

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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: 11781048

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 Aug/31/2020
----	--------------	--

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11781048]
2.	Birth Date:	(b) (6) 1961
3.	Sex:	FEMALE
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: 11781048

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	Aug/31/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1178

Subject No: 11781048

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
----	---	----------------

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1178

Subject No: 11781048

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	Aug/31/2020
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: 11781048

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[attention deficit disorder]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bipolar disorder]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[post menopausal]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[penicillin allergy]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[sulfa allergy]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1178

Subject No: 11781048

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:	Aug/31/2020
2.	Weight:	[230.0]
3.	Unit:	LB
4.	Height:	[65.0]
5.	Unit:	in
6.	Body Mass Index:	[38.3]

Vital Signs Details

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

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1178

Subject No: 11781048

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/31/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3fa7\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: 11781048

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 :	Aug/31/2020
2.	Randomization Number:	[246527]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1178

Subject No: 11781048

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: Aug/31/2020
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	[BPY88T]
5.b	Sample ID	[BPY88V]
5.c	Sample ID	[BPY88W]
5.d	Sample ID	[BNWNZW]
5.e	Sample ID	[BNWNZX]

090177e196ae3fa7\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: 11781048

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: Aug/31/2020
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	[BPY88S]
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090177e196ae3fa7\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: 11781048

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:	Aug/31/2020 11:01
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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1178

Subject No: 11781048

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

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](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781048

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/21/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1178

Subject No: 11781048

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/21/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1178

Subject No: 11781048

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/21/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1178

Subject No: 11781048

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/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPY8S2]
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090177e196ae3fa7\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: 11781048

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/21/2020 10:41
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

090177e196ae3fa7\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: 11781048

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/19/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1178

Subject No: 11781048

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/19/2020
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	[BPW3WY]
5.b	Sample ID	[BRVDT3]
5.c	Sample ID	[BRVDT4]

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

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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090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

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

Header Text: C4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: C4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: 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: 11781048

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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
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Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1178

Subject No: 11781048

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/19/2020
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: 11781048

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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

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	Sialolithiasis	Sep/20/2020 18:00	NO End Date Time: Nov/12/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Post operative infection (sialolithiasis removal)	Nov/18/2020 UNK:UNK	NO End Date Time: Nov/29/2020 UNK:UNK	Repeating Pages

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Sialolithiasis]
4.	Start Date Time:	Sep/20/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/12/2020 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).	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

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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: [Salivary stone]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[2020375644]

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Post operative infection (sialolithiasis removal)]
4.	Start Date Time:	Nov/18/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/29/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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: [microbes]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[2021041916]

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1178

Subject No: 11781048

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

[Back to Form](#)

Medication Error

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

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

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: 11781048

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.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

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.	Date:	//

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1178

Subject No: 11781048

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3fa7\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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781048

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

[Back to Form](#)

Radiation Treatment

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

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:03
Site No: 1178
Subject No: 11781048
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: 11781048

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: 11781048

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: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Lab Urinalysis

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

Lab Result

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

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

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: 11781048

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?	

090177e196ae3fa7\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: 11781048

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: 11781048

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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/18/2021
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: 11781048

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
----	---	---

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1178

Subject No: 11781048

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/18/2021
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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

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: 11781048	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: 11781048

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/25/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1178

Subject No: 11781048

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/25/2021
----	--------------	--

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: 11781048

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: 11781048

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/25/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1178

Subject No: 11781048

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/25/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3fa7\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: 11781048

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/25/2021
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	[BR7SDS]
5.b	Sample ID	[BSGFKP]
5.c	Sample ID	[BSGFKR]

090177e196ae3fa7\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: 11781048

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/25/2021
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	[BR7SDR]
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090177e196ae3fa7\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: 11781048

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/25/2021 13:25
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

090177e196ae3fa7\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: 11781048

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	Feb/22/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1178

Subject No: 11781048

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/22/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1178

Subject No: 11781048

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: Feb/22/2021
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	[BR7SL9]
-----	-----------	----------

090177e196ae3fa7\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: 11781048

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:	Feb/22/2021 10:46
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

090177e196ae3fa7\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: 11781048

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: 11781048

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: 11781048

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: 11781048

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: 11781048

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	Form: CONTACT OUTCOME
Visit: V105_MONTH18	Form Status: Not Started
Form Version: 22-Apr-2020 21:04	Site Name: (1178) Clinical Research Associates Inc
Site No: 1178	Subject Initials: ---
Subject No: 11781048	Generated Time (GMT): 29-Mar-2021 12:55
Generated By: (b) (4)	

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: 11781048

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: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/19/2020

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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: 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: 11781048

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: 11781048

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	Aug-31-2020 13:07:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Jan-25-2021 14:28:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

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	Jan-25-2021 14:28:08 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Stephan Sharp	Approved	Jan-20-2021 10:12:16 (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	Jan-19-2021 08:24:57 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephan Sharp	Approved	Oct-26-2020 10:17:50 (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.

090177e196ae3fa7\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: 11781048

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
Aug-31-2020 13:06:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 13:06:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781048

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
Aug-31-2020 13:07:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/31/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1178

Subject No: 11781048

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
Aug-31-2020 13:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11781048	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-31-2020 13:06:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1961	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-31-2020 13:07:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-31-2020 13:07:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 13:07:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3fa7\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: 11781048

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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I. Date of Visit

Date	Location	User	Value	Reason
Aug-31-2020 13:07:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1178

Subject No: 11781048

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
Aug-31-2020 13:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-31-2020 13:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-31-2020 13:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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.a

Date	Location	User	Value	Reason
Aug-31-2020 13:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History T Depression erm: Start Date: UNK/UNK/2 011 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 13:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 13:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Depression	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 13:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2011	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 13:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Date	Location	User	Value	Reason
Aug-31-2020 13:14:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 er: Medical History attention deficit Term: disorder Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 13:14:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 13:14:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: attention deficit disorder	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 13:14:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 13:14:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-31-2020 13:16:33 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Time (US & Canada)			Medical History Term: bipolar disorder Start Date: UNK/UNK/2010 Ongoing: YES	
--------------------	--	--	---	--

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 13:16:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 13:16:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bipolar disorder	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 13:16:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 13:16:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-31-2020 13:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 4 Medical History Term: post menopausal	Transcription Error

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			Start Date: UNK/UNK/2005	
			Ongoing: YES	
Aug-31-2020 13:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: post menopausal Start Date: UNK/UNK/2006 Ongoing: YES	Initial Entry

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 13:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 13:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: post menopausal	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 13:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Transcription Error
Aug-31-2020 13:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2006	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 13:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

I.e

Date	Location	User	Value	Reason
Sep-01-2020 07:34:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 5 Medical History Term: penicillin allergy Start Date: UNK/UNK/1970 Ongoing: YES	Transcription Error
Aug-31-2020 13:18:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: penicillin allergy Start Date: UNK/UNK/1970 Ongoing: YES	Initial Entry

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 13:18:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 09:47:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Clos ed	Discrepancy has been closed.
Sep-01-2020 07:34:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Sep-01-2020 07:34:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: penicillin aller gy	Transcription Error
Aug-31-2020 17:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Open ed	Clarify PENCILLIN ALLERGY as follows...Should spelling be PENICILLIN ALLERGY? If so,edit. Otherwise, clarify. Thank you.
Aug-31-2020 13:18:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: penicillin aller gy	Initial Entry

1.e Start Date:

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Date	Location	User	Value	Reason
Aug-31-2020 13:18:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1970	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 13:18:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-31-2020 13:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: sulfa allergy Start Date: UNK/UNK/1970 Ongoing: YES	Initial Entry

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 13:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 13:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sulfa allergy	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 13:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1970	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 13:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3fa7\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: 11781048

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
Aug-31-2020 13:10:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 230.0	Initial Entry

3. Unit:

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

4. Height:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 65.0	Initial Entry

5. Unit:

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

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 38.3	Initial Entry

090177e196ae3fa7\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: 11781048

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

7.a

Date	Location	User	Value	Reason
Aug-31-2020 13:10:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 97.9 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.9	Initial Entry

7.a Unit:

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

7.a Temperature Location:

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

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-31-2020 13:10:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-31-2020 13:10:16 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fa7\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: 11781048

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
Aug-31-2020 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-31-2020 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 246527	Initial Entry

