09:16:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:56:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Dec-14-2020 09:16:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 14:13:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.a Temperature Location:

Date	Location	User	Value	Reason
Dec-14-2020 09:16:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 14:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EAR	Initial Entry

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form Version: 15-Sep-2020 21:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Assessment:

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:56:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

2. Injection Site Location

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:56:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

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Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form Version: 15-Sep-2020 21:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

4.a

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: REDNESS Reaction Present: Not Applicable	Initial Entry
Sep-29-2020 13:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: REDNESS Reaction Present::	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: REDNESS Reaction Present:: NO	Initial Entry

4.a Reaction:

Date	Location	User	Value	Reason
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

4.a Reaction Present:

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: SWELLING	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001**Visit:** Unplanned 1 - Unscheduled Visit on Sep/16/2020**Form Version:** 15-Sep-2020 21:51**Site No:** 1174**Subject No:** 11741042**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55

			Reaction Present: Not Applicable	
Sep-29-2020 13:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: SWELLING Reaction Present::	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: SWELLING Reaction Present:: NO	Initial Entry

4.b Reaction:

Date	Location	User	Value	Reason
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: PAIN AT INJECTION SITE Symptom Present:: Not Applicable	Initial Entry
Sep-29-2020 13:57:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: PAIN AT INJECTION SITE	Transcription Error

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form Version: 15-Sep-2020 21:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

			ON SITE	
			Symptom Present::	
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: PAIN AT INJECTION SITE Symptom Present:: NO	Initial Entry

5.a Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:57:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGUE/TIRED NESS Symptom Present:: Not Applicable	Initial Entry
Sep-29-2020 13:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGUE/TIRED NESS	Transcription Error

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Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form Version: 15-Sep-2020 21:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

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			Symptom Present::	
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGUE/TIRE NESS Symptom Present: NO	Initial Entry

5.b Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE/TIREDNESS	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACHE Symptom Present Not Applicabl :: e	Initial Entry
Sep-29-2020 13:58:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACH E Symptom Present: :	Transcription Error

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Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form Version: 15-Sep-2020 21:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACHE Symptom Present: NO	Initial Entry
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5.c Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:58:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VOMITING Symptom Present Not Applicable	Initial Entry
Sep-29-2020 13:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VOMITING Symptom Present::	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VOMITING Symptom Present:: NO	Initial Entry

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Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

5.d Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIARRHEA Symptom Present Not Applicabl :: e	Initial Entry
Sep-29-2020 13:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIARRHEA Symptom Present::	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIARRHEA Symptom Present:: NO	Initial Entry

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Header Text: C4591001

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Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

5.e Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR WORSENE : D MUSCLE PAIN Symptom Present:: Not Applicable	Initial Entry
Sep-29-2020 13:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR WORSENE : D MUSCLE PAIN Symptom Present::	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR WORSENE : D MUSCLE PAIN Symptom Present:: NO	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

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Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

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5.f Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED MUSCLE PAIN	Initial Entry

5.f Symptom Present:

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERED JOINT PAIN Symptom Present:: Not Applicable	Initial Entry
Sep-29-2020 13:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERED JOINT PAIN Symptom Present::	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERED JOINT PAIN Symptom Present:: NO	Initial Entry

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Header Text: C4591001

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Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

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5.g Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAI N	Initial Entry

5.g Symptom Present:

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.h

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CHILLS Symptom Present: Not Applicabl e	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/16/2020

Form Version: 15-Sep-2020 21:51

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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5.h

Date	Location	User	Value	Reason
Sep-29-2020 13:59:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CHILLS Symptom Present::	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CHILLS Symptom Present:: NO	Initial Entry

5.h Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

5.h Symptom Present:

Date	Location	User	Value	Reason
Dec-14-2020 09:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-29-2020 13:59:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-23-2020 10:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-05-2020 11:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-05-2020 11:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-05-2020 11:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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Date	Location	User	Value	Reason
Oct-07-2020 11:16:04 (UTC-05:00) Eastern 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: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

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Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern 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: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-11-2020 15:26:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-11-2020 14:55:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Thank you.
Nov-11-2020 11:06:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Nephrolithiasis on medical history was resolved in 2008; it's not a baseline condition. Nephrolithiasis in 10/02/2020 is a new condition.
Nov-10-2020 15:23:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 3: Opened	The AE nephrolithiasis was reported but is also listed in Medical History. Please clarify if

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Header Text: C4591001

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Subject No: 11741042

Generated By: (b) (4)

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				this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. (b) (4)
Nov-10-2020 10:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The test was not performed and this information will be reflected in the updated SAE case narrative.
Oct-22-2020 13:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued: Opened	If test was NOT performed or NOT available, please add this information as well so it is reflected in the SAE case narrative. Thank you.
Oct-21-2020 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	COVID testing was NOT performed during hospitalization.
Oct-21-2020 11:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form to provide whether COVID

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Generated By: (b) (4)

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				testing was performed during hospitalization (yes/no) and if yes, the results. Thank you.
Oct-09-2020 13:07:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Oct-09-2020 11:53:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The CRF was updated to include Hydronephrosis.
Oct-08-2020 16:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	On review of the SAE report for nephrolithiasis, an event of hydronephrosis has been mentioned, yet it does not appear in the CRF. Please review for safety and update AE log CRF accordingly. If safety update is required, submit a follow-up SAE Form.
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: nephrolithiasis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-28-2020 10:12:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Header Text: C4591001

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Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Oct-28-2020 08:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	the subject did not meet the TDV criteria at V2.
Oct-27-2020 10:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please confirm the subject did not meet TDV criteria at V2 listed in protocol section 5.5 as a result of Nephrolithiasis and Hydronephrosis. Thanks.
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/6/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-08-2020 06:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

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Subject No: 11741042

Generated By: (b) (4)

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Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE nephrolithiasis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: 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>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/in capacity?</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>	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
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Subject No: 11741042

Generated By: (b) (4)

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Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-13-2020 02:25:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 11:34:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	History of nephrolithiasis
Oct-08-2020 08:17:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Intercurrent illness]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)
Oct-07-2020 11:30:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is	New Information

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Subject No: 11741042

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

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			due to: OTHER <i>If Other, specify:</i> Intercur rent illn ess	
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELAT ED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

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Header Text: C4591001

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Oct-07-2020 11:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-08-2020 06:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020389747	Initial Entry

Header Text: C4591001

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Subject No: 11741042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Category:

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hydronephrosis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/6/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER If Other, specify: Nephrolithiasis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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Header Text: C4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-09-2020 11:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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Date	Location	User	Value	Reason
Sep-11-2020 17:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1174

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject No: 11741042

Subject Initials: ---

Generated By: (b) (4)

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Sep-11-2020 17:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Sep-11-2020 17:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Sep-11-2020 17:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Sep-11-2020 17:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Sep-11-2020 17:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/2/2020	Initial Entry

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Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-07-2021 12:42:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious
Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-07-2021 12:42:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for V accination 3 Participant is: eligible and NOT confirmed to h ave received only placebo at Vac cination 1/2	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-07-2021 12:42:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-07-2021 12:42:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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1. Subject Status

Date	Location	User	Value	Reason
Nov-05-2020 11:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-16-2020 09:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-09-2020 16:07:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-05-2020 11:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/5/2020	Initial Entry
Sep-16-2020 09:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/16/2020	Initial Entry
Sep-09-2020 16:07:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/9/2020	Initial Entry

090177e196ae3d42\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1174

Subject No: 11741042

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1174) Clinical Alliance for Research and Education - Infectious Diseases, LLC CARE-ID

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-13-2020 13:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry