

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1178) Clinical Research Associates Inc

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/8/2020
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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11781122]
2.	Birth Date:	(b) (6) /1947
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:	

**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DATE OF VISIT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/8/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1178) Clinical Research Associates Inc

**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 _____
----	---	-------------------------

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
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**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/8/2020
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: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

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:	[cardiomyopathy]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[left ventricular hypertrophy]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[gout]
	Start Date:	Feb/UNK/2018
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[atrial fibrillation]
	Start Date:	Jan/UNK/2020
	Ongoing:	YES

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**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[elevate prostate-specific antigen]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hiatal hernia]
	Start Date:	UNK/UNK/1947
	Ongoing:	YES



**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/8/2020
2.	Weight:	[222.0]
3.	Unit:	LB
4.	Height:	[70.5]
5.	Unit:	in
6.	Body Mass Index:	[31.4]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** RANDOMIZATION

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/8/2020
2.	Randomization Number:	[254895]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1178) Clinical Research Associates Inc

**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/8/2020
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	[BPY8H4]
5.b	Sample ID	[BNWP4R]
5.c	Sample ID	[BNWP4S]

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**Header Text:** C4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1178  
**Subject No:** 11781122  
**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1178) Clinical Research Associates Inc  
**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/8/2020
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	[BPY8H7]
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**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** VACCINATION

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

**Site Name:** (1178) Clinical Research Associates Inc

**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:	Sep/8/2020 16:26
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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<b>Header Text:</b> C4591001	<b>Form:</b> REACTOGENICITY DIARY
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 06-Jul-2020 21:53	<b>Site Name:</b> (1178) Clinical Research Associates Inc
<b>Site No:</b> 1178	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11781122	<b>Generated Time (GMT):</b> 29-Mar-2021 12:55
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DATE OF VISIT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/28/2020
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/28/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**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/28/2020
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	[BPW3KK]
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** VACCINATION

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

**Site Name:** (1178) Clinical Research Associates Inc

**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:	Sep/28/2020 14:03
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DATE OF VISIT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1178) Clinical Research Associates Inc

**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: Oct/26/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPW406]
5.b	Sample ID	[BRVDYV]
5.c	Sample ID	[BRVDYW]

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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**Date of Visit**

1.	Date of Visit	Feb/8/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Feb/8/2021
2.	Date of First Symptom Started:	Feb/6/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Feb/26/2021

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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**Header Text:** C4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jan/31/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>
2.	Feb/10/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>
3.	Feb/10/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN  
on Feb/08/2021

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Jan/31/2021	<a href="#">Comments</a>
2.	Specimen Type:	SWABBED MATERIAL	<a href="#">Comments</a>
3.	Specimen Collection Location:	NASOPHARYNX	<a href="#">Comments</a>
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	<a href="#">Comments</a>
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Comments</a>
6.	Trade Name:	OTHER	<a href="#">Comments</a>
7.	Test Result:	NEGATIVE	<a href="#">Comments</a>
8.	Comments/Findings/Details:	[ ]	<a href="#">Comments</a>
9.	Trade Name Other, Specify:	[NALT Unknown]	<a href="#">Comments</a>

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN  
on Feb/08/2021

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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**Microbiology Specimen**

1.	Actual Date of Collection:	Feb/10/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	POSITIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[Ortho's VITROS SARS-CoV-2 Antigen Test]

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN  
on Feb/08/2021

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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**Microbiology Specimen**

1.	Actual Date of Collection:	Feb/10/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[Accula SARS CoV 2 Test]

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

**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: Feb/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR7SHR]
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090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** HEALTH CARE UTILIZATION  
on Feb/08/2021

**Form Version:** 14-Jan-2021 02:24

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

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

**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT  
on Feb/08/2021

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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**Respiratory Treatment**

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



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS  
on Feb/08/2021

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [COVID-19 Illness]  Date of Diagnosis: Feb/10/2021
3.	Toxicity Grade:	1

**Header Text:** C4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE  
on Feb/08/2021

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

**Header Text:** C4591001

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

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test :	Result :	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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**Lab Chemistry Details**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Feb/08/2021

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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**Laboratory Data Hematology**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details			Form Instance
1.		<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Feb/08/2021

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

**Header Text:** C4591001

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details		Form Instance
1.		<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021

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

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** C4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

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**Header Text:** C4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

**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.	Start Date:	//
6.	Ongoing?	

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**Header Text:** C4591001

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

**Form:** IMAGING

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING  
on Feb/08/2021

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Mar/01/2021

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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	Mar/1/2021	
2.	Erroneous Visit	Not Applicable	<a href="#">Comments</a>

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	Not Applicable	<a href="#">Comments</a>
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**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Mar/01/2021

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Data Complete, Verified

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	Not Applicable _____	<a href="#">Comments</a>
2.	Sample Type	Not Applicable _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Applicable _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	Not Applicable _____ [ ]
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090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

**Unplanned Assessments**

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

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/26/2020
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:** 1178

**Subject No:** 11781122

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1178) Clinical Research Associates Inc

**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:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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:	
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**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:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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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090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

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	Basal Cell Carcinoma (face)	Oct/15/2020 09:00	NO End Date Time:  Oct/29/2020 UNK: UNK	<a href="#">Repeating Pages</a>
2. DELETED	ADVERSE EVENT	2	basal cell carcinoma	Nov/15/2020 UNK:UNK	NO End Date Time:  Dec/15/2020 UNK: UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	tenderness at injection site	Jan/22/2021 UNK:UNK	NO End Date Time:  Jan/29/2021 11:00	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	worsening of paroxysmal atrial fibrillation	Jan/14/2021 UNK:UNK	NO End Date Time:  Feb/4/2021 UNK:UNK	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	intestinal obstruction	Feb/9/2021 UNK:UNK	NO End Date Time:  Feb/19/2021 UNK: UNK	<a href="#">Repeating Pages</a>
6.	ADVERSE EVENT	6	GERD	Feb/4/2021 UNK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1178) Clinical Research Associates Inc

**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)	[Basal Cell Carcinoma (face)]
4.	Start Date Time:	Oct/15/2020 09:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/29/2020 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: [Mitosis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[basal cell carcinoma]
4.	Start Date Time:	Nov/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/15/2020 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:
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[tenderness at injection site]
4.	Start Date Time:	Jan/22/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/29/2021 11:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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



Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[worsening of paroxysmal atrial fibrillation]
4.	Start Date Time:	Jan/14/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/4/2021 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).	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

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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: [hx of atrial fibrillation]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021148943]

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[intestinal obstruction]
4.	Start Date Time:	Feb/9/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/19/2021 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 YES
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

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[2021195271]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[GERD]
4.	Start Date Time:	Feb/4/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
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: [acid in wrong location]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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**Medication Error**

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

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**Header Text:** C4591001

**Visit:** Logs

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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	Oct/27/2020	<a href="#">Repeating Pages</a>

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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**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:	Oct/27/2020

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

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

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1178) Clinical Research Associates Inc

**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?	

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1178) Clinical Research Associates Inc

**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:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1178) Clinical Research Associates Inc

**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:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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?	

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (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:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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**Date of Visit**

1.	Date of Visit	Jan/15/2021
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:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/15/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION



**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

**Withdrawal Of Consent**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

**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:** V101\_VAX3

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DATE OF VISIT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/19/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/19/2021
----	--------------	--

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

[Form Comments](#)

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Jan/19/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1178) Clinical Research Associates Inc

**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: Jan/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR7H0J]
5.b	Sample ID	[BSGFGP]
5.c	Sample ID	[BSGFGR]

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**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: Jan/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR7H0H]
-----	-----------	----------

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)



**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** VACCINATION

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

**Site Name:** (1178) Clinical Research Associates Inc

**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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/19/2021 14:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DATE OF VISIT

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/1/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**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: Mar/1/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR7SMY]
-----	-----------	----------

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** VACCINATION

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

**Site Name:** (1178) Clinical Research Associates Inc

**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: Feb/8/2021  Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/1/2021 14:08
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

**Contact Outcome**

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



**Header Text:** C4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Not Started

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

**Disposition - Treatment**

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

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1178) Clinical Research Associates Inc

**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	Oct/26/2020

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Verified

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
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**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

**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
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Sep-08-2020 17:39:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Feb/08/2021

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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Item	Date	User	Comment
Form	Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
Form	Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Feb/08/2021

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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Item	Date	User	Comment
1	Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
1	Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021      **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2	Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021      **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
3	Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Feb/08/2021

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
4	Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021      **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5	Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5	Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Feb/08/2021

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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Item	Date	User	Comment
6	Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
6	Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Feb/08/2021

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
7	Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
7	Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021      **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
8	Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
8	Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021      **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
9	Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
9	Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1

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

**Site No:** 1178

**Subject No:** 11781122

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Mar-02-2021 13:27:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1

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

**Site No:** 1178

**Subject No:** 11781122

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Mar-02-2021 12:24:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Mar/01/2021

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Mar-09-2021 08:32:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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Item	Date	User	Comment
1	Mar-09-2021 08:32:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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Item	Date	User	Comment
2	Mar-09-2021 08:32:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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Item	Date	User	Comment
3	Mar-09-2021 08:32:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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Item	Date	User	Comment
4	Mar-09-2021 08:32:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER  
VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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Item	Date	User	Comment
Form	Jan-19-2021 15:43:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-02-2021 12:41:55 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Stephan Sharp	Approved	Jan-20-2021 11:19:52 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-19-2020 16:08:25 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephan Sharp	Approved	Nov-02-2020 09:55:04 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, StephanSharp, 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.

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

**Site Name:** (1178) Clinical Research Associates Inc

**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-08-2020 17:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 17:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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*I. Consent Was:*

Date	Location	User	Value	Reason
Sep-08-2020 17:36:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/8/2020	Initial Entry

Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-08-2020 17:36:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11781122	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-08-2020 17:36:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) /1947	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-08-2020 17:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-08-2020 17:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 17:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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***1. Date of Visit***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-08-2020 17:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1178) Clinical Research Associates Inc

**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-08-2020 17:39:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-08-2020 17:39:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-08-2020 17:39:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

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*I.a*

Date	Location	User	Value	Reason
Sep-08-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> cardiomyopathy <b>Start Date:</b> UNK/UNK/2008 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-08-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cardiomyopathy	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Sep-08-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2008	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Sep-08-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.b*

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-08-2020 17:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Num 2 <b>ber:</b> <b>Medical Histor</b> left ventricular hy <b>y Term:</b> pertrophy <b>Start Date:</b> UNK/UNK/2008 <b>Ongoing:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 17:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 17:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> left ventricular hypertrophy	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Sep-08-2020 17:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2008	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Sep-08-2020 17:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Sep-08-2020 17:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 3	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Medical History Term:</b> <b>Start Date:</b> UNK/UNK/2000 <b>Ongoing:</b> YES	
--	--	--	--	--

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

Date	Location	User	Value	Reason
Sep-08-2020 17:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 17:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hypertension	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Sep-08-2020 17:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2000	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Sep-08-2020 17:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Sep-08-2020 17:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> gout <b>Start Date:</b> Feb/UNK/2018	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Ongoing:</b>	YES	
--	--	--	-----------------	-----	--

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

Date	Location	User	Value	Reason
Sep-08-2020 17:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 17:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> gout	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Sep-08-2020 17:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/UNK/2018	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Sep-08-2020 17:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.e**

Date	Location	User	Value	Reason
Sep-08-2020 17:42:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> atrial fibrillation <b>Start Date:</b> Jan/UNK/2020 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Sep-08-2020 17:42:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 17:42:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> atrial fibrillation	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 17:42:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/UNK/2020	Initial Entry

***1.e Ongoing:***

Date	Location	User	Value	Reason
Sep-08-2020 17:42:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Sep-08-2020 17:43:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> elevate prostate-specific antigen <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

*I.f Line/MH Number:*

Date	Location	User	Value	Reason
Sep-08-2020 17:43:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 17:43:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> elevate prostate-specific antigen	Initial Entry

*I.f Start Date:*

Date	Location	User	Value	Reason
Sep-08-2020 17:43:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

*I.f Ongoing:*

Date	Location	User	Value	Reason
Sep-08-2020 17:43:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.g*

Date	Location	User	Value	Reason
Mar-02-2021 13:30:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> hiatal hernia <b>Start Date:</b> UNK/UNK/1947 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Mar-02-2021 13:30:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 13:30:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hiatal hernia	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 13:30:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1947	Initial Entry

***1.g Ongoing:***

Date	Location	User	Value	Reason
Mar-02-2021 13:30:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-08-2020 17:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-08-2020 17:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 222.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-08-2020 17:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-08-2020 17:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 70.5	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-08-2020 17:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-08-2020 17:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 31.4	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

7.a

Date	Location	User	Value	Reason
Sep-08-2020 17:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.9 <b>Temperature Unit:</b> F <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-08-2020 17:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-08-2020 17:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-08-2020 17:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-08-2020 17:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-08-2020 17:44:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-08-2020 17:44:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 254895	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (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:** 1178**Site Name:** (1178) Clinical Research Associates Inc**Subject No:** 11781122**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-08-2020 18:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-08-2020 18:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-08-2020 18:09:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-08-2020 18:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-08-2020 18:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Sep/8/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-08-2020 18:09:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPY8H4	Initial Entry

**5.a Sample ID**

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: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-08-2020 18:09:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPY8H4	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-08-2020 18:09:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNWP4R	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 18:09:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNWP4R	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-08-2020 18:09:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNWP4S	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 18:09:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNWP4S	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (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: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

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-08-2020 18:08:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-08-2020 18:08:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-08-2020 18:09:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-08-2020 18:08:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-08-2020 18:08:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Sep/8/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-08-2020 18:09:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPY8H7	Initial Entry

**5.a Sample ID**

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (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:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-08-2020 18:09:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPY8H7	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

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-08-2020 17:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-08-2020 17:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-08-2020 17:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-08-2020 17:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020 16:26	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-08-2020 17:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-08-2020 17:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

**7. Route:**

Date	Location	User	Value	Reason
Sep-08-2020 17:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-08-2020 17:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 17:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1178) Clinical Research Associates Inc

**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-08-2020 17:45:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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***1. Date of Visit***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-28-2020 16:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-28-2020 16:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-28-2020 16:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.6 <b>Temperature Unit:</b> F <b>Temperature Locat ion::</b> ORAL CAVI TY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-28-2020 16:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-28-2020 16:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.6	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-28-2020 16:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
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090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

Sep-28-2020 16:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (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: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

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-28-2020 13:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-28-2020 13:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-28-2020 13:40:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-28-2020 13:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-28-2020 13:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/28/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-30-2020 07:41:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPW3KK	Transcription Error
Sep-28-2020 13:40:38	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (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:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	<b>Sample ID:</b> BPW3KL	
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**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-30-2020 07:41:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPW3KK	Transcription Error
Sep-28-2020 13:40:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPW3KL	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

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-28-2020 16:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-28-2020 16:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-28-2020 16:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-28-2020 16:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020 14:03	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-28-2020 16:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-28-2020 16:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

**7. Route:**

Date	Location	User	Value	Reason
Sep-28-2020 16:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-28-2020 16:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 16:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-26-2020 13:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/26/2020	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: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

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-26-2020 13:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-26-2020 13:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-26-2020 13:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-26-2020 13:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-26-2020 13:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/26/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-26-2020 13:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPW406	Initial Entry

**5.a Sample ID**

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-26-2020 13:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPW406	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-26-2020 13:41:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRVDYV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 13:41:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRVDYV	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-26-2020 13:41:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRVDYW	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 13:41:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRVDYW	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1178**Site Name:** (1178) Clinical Research Associates Inc**Subject No:** 11781122**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-08-2021 10:16:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 10:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-08-2021 10:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-08-2021 10:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/8/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 10:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/8/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/6/2021	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Mar-02-2021 14:50:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved: Feb/26/2021	New Information
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

4.c Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

			Symptom Present:	NO
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4.e Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms : NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
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090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom s:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> NO	Initial Entry
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4.g Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.i

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Audit Trail History

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

**4.i Symptoms:**

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Feb-08-2021 15:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Feb/08/2021

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

**Form Status:**

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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Date	Location	User	Value	Reason
Feb-08-2021 15:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Form Created	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Feb/08/2021

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

**Form Status:**

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Mar-02-2021 15:05:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Feb/08/2021

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

**Form Status:**

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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Date	Location	User	Value	Reason
Mar-03-2021 11:21:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Form Created	

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/08/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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***1. Actual Date of Collection:***

Date	Location	User	Value	Reason
Mar-04-2021 08:20:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-03-2021 11:02:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-03-2021 11:02:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/31/2021	Transcription Error
Mar-03-2021 10:29:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Per source, date of collection was 31-Jan-21. Please review and update as needed.
Mar-02-2021 15:04:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/2/2021	Initial Entry
Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 08:22:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-10-2021 14:24:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-10-2021 14:24:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Feb-10-2021 12:29:41 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of local COVID test is prior

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/08/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)		(b) (4), (b) (6)		to date of symptom onset. Please confirm if local COVID testing was triggered by potential COVID symptoms?
Feb-08-2021 15:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/31/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Mar-02-2021 15:04:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry
Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-10-2021 14:26:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-08-2021 15:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Mar-02-2021 15:04:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry
Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-10-2021 14:26:43	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/08/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
Feb-10-2021 14:26:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-08-2021 15:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Mar-02-2021 15:04:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry
Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-10-2021 14:24:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Feb-08-2021 15:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Mar-02-2021 15:04:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry
Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/08/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

Feb-10-2021 14:24:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Feb-08-2021 15:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Mar-03-2021 09:31:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-03-2021 09:31:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Trade Name is Other, however Trade Name Other, Specify is not completed. Please update.
Mar-02-2021 15:04:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry
Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-10-2021 14:26:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-08-2021 15:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Mar-02-2021 15:04:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/08/2021

Form Version: 06-Jul-2020 21:54

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Generated By: (b) (4)

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

Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-10-2021 14:26:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-08-2021 15:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Mar-03-2021 13:15:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	data updated
Mar-03-2021 09:31:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT Unknown	Initial Entry
Mar-03-2021 09:31:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-03-2021 09:31:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/08/2021

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Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Mar-03-2021 04:09:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: As per CRF CR Section 8.31.7, If the Trade Name is not known, please enter "NALT Unknown" in the specified field, Thank you.
Mar-02-2021 15:04:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SARS-CoV-2	Initial Entry
Mar-02-2021 15:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-10-2021 14:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-10-2021 14:26:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-09-2021 15:10:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 14:33:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-09-2021 14:33:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT Unknown	Transcription Error
Feb-09-2021 12:19:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Per CRF CRs 8.31.7, please provide manufacturer and test kit name. If not available, please

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

				enter if test conducted at 'CLIA-certified lab' or 'ISO 15189 accredited lab.' If both trade name and lab are not known, enter 'NALT Unknown.'
Feb-08-2021 15:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/08/2021

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Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Mar-04-2021 14:45:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 13:52:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Mar-04-2021 11:41:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: 2 local swabs were recorded as collected on 10Feb2021 with 1 positive result and 1 negative result, please confirm.
Mar-02-2021 15:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/10/2021	New Information
Mar-02-2021 15:05:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/9/2021	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Mar-02-2021 15:05:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Mar-02-2021 15:05:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/08/2021

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Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-02-2021 15:05:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Mar-02-2021 15:05:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Mar-02-2021 15:05:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Mar-02-2021 15:05:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> POSITIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Mar-08-2021 03:50:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: C losed	Response satisfies query
Mar-05-2021 08:02:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: A nswered	New Information
Mar-05-2021 08:02:55 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entr y:</b> Ortho's VI	New Information

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**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Feb/08/2021**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1178**Site Name:** (1178) Clinical Research Associates Inc**Subject No:** 11781122**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55

Central Time (US & Canada)			TROS SARS-CoV-2 Antigen Test	
Mar-05-2021 01:01:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 3: Opened	Trade name Manufacturer name provided as Vitros Sars COV 2 total antibody assay does not uniquely match with the FDA List. Kindly update data as requested else please confirm and add text "CLIA certified lab", Thank you. (b) (4)
Mar-04-2021 08:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-03-2021 11:04:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-03-2021 11:04:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Vitros Sars -COV-2 total antibody assay	Transcription Error
Mar-03-2021 10:45:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Per source, this test was a Vitros Sars-COV-2 total antibody assay. Please

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
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**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

				review and update trade name other field as needed.
Mar-03-2021 10:45:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Updating text of query
Mar-03-2021 10:41:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, this test was a Vitro Sars-COV-2 total antibody assay. Please review and update trade name other field as needed.
Mar-03-2021 09:32:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT Unknown	Transcription Error
Mar-02-2021 15:05:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SARS-CoV-2	Initial Entry

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**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Feb/08/2021**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1178**Site Name:** (1178) Clinical Research Associates Inc**Subject No:** 11781122**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Mar-03-2021 11:21:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/10/2021	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Mar-03-2021 11:21:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Transcription Error
Mar-03-2021 11:21:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RESPIRATORY SECRETIONS	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Mar-03-2021 11:21:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Mar-03-2021 11:21:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Mar-03-2021 11:21:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1178

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Mar-03-2021 11:21:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry
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**7. Test Result:**

Date	Location	User	Value	Reason
Mar-03-2021 11:21:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Mar-05-2021 05:07:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: C losed	Response satisfies query
Mar-04-2021 07:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: A nswered	Transcription Error
Mar-04-2021 07:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Accula SA RS CoV 2 Test	Transcription Error
Mar-04-2021 06:00:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: O pened	As per FDA List of Trade names and CRF CR, data should be updated as Accula SARS Cov 2 Test (Mesa Biotech Inc.) Kindly confirm and update data as requested, else clarify, Thank you. (b) (4)

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

				(b) (4)
Mar-03-2021 11:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Accula SARS-CoV-2 molecular PCR	Transcription Error
Mar-03-2021 11:21:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Accula SARS-CoV-2 molecular test	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**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
Feb-08-2021 15:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-08-2021 15:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-08-2021 15:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Feb-08-2021 15:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> In-Clinic Visit	Initial Entry

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-08-2021 10:16:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-08-2021 10:16:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-08-2021 10:16:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 10:16:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-08-2021 10:16:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/8/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-08-2021 10:16:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR7SHR	Initial Entry

**5.a Sample ID**

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Feb/08/2021

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Feb-08-2021 10:16:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR7SHR	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/08/2021

**Form Version:** 14-Jan-2021 02:24

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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*1.a*

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*1.b*

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/08/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1178**Site Name:** (1178) Clinical Research Associates Inc**Subject No:** 11781122**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Feb/08/2021

**Form Version:** 14-Jan-2021 02:24

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
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**1.d Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

**1.d Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**1.e**

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/08/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Feb-10-2021 14:27:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Feb-10-2021 14:27:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b>	Transcription Error
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/08/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

***If Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***If Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-10-2021 14:27:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
Feb-10-2021 14:27:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

***2. Other Type of Practitioner Specify:***

Date	Location	User	Value	Reason
Feb-10-2021 14:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-09-2021 15:10:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 14:32:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-09-2021 14:32:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Vanderbilt Hospital COVID-19 Te sting	Transcription Error
Feb-09-2021 12:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Please specify practitioner. If this was COVID-19

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Feb/08/2021

**Form Version:** 14-Jan-2021 02:24

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

		(b) (4), (b) (6)		testing, please specify.
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Vanderbilt Hospital	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 15:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Feb/08/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Feb-08-2021 15:43:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Mar-03-2021 09:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  COVID-19 Illness  Date of Diagnosis:  Feb/10/2021	New Information
Feb-08-2021 15:43:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-08-2021 15:43:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Mar/01/2021**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit  
Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Verified**Site No:** 1178**Site Name:** (1178) Clinical Research Associates Inc**Subject No:** 11781122**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-02-2021 13:27:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-02-2021 08:45:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: As visit is initiated in error, please consider adding form level comment "Not applicable" in this form. Thank you.
Mar-01-2021 15:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-01-2021 15:43:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/1/2021	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Mar-02-2021 13:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-02-2021 13:27:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Mar/01/2021

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

Mar-01-2021 15:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry
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**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Mar-02-2021 12:24:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 15:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-01-2021 15:43:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Mar/01/2021

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

**Site No:** 1178

**Subject No:** 11781122

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-09-2021 08:32:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-09-2021 08:32:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-09-2021 08:32:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Mar-09-2021 08:32:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

**Site Name:** (1178) Clinical Research Associates Inc

**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
Oct-26-2020 13:20:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/26/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-26-2020 13:20:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-26-2020 13:20:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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

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Date	Location	User	Value	Reason
Jan-19-2021 15:49:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Form Deleted	Transcription Error
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Basal Cell Carcinoma (face)	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020 09:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-19-2020 16:08:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Oct/29/2020 UNK:UNK	New Information
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

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Subject No: 11781122

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

*Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Oct-26-2020 13:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Mitosis	New Information
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

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Site Name: (1178) Clinical Research Associates Inc

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Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Nov-19-2020 16:08:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-19-2020 16:08:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Nov-19-2020 16:08:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Basal Cell Carcinoma (face): Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESO LVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1178

**Subject No:** 11781122

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Oct-26-2020 13:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

Header Text: C4591001

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Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

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

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1. Category:

Date	Location	User	Value	Reason
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> basal cell carcinoma	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/15/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Dec/15/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Subject No: 11781122

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

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

Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Generated By: (b) (4)

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Subject Initials: ---

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

Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Jan-19-2021 15:46:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

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Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> tenderness at injection site	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/22/2021 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-02-2021 13:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Jan/29/2021 11:00	New Information
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-02-2021 13:29:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000		auto query (autoquery)	Query 2: Closed Close Auto Query
Mar-02-2021 13:29:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> : REC OVE RED/ RESO LVED	New Information
Mar-02-2021 13:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000		auto query (autoquery)	Query 2: Opened For AE tenderness at injection site: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Feb-03-2021 13:16:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-03-2021 07:38:36	ACV0PFEINFP6000		auto query (autoquery)	Query 1: An Transcription Error

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Generated By: (b) (4)

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(UTC-06:00) Central Time (US & Canada)			swere d	
Feb-03-2021 07:38:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : NOT REC OVE RED/ NOT RESO LVED	Transcription Error
Feb-02-2021 20:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7120228;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : REC OVE RED/ RESO LVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-02-2021 14:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

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Subject No: 11781122

Generated By: (b) (4)