090177e196ae3fa7\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:** 11781048**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
Aug-31-2020 14:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 14:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-31-2020 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 14:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 14:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPY88T	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 14:43:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPY88T	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-31-2020 14:43:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPY88V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 14:43:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPY88V	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-31-2020 14:43:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPY88W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 14:43:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPY88W	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-31-2020 14:43:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNWNZW	Initial Entry

090177e196ae3fa7\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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 14:43:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWNZW	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-31-2020 14:44:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNWNZX	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 14:44:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWNZX	Initial Entry

090177e196ae3fa7\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:** 11781048**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
Aug-31-2020 14:44:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 14:44:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-31-2020 14:44:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 14:44:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 14:44:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 14:44:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPY88S	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 14:44:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPY88S	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1178

Subject No: 11781048

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
Aug-31-2020 13:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-31-2020 13:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-31-2020 13:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-31-2020 13:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020 11:01	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-31-2020 13:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-31-2020 13:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3fa7\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: 11781048

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
Aug-31-2020 13:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-31-2020 13:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Aug-31-2020 13:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3fa7\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: 11781048

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
Aug-31-2020 13:11:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781048

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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I. Date of Visit

Date	Location	User	Value	Reason
Sep-21-2020 11:30:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1178

Subject No: 11781048

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-21-2020 11:30:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 11:30:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.8 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 11:30:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-21-2020 11:30:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-21-2020 11:30:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae3fa7\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: 11781048

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

Date	Location	User	Value	Reason
Sep-21-2020 11:30:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-21-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-21-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-21-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-21-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-21-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-21-2020 11:31:02 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-21-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-21-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-21-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fa7\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:** 11781048**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-21-2020 10:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 10:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-21-2020 10:53:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 10:52:45 (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-21-2020 10:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-21-2020 10:53:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPY8S2	Initial Entry

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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 10:53:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPY8S2	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1178

Subject No: 11781048

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-21-2020 11:32:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-21-2020 11:32:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-21-2020 11:32:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 11:32:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020 10:41	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 11:32:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-21-2020 11:32:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1178

Subject No: 11781048

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-21-2020 11:32:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-21-2020 11:32:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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-21-2020 11:32:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781048

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: ---

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 14:30:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	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:** 11781048**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
Oct-19-2020 10:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-19-2020 10:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-19-2020 10:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 10:21:49 (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-19-2020 10:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-19-2020 10:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPW3WY	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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 10:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPW3WY	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 10:22:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRVDT3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 10:22:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRVDT3	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 10:22:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRVDT4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 10:22:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRVDT4	Initial Entry

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Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1178

Subject No: 11781048

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-19-2020 14:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 14:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 14:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781048

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1178
Subject No: 11781048
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
Jan-19-2021 08:29:51 (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: 11781048

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-11-2021 08:37:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sialolithiasis	New Information
Oct-23-2020 23:16:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Appreciate the prompt response. Thank you.
Oct-23-2020 11:50:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	follow-up report submitted
Oct-22-2020 12:36:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	If test was NOT performed or NOT available, please add this information as well so it is reflected in the SAE case narrative. Thank you.
Oct-21-2020 16:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no report of Covid testing
Oct-21-2020 10:22:14 (UTC-06:00) Central	ACV0PFEINFP6000	Giselle Castillo	Query 1: Opened	COVID testing has not been reported in

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781048

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

Time (US & Canada)		(b) (4)		the SAE submitted to safety. Please submit a follow-up SAE form to provide whether COVID testing was performed (yes/no) and if yes, the results. Thank you.
Sep-29-2020 08:24:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: salivary gland stone	New Information
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Salivary gland - Left submandibular swelling	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-01-2020 14:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Oct-01-2020 09:34:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-30-2020 20:20:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please verify if the AE occurred at the evening right before the day of the 2nd study dose.
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/20/2020 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-19-2021 08:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	New Information

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Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1178**Subject No:** 11781048**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1178) Clinical Research Associates Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55

			Nov/12/2020 UNK:UNK	
Nov-10-2020 19:54:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-10-2020 08:27:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ongoing
Nov-09-2020 16:41:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Grade 2 SALIVARY GLAND STONE is reported as ONGOING since 20SEP2020. Please clarify if this AE remains ONGOING. If RESOLVED, please provide STOP DATE and update OUTCOME accordingly.
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-01-2020 14:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 3: Closed	Response satisfies query

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781048

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

Oct-01-2020 09:33:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Per SAE report subject was hospitalized
Sep-30-2020 20:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 3: Opened	GPDClin: Per SAE report, the condition led to ER visit not hospitalization. Please clarify.
Sep-30-2020 05:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event recorded in AE CRF
Sep-30-2020 05:30:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-29-2020 08:36:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? 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	Changed Information

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781048

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

			serious event YES	
Sep-29-2020 08:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE salivary gland stone: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-29-2020 08:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-29-2020 08:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associa ted with congenital anomal y or birth defect? NO Did this serious event resul t in death? NO Did this serious event requi re or prolong hospitalizatio n? YES Did this serious event resul t in persistent or significant disability/incapacity? NO Is this serious event life thr eatening? NO Other medically important serious event NO	New Information

090177e196ae3fa7\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: 11781048

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site Name: (1178) Clinical Research Associates Inc

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

Sep-29-2020 06:40:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020375644 salivary gland stone(onset date:20Sep2020)was reported as serious in Safety database. Please confirm if this is the same event and seriousness should be updated to Yes. If safety update is required, submit a follow-up SAE Form.
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-29-2020 08:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER <i>If Other, specify:</i> Salivary stone	New Information
Sep-21-2020 13:29:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: CONCOMITANT DRUG TRE ATMENT	Changed Information

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

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Subject Initials: ---

Generated By: (b) (4)

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Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-29-2020 08:28:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-19-2021 08:25:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Jan-19-2021 08:25:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESO LVED	New Information
Jan-19-2021	ACV0PFEINFP6000	auto query	Query 3: Opened	For AE salivary gland stone:

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781048

Generated By: (b) (4)

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Form Status: Data Complete, Frozen

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

08:24:57 (UTC-06:00) Central Time (US & Canada)		(autoquery)		Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-01-2020 14:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Closed	Response satisfies query
Oct-01-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Medical Records have been requested. Will update when available
Sep-30-2020 23:18:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-30-2020 20:16:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Opened	GPDClin: For this condition, the treatment goal is to remove the stone using ono-invasive or invasive methods. Without that, it can not be resolved. Please obtain the treatment received and verify the outcome.
Sep-30-2020 07:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-30-2020 07:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RES OLVING	Changed Information
Sep-30-2020 05:33:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020375644,outcome was reported as Recovering/Resolving to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct

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				outcome. If safety update is required, please submit a follow-up form.
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/ NOT RESOLVED	Initial Entry

Header Text: C4591001

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Subject No: 11781048

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1178) Clinical Research Associates Inc

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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-21-2020 11:40:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-30-2020 05:30:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020375644	Initial Entry

Header Text: C4591001

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Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-09-2021 15:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Feb-04-2021 08:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	To clarify, the cultures referenced are for a different SAE (2020375644), which is for the original Salivary Gland Stone. Sorry for the confusion.
Feb-03-2021 12:46:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thanks for confirming. Pls submit this information in a FU form so it is added to the safety report. Thanks
Feb-02-2021 07:36:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Group A Beta-Hemolytic Culture, Blood Cultures X 2 performed on

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Generated By: (b) (4)

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				22Sep2020.
Feb-01-2021 17:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	CLINICAL_ pls advise if any cultures were taken during hospital stay. Thanks.
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Post operative infection (sialolith iasis removal)	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/18/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/29/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
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Jan-20-2021 06:10:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 08:32:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birt h defect? NO Did this serious event result in d eath? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in p ersistent or significant disability /incapacity? NO Is this serious event life threaten ing? NO Other medically important serio us event YES	Changed Information
Jan-19-2021 08:31:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-19-2021 08:31:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birt h defect?	Transcription Error

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Subject No: 11781048

Generated By: (b) (4)

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			<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>NO</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>	
Jan-19-2021 08:30:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>YES</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	Transcription Error
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.

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Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Post operative infection (sialolithiasis removal): Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Did this serious event require or prolong hospitalization? YES	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 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: microbes	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1178

Subject No: 11781048

Generated By: (b) (4)

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Subject Initials: ---

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-21-2021 10:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Jan-20-2021 07:59:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-20-2021 07:59:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Jan-19-2021 22:06:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Per SAE report, antibiotics were given . If yes, please make change to "Yes".
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-19-2021 08:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1178

Subject No: 11781048

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1178) Clinical Research Associates Inc

Subject Initials: ---

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

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-20-2021 06:10:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021041916	Initial Entry

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

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Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-28-2021 10:39:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-28-2021 10:12:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-28-2021 10:12:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/18/2021	Transcription Error
Jan-28-2021 10:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, subject was contacted on 18Jan21. Please review and update as needed.
Jan-19-2021 08:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/14/2021	Initial Entry

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Header Text: C4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1178**Subject No:** 11781048**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[Back to Form](#)**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Jan-19-2021 08:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 08:33:33 (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-19-2021 08:33:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1178

Subject No: 11781048

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-24-2021 01:25:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_36
Feb-23-2021 13:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error
Feb-23-2021 13:05:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Jan/18 /2021	Transcription Error
Feb-23-2021 12:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7352745;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-19-2021 08:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Jan/14 /2021	Initial Entry

2. Primary Reason for Unblinding:

090177e196ae3fa7\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: 11781048

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

Date	Location	User	Value	Reason
Jan-19-2021 08:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1178

Subject No: 11781048

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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I. Date of Visit

Date	Location	User	Value	Reason
Jan-25-2021 14:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021	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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-25-2021 14:28:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/25/2021	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: 11781048

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-25-2021 14:28:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-25-2021 14:28:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-25-2021 14:28:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-25-2021 14:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-25-2021 14:29:04 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fa7\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:** 11781048**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
Jan-25-2021 15:32:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-25-2021 15:32:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-25-2021 15:32:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 15:32:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-25-2021 15:32:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 15:32:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7SDS	Initial Entry

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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 15:32:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR7SDS	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-25-2021 15:32:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSGFKP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 15:32:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSGFKP	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-25-2021 15:32:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSGFKR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 15:32:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSGFKR	Initial Entry

090177e196ae3fa7\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:** 11781048**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
Jan-25-2021 15:33:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-25-2021 15:33:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-25-2021 15:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 15:33:05 (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-25-2021 15:33:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 15:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7SDR	Initial Entry

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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 15:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR7SDR	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1178

Subject No: 11781048

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-25-2021 14:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-25-2021 14:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021 13:25	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3fa7\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: 11781048

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

7. Route:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-25-2021 14:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-25-2021 14:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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-25-2021 14:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3fa7\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: 11781048

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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I. Date of Visit

Date	Location	User	Value	Reason
Mar-01-2021 00:41:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-26-2021 08:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	We were closed the week of 15Feb2021 through 19Feb2021 due to inclement weather. This subject was seen on 22Feb2021 when we reopened.
Feb-26-2021 01:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit V102_VAX4 is out of window for 5 days from V101_VAX3 Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Feb-22-2021 15:20:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Ent ry: Feb/22/20 21	Initial Entry

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-22-2021 15:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-22-2021 15:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-22-2021 15:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/22/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-22-2021 15:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-22-2021 15:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-22-2021 15:20:33 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1178

Site Name: (1178) Clinical Research Associates Inc

Subject No: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-22-2021 15:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-22-2021 15:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-22-2021 15:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

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:** 11781048**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
Feb-22-2021 12:37:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-22-2021 12:37:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-22-2021 12:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 12:37:43 (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-22-2021 12:37:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/22/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 12:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7SL9	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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 12:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR7SL9	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1178

Subject No: 11781048

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
Feb-22-2021 15:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-22-2021 15:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-22-2021 15:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-22-2021 15:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/22/2021 10:46	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-22-2021 15:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-22-2021 15:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3fa7\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: 11781048

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

7. Route:

Date	Location	User	Value	Reason
Feb-22-2021 15:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-22-2021 15:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-22-2021 15:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-22-2021 15:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Feb-22-2021 15:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3fa7\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: 11781048

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-19-2020 14:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-31-2020 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-31-2020 13:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-19-2020 14:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry
Aug-31-2020 13:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry
Aug-31-2020 13:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae3fa7\Final\Final On: 01-Apr-2021 05:21 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - 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: 11781048

Subject Initials: ---

Generated By: (b) (4)

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-26-2020 10:17:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Stephan Sharp (b) (4)	Data Entry: Click Here to Enable	Initial Entry