

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:31

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[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	01 DEC 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: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/16/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10061272]
2.	Birth Date:	(b) (6) 2007
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[Form Comments](#)

[eCRF Audit Trail History](#)

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	
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Exclusion Criteria Met

2.a	Description of Exclusion Criterion Met	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
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090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Dec/16/2020
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:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[eCRF Audit Trail History](#)**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Attention Deficit Hyperactivity Disorder]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Post Traumatic Stress Disorder]
	Start Date:	Nov/6/2015
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Disruptive Mood Dysregulation Disorder]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Separation Anxiety Disorder]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Recurring Insomnia]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Aggressive Behaviors]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Recurring Nightmares]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	---	---

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Dec/16/2020
2.	Weight:	[148.0]
3.	Unit:	LB
4.	Height:	[68.0]
5.	Unit:	in
6.	Body Mass Index:	[22.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[99.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**eCRF Audit Trail History****Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Dec/16/2020
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:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Dec/16/2020
2.	Randomization Number:	[22821]
3.	Randomization Group:	[]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**eCRF Audit Trail History****Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BCSY28]
5.b	Sample ID	[BCSY29]
5.c	Sample ID	[BS8WKK]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRL0NW]
-----	-----------	----------

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**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:	Dec/16/2020 12:07
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: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Dec/19/2020
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/6/2021
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**eCRF Audit Trail History****Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/6/2021
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:	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/6/2021
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	[BRBCD9]
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090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[Form Comments](#)

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	Not Done _____	Comments
2.	Treatment Name	Not Done _____ []	Comments
3.	Formulation:	Not Done _____	Comments
4.	Dose Date Time:	Not Done _____ //	Comments
5.	Anatomical Location:	Not Done _____	Comments
6.	Body Side:	Not Done _____	Comments
7.	Route:	Not Done _____	Comments
8.	Actual Dose:	Not Done _____ []	Comments
9.	Unit:	Not Done _____	Comments
10.	Timeframe Subject Was Observed	Not Done _____	Comments
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done _____	Comments

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[Form Comments](#)

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	Not Done _____	Comments
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	Comments
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	Comments
3.	Injection Site Location:	Not Done	Comments
4.	Injection Site Body Side:	Not Done	Comments
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done	Comments
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done	Comments
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done	Comments

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRBMZY]
5.b	Sample ID	[BRBMZZ]
5.c	Sample ID	[BJ7MY9]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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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090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V5_MONTH12_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** DATE OF VISIT**Form Status:** Not Started**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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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090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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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090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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:	[]
----	------------------------	-----

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

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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090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

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 Version: 06-Jul-2020 21:52

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ILLNESS DETAILS

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Illness Details

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

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT Visit

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

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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090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT - REPEAT SWAB

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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 Version: 10-Oct-2020 15:57

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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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090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Logs

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Worsening of Depression	Dec/23/2020 UNK:UNK	NO End Date Time: Jan/18/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Worsening of anxiety	Dec/23/2020 UNK:UNK	NO End Date Time: Jan/18/2021 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Contusion left elbow	Feb/5/2021 UNK:UNK	YES	Repeating Pages

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[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)	[Worsening of Depression]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/18/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Stress]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021009347]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of anxiety]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/18/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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: [Stress]	
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN	Comments
11.	Was a Concomitant Medication given?	YES	
12.	Was a Non-Drug Treatment given?	YES	
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED	
14.	Did the adverse event cause the subject to be discontinued from the study?	NO	
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021009347]	

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Medication Error

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

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

#	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 Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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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:	//

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

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

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Concomitant Medications

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

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

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

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

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

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: UNPLANNED VISIT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 20-Feb-2021 02:16

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form Version:** 20-Feb-2021 02:14**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Not Started**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**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:	

Header Text: c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form Version:** 10-Dec-2020 02:26**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Not Started**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**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?	