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Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-03-2021 06:36:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Thanks for confirming. Clinical will continue to FU at a later date.
Feb-23-2021 12:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Will request medical records and submit a follow up form once available
Feb-17-2021 04:28:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Medical monitor_ Per report, subject was hospitalized. Pls provide information on workup performed(tropinins, X-ray, ECG)in a FU form. Thanks.
Feb-11-2021 08:42:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 14:28:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

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Header Text: C4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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Feb-10-2021 14:28:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> worsening of paroxysmal atrial fibrillation	New Information
Feb-10-2021 09:32:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: subject has atrial fibrillation noted in MedHx CRF. Does this reflect a worsening of the subject's underlying condition? if so pls update AE term to reflect this. Consider change causality to known underlying hx of atrial fib. Thanks
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> paroxysmal atrial fibrillation	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-23-2021 14:04:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 12:47:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated
Feb-23-2021 12:47:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/14/2021 UNK:UNK	updated
Feb-22-2021 16:14:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: Onset Date in Safety Database is 14-JAN-2021 however onset date reported in CRF is 3/FEB/2021. Please review and update accordingly. If safety update is required, please submit a follow-up form.

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Feb-08-2021 15:49:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021 UNK:UNK	Transcription Error
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-08-2021 15:49:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For paroxysmal atrial fibrillation End Date & Time 04/Feb/2021 UNK:UNK is before the Start Date & Time 05/Feb/2021 UNK:UNK.
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/4/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?****If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
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Feb-22-2021 16:10:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Feb-22-2021 16:10:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-22-2021 13:41:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE worsening of paroxysmal atrial fibrillation : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-22-2021 13:41:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	updated
Feb-22-2021 13:41:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associ- ated with congenital anom- aly or birth defect?  NO  Did this serious event resul- t in death?  NO  Did this serious event requ- ire or prolong hospitalizati- on?  YES  Did this serious event resul- t in persistent or significan- t disability/incapacity?  NO  Is this serious event life thr- eatening?  NO	updated

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			Other medically important serious event	
			NO	
Feb-22-2021 13:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Clinical has issued query requesting same information.
Feb-18-2021 01:08:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021148943 worsening of paroxysmal atrial fibrillation(onset date:14Jan2021)was reported as serious in Safety database but nonserious in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form
Feb-12-2021 11:05:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per email correspondence, event meets seriousness criteria due to overnight hospitalization. Please review and update as needed.
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?***If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-10-2021 14:29:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(	Changed Information

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			s), this event is due to:  OTHER  <i>If Other, specify:</i>  hx of atrial fibrillation	
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  aging myocytes	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-08-2021 15:47:20 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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Time (US & Canada)

(b) (4), (b) (6)

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-08-2021 15:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Feb-22-2021 16:10:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021148943	Initial Entry



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**1. Category:**

Date	Location	User	Value	Reason
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-04-2021 04:03:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	SDB updated
Mar-03-2021 13:52:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Mar-03-2021 08:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Pending SDB update
Mar-03-2021 08:19:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The correct term is 'intestinal obstruction.' This was updated in a follow up safety report faxed on 02Mar21.
Mar-03-2021 07:42:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON 1: The term in Safety database was updated to 'partial small bowel obstruction' while the term in AE CRF was also updated to 'intestinal obstruction'.If the

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				correct term is 'partial small bowel obstruction', please edit as such.
Mar-03-2021 07:26:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	GERD is a recent occurrence and subject denies history.
Mar-02-2021 20:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Reissued:Opened	GPDClin: Thank you for adding hiatal hernia to MHx! However, GERD was not added to MHx, please add in.
Mar-02-2021 13:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Mar-02-2021 13:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> intestinal obstruction	New Information
Mar-02-2021 04:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2021195271, the term was reported as 'intestinal blockage' in Safety database while updated to 'partial small bowel obstruction' in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up form.
Mar-01-2021 15:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Added GERD and Hiatal Hernia to medical history.
Feb-28-2021 10:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: SAE reported ".....to treat GERD from his hiatal hernia." Both terms are not in MHx or AE log. Please add those in proper CRF modules.

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Feb-26-2021 12:18:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> partial small bowel obstruction	New Information
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> intestinal blockage	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/9/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/19/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-24-2021 02:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 18:03:24 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE intestinal blockage: Response

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Time (US & Canada)				to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> 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/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	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
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> NO</p>	Initial Entry

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
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Feb-22-2021 18:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Feb-24-2021 02:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021195271	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-04-2021 15:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Mar-04-2021 15:19:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	pt. denies any history of GERD. This is a new event and therefore an AE.
Mar-04-2021 11:54:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Medical Monitor_ pls advise if GERD refers to a prior event before enrollment and update MedHx CRF as appropriate. Thanks
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> GERD	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)



Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

			s), this event is due to:  OTHER  If Other, specify:  acid in wrong location	
--	--	--	--	--

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-02-2021 13:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Jan-19-2021 15:45:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-19-2021 15:45:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Jan-19-2021 15:45:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Jan-19-2021 15:45:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Jan-19-2021 15:45:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> influenza vaccine	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Jan-19-2021 15:45:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/27/2020	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-02-2021 12:41:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/15/2021	Transcription Error
Jan-15-2021 12:42:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/14/2021	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail  
History

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

**Site Name:** (1178) Clinical Research Associates Inc

**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-15-2021 12:42:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-15-2021 12:42:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-15-2021 12:42:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national reco mmendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001**Visit:** Disposition - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1178**Subject No:** 11781122**Generated By:** (b) (4)**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1178) Clinical Research Associates Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-24-2021 18:34:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_36
Feb-24-2021 08:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-24-2021 08:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/15/ 2021	Transcription Error
Feb-23-2021 14:16:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7352983;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Jan-15-2021 12:42:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/14/ 2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

Jan-15-2021 12:42:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry
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**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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***1. Date of Visit***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-19-2021 15:43:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021	Initial Entry



**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF  
Audit Trail History

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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**I. Consent Was:**

Date	Location	User	Value	Reason
Jan-19-2021 15:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/19/2021	Initial Entry

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Jan-19-2021 15:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-19-2021 15:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-19-2021 15:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

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
Jan-20-2021 09:04:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-20-2021 09:04:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-20-2021 09:04:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 09:04:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-20-2021 09:04:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/19/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-20-2021 09:04:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR7H0J	Initial Entry

**5.a Sample ID**

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-20-2021 09:04:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR7H0J	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-20-2021 09:04:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSGFGP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 09:04:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSGFGP	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-20-2021 09:04:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSGFGR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 09:04:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSGFGR	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

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
Jan-20-2021 09:05:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-20-2021 09:05:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-20-2021 09:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 09:05:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-20-2021 09:05:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/19/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-20-2021 09:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR7H0H	Initial Entry

**5.a Sample ID**

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-20-2021 09:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR7H0H	Initial Entry

Header Text: C4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

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
Jan-19-2021 15:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-19-2021 15:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-19-2021 15:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-19-2021 15:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021 14:40	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-19-2021 15:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-19-2021 15:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

7. Route:

Date	Location	User	Value	Reason
Jan-19-2021 15:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-19-2021 15:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-19-2021 15:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-19-2021 15:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 15:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)



**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1178

**Subject No:** 11781122

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

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

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

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-01-2021 15:41:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/1/2021	Initial Entry

**Header Text:** C4591001**Visit:** V102\_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1178**Site Name:** (1178) Clinical Research Associates Inc**Subject No:** 11781122**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-01-2021 15:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-01-2021 15:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-01-2021 15:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 15:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-01-2021 15:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/1/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-01-2021 15:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR7SMY	Initial Entry

**5.a Sample ID**

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

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

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

**Site No:** 1178

**Site Name:** (1178) Clinical Research Associates Inc

**Subject No:** 11781122

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Mar-01-2021 15:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR7SMY	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1178

Subject No: 11781122

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1178) Clinical Research Associates Inc

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
Mar-01-2021 15:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of First Delay:  Feb/8/2021  Reason(s) for Temporary Delay of Vaccination  FEVER OR ACUTE ILLNESS	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Mar-01-2021 15:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Mar-01-2021 15:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Mar-01-2021 15:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/1/2021 14:08	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Mar-01-2021 15:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781122

Subject Initials: ---

Generated By: (b) (4)

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

6. Body Side:

Date	Location	User	Value	Reason
Mar-01-2021 15:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-01-2021 15:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-01-2021 15:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-01-2021 15:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-01-2021 15:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 15:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-26-2020 13:20:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-08-2020 17:44:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-08-2020 17:39:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-26-2020 13:20:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/26/2020	Initial Entry
Sep-08-2020 17:44:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/8/2020	Initial Entry
Sep-08-2020 17:39:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

090177e196ae3fa9\Final\Final On: 01-Apr-2021 05:21 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1178

**Subject No:** 11781122

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1178) Clinical Research Associates Inc

**Subject Initials:** ---

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

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**1. Casebook Signature**

Date	Location	User	Value	Reason
Nov-02-2020 09:54:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Stephan Sharp (b) (4)	<b>Data Entry:</b> Click Here to Enable	Initial Entry