Header Text: c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form Version:** 10-Oct-2020 15:57**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - MONTH 1**Form Status:** Not Started**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**Contact Outcome**

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

Header Text: c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form Version:** 10-Oct-2020 16:01**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - MONTH 6**Form Status:** Not Started**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**Contact Outcome**

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 14-Jan-2021 02:29

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Not Started**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Jan/6/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 10-Dec-2020 02:27

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Treatment Unblinded

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Withdrawal Of Consent

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

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Jan/6/2021

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Casebook Signature Form

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

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** Investigator Signature - Unscheduled**Form Version:** 22-Apr-2020 21:04**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** CASEBOOK SIGNATURE FORM**Form Status:** Data Complete, Signed, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
James Peterson	Approved	Mar-11-2021 17:31:38 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, JamesPeterson, 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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
Form	Feb-25-2021 10:23:02 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	
Form	Dec-22-2020 09:49:26 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
Form	Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Patient no longer meets exclusion criteria #1.
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
1	Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient no longer meets exclusion criteria #1. Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
2	Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient no longer meets exclusion criteria #1. Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
3	Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient no longer meets exclusion criteria #1. Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
4	Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient no longer meets exclusion criteria #1. Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
5	Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient no longer meets exclusion criteria #1. Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
6	Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient no longer meets exclusion criteria #1. Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
7	Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient no longer meets exclusion criteria #1. Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
8	Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient no longer meets exclusion criteria #1. Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
9	Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient no longer meets exclusion criteria #1. Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
10	Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient no longer meets exclusion criteria #1. Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
11	Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient no longer meets exclusion criteria #1. Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Done
Form	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[Back to Form](#)

Item	Date	User	Comment
1	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Done
1	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[Back to Form](#)

Item	Date	User	Comment
2.a	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Done
2.a	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[Back to Form](#)

Item	Date	User	Comment
2.b	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. <hr/> Not Done
2.b	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. <hr/> Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

[Back to Form](#)

Item	Date	User	Comment
2.c	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. <hr/> Not Done
2.c	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. <hr/> Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
2.d	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Done
2.d	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
2.e	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Done
2.e	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
2.f	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Done
2.f	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
2.g	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Done
2.g	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
2.h	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Done
2.h	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
3	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Done
3	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
4	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Done
4	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
5.a	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Done
5.a	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
5.b	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Done
5.b	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
5.c	Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. <hr/> Not Done
5.c	Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Subject no longer eligible for 2nd IP Vaccination and is being followed for safety. <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Item	Date	User	Comment
10	Jan-13-2021 14:00:24 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Drug withdrawn due to Adverse Events

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Status: Data Complete, Signed, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
James Peterson	Approved	Mar-11-2021 17:31:38 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, JamesPeterson, 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.

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:31

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Dec-22-2020 09:48:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 09:48:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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1. Consent Was:

Date	Location	User	Value	Reason
Dec-22-2020 09:48:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Dec/16/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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1. Subject ID

Date	Location	User	Value	Reason
Dec-22-2020 09:48:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10061272	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Dec-22-2020 09:48:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 2007	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Dec-22-2020 09:49:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Dec-22-2020 09:49:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 09:49:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRICAN AMERICA N	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-28-2021 23:43:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - updated PD tracker
Feb-26-2021 08:58:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirm correct
Feb-26-2021 02:03:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: Inclusion/Exclusion criteria have been completed. However, vaccination is completed. INC EXC CRF is expected with the form level comment of "Not Applicable" when the subject is completed vaccination. Please review and update else clarify.
Dec-22-2020 09:49:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Oct-2020 16:00**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**2.a**

Date	Location	User	Value	Reason
Feb-25-2021 10:23:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Crit Other medical or psychiatric erio condition incl. recent (within n De past year) or active suicidal i scrip deation/behavior/lab abnorm tion: ality that may increase the ris k of study participation	Initial Entry

2.a Description of Exclusion Criterion Met

Date	Location	User	Value	Reason
Mar-05-2021 01:49:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Raised in error.
Mar-03-2021 06:11:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: Inclusion/Exclusion criteria have been completed. However, vaccination is completed. INC EXC CRF is expected with the form level comment of "Not Applicable" when the subject is completed vaccination. Please review and update else clarify.
Feb-25-2021 10:23:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Other medical or psychiatric condit ion incl. recent (within past year) o r active suicidal ideation/behavior/l ab abnormality that may increase t he risk of study participation	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Dec-22-2020 09:49:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-22-2020 09:49:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-22-2020 09:49:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Dec-22-2020 09:50:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 1 mber: Medical Hist Attention Deficit Hyp ory Term: eractivity Disorder Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Dec-22-2020 09:50:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 09:50:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Attention Deficit Hyperactivity Diso rder	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Dec-22-2020 09:50:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Dec-22-2020 09:50:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Dec-22-2020 09:50:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Te Depression rm: Start Date: UNK/UNK/20 14 Ongoing: YES	Initial Entry
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I.b Line/MH Number:

Date	Location	User	Value	Reason
Dec-22-2020 09:50:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 09:50:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Depression	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Dec-22-2020 09:50:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Dec-22-2020 09:50:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Dec-22-2020 09:51:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Te Anxiety rm:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

			Start Date:	UNK/UNK/2014	
			Ongoing:	YES	

1.c Line/MH Number:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 09:51:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anxiety	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Dec-22-2020 09:51:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Asthma Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

1.d Line/MH Number:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:14 (UTC-07:00) Mountain 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
Dec-22-2020 09:51:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Asthma	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-21-2021 10:32:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 5 ber: Medical Histo Post Traumatic Stre ry Term: ss Disorder Start Date: Nov/6/2015 Ongoing: YES	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

I.e Line/MH Number:

Date	Location	User	Value	Reason
Jan-21-2021 10:32:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 10:32:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Post Traumatic Stress Disorder	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 10:32:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/6/2015	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Jan-21-2021 10:32:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Jan-21-2021 10:33:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Disruptive Mood Dysregulation Disorder Start Date: UNK/UNK/2012 Ongoing: YES	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

I.f Line/MH Number:

Date	Location	User	Value	Reason
Jan-21-2021 10:33:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 10:33:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Disruptive Mood Dysregulation Dis order	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 10:33:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Jan-21-2021 10:33:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Jan-21-2021 10:34:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 7 ber: Medical Histor Separation Anxiet y Term: y Disorder Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Jan-21-2021 10:34:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 10:34:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Separation Anxiety Disorder	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 10:34:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Jan-21-2021 10:34:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Jan-21-2021 10:34:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 8 : Medical History T Recurring Inso erm: mnia Start Date: UNK/UNK/201 4 Ongoing: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

1.h Line/MH Number:

Date	Location	User	Value	Reason
Jan-21-2021 10:34:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 10:34:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Recurring Insomnia	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 10:34:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Jan-21-2021 10:34:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Feb-18-2021 11:46:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 9 Medical History Term: Aggressive Behaviors Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/2017	Transcription Error

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Jan-21-2021 10:34:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Aggressive Behaviors Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry
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090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

1.i Line/MH Number:

Date	Location	User	Value	Reason
Jan-21-2021 10:34:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 10:34:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aggressive Behaviors	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 10:34:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Feb-20-2021 13:00:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 11:46:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-18-2021 11:46:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2017	Transcription Error
Feb-16-2021 14:00:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source documents stop date is UNK2017. Please confirm or clarify.
Jan-21-2021 10:34:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Date	Location	User	Value	Reason
Jan-21-2021 10:35:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: Recurring Night mares Start Date: UNK/UNK/201 5 Ongoing: YES	Initial Entry

1.j Line/MH Number:

Date	Location	User	Value	Reason
Jan-21-2021 10:35:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 10:35:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Recurring Nightmares	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 10:35:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Jan-21-2021 10:35:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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

Date	Location	User	Value	Reason
Dec-22-2020 09:51:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HI V POSITIVE	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:29**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Dec-22-2020 11:01:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-22-2020 11:01:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020	Transcription Error
Dec-22-2020 09:55:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital Signs Date is not the same as Vaccination Date in the same visit. Please review and update as appropriate or clarify.
Dec-22-2020 09:51:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/6/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 148.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 68.0	Initial Entry

5. Unit:

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:29**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Dec-22-2020 09:51:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Dec-22-2020 09:51:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 99.1 Temperature Unit: F Temperature Locati ORAL CAVI on:: TY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 99.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

7.a Temperature Location:

Date	Location	User	Value	Reason
Dec-22-2020 09:51:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-22-2020 09:52:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Dec-22-2020 09:52:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-22-2020 09:52:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Dec-22-2020 09:52:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Dec-22-2020 09:52:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Dec-22-2020 09:52:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:23

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

			d Identifier:	
			Test::	Choriogonadotropin Beta_PX113
			Result::	NEGATIVE
			Not Done::	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-22-2020 09:52:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Dec-22-2020 09:52:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Dec-22-2020 09:52:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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1. Randomization Date :

Date	Location	User	Value	Reason
Dec-22-2020 09:52:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Dec-22-2020 09:52:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22821	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 09:53:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 09:53:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-22-2020 09:53:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 09:53:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 09:53:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 09:53:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BCSY28	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Dec-22-2020 09:53:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BCSY28	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-22-2020 09:54:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BCSY29	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 09:54:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BCSY29	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-22-2020 09:54:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS8WKK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 09:54:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS8WKK	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 09:54:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 09:54:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-22-2020 09:54:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 09:54:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 09:54:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 09:54:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRL0NW	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Dec-22-2020 09:54:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRL0NW	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-22-2020 09:55:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-22-2020 09:55:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-22-2020 09:55:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-22-2020 09:55:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020 12:07	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-22-2020 09:55:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-22-2020 09:55:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

7. Route:

Date	Location	User	Value	Reason
Dec-22-2020 09:55:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-22-2020 09:55:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 09:55:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Dec-22-2020 09:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DIA RY COLLECTED FOR THIS SUBJ ECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-07-2021 09:18:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sympt NO oms present on the last day t he Subject Diary was comple ted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGUE	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing ? NO Stop Date: Dec /19/ 2020	
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2.b Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Ongoing? NO Stop Date: Dec/19/2020	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

2.c Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH ILL S Were fever or systemic symp NO toms present on the last day t he Subject Diary was comple ted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sym NO ptoms present on the last da y the Subject Diary was co mpleted?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sym NO ptoms present on the last da y the Subject Diary was co mpleted?:	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:04**2.f Symptom:**

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE ED MUSC LE PAIN Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOIN T PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOINT PAI N	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction NO s present on the last day the Subject Diary was complete d?:	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 09:19:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:27**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-07-2021 09:20:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-07-2021 09:20:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.5 Temperature Unit: F Temperature Locat ORAL CAVI ion:: TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-07-2021 09:20:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jan-07-2021 09:20:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jan-07-2021 09:20:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Jan-07-2021 09:20:37
(UTC-07:00) Mountain
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:** 10-Dec-2020 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-07-2021 09:20:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-07-2021 09:20:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-07-2021 09:20:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-07-2021 09:20:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-07-2021 09:20:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-07-2021 09:20:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:23

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

			d Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 09:20:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-07-2021 09:20:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-07-2021 09:20:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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1. Data Origin

Date	Location	User	Value	Reason
Jan-07-2021 09:20:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-07-2021 09:20:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-13-2021 14:45:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-08-2021 06:05:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-07-2021 09:20:59 (UTC-07:00) Mountain 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-07-2021 09:20:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection: Jan/6/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061272

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:04

Jan-13-2021 14:45:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRBCD9	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 14:45:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRBCD9	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae4049\Final\On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

7. Route:

Date	Location	User	Value	Reason
Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	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-07-2021 10:57:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-08-2021 10:39:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/8/2021	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-11-2021 01:45:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-10-2021 17:39:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject did not receive the second vaccine, so the vaccination diary was not completed.
Feb-09-2021 03:32:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7189105;Were medications to treat fever/pain given on the last day the Subject Diary was completed? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:04**2.a**

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicable Were fever or systemic sy Not mptoms present on the last Done day the Subject Diary was completed?:	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicable Were fever or systemic sy Not mptoms present on the last Appl day the Subject Diary was icabl completed?: e	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.b

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:04

Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Appl icabl e Were fever or systemic sy Not mptoms present on the last Done day the Subject Diary was completed?:	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Appl icabl e Were fever or systemic sy Not mptoms present on the last Appl day the Subject Diary was icabl completed?: e	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Appl icabl	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:04

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>Not Done</p>	
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom::</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>Not Applicable</p>	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Not Applicable</p>	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Not Done</p>	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Not Applicable</p>	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom::</p> <p>Not Applicable</p>	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:04

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Not Done
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom::	Not Applicable
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Not Applicable

2.d Symptom:

Date	Location	User	Value	Reason
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.e

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom::	Initial Entry
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Not Done

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:04

Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	Not Appl icabl e Not Appl icabl e	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry <

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Not Applicable
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2.f Symptom:

Date	Location	User	Value	Reason
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicable	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:04

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Not Applicable
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2.g Symptom:

Date	Location	User	Value	Reason
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

2.h Symptom:

Date	Location	User	Value	Reason
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-11-2021 01:46:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_02
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-10-2021 17:39:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject did not receive the second vaccine, so the vaccination diary was not completed.
Feb-09-2021 03:35:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7188914;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Injection Site Location:

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: Not Appli cable Were injection site reactio Not ns present on the last day t Done he Subject Diary was com pleted?:	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: Not Appli cable Were injection site reactio Not ns present on the last day t Appli he Subject Diary was com cable pleted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: Not Appli cable Were injection site reactio Not ns present on the last day t Done he Subject Diary was com pleted?:	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: Not Appli cable Were injection site reactio Not ns present on the last day t Appli he Subject Diary was com cable pleted?:	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-11-2021 01:50:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_03
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-10-2021 17:39:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject did not receive the second vaccine, so the vaccination diary was not completed.
Feb-09-2021 03:52:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7188984:Reactions Occur? is not expected to be Unknown or Not Applicable for 5.a to 5.c entry on this page. Please review and update appropriately or clarify.
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: Not Applicable Were injection site reactions present on the last day the Subject Diary was completed?: Not Done	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: Not Applicable Were injection site reactions present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-10-2021 17:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-08-2021 10:41:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-08-2021 10:41:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-08-2021 10:41:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-08-2021 14:43:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 10:41:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-08-2021 10:41:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-08-2021 14:43:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRBMZY	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Feb-08-2021 14:43:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRBMZY	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-08-2021 14:44:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRBMZZ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-08-2021 14:44:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRBMZZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-08-2021 17:49:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BJ7MY9	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-08-2021 17:49:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BJ7MY9	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Date	Location	User	Value	Reason
Jan-07-2021 09:29:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Date	Location	User	Value	Reason
Jan-07-2021 10:55:00 (UTC-07:00) Mountain 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: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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Date	Location	User	Value	Reason
Feb-09-2021 16:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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1. Category:

Date	Location	User	Value	Reason
Jan-07-2021 09:29:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-07-2021 09:29:24 (UTC-07:00) Mountain 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-28-2021 18:25:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-23-2021 15:54:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Will send in an updated form asap.
Feb-22-2021 20:31:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - please submit a SAE safety followup with information on subject's admission, treatment, and stop date of event 'Worsening of depression & anxiety', if available
Jan-29-2021 15:07:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Thank you. history of hospitalization has been added to SAE report
Jan-29-2021 14:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-25-2021 06:09:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPD Clin: Medhx form is unfrozen. Please update as appropriate. Thank you
Jan-20-2021 18:59:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirmed subject's history of hospitalizations - will update once med history is unlocked, CRA has been contacted to unlock.
Jan-10-2021 16:15:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please clarify if participant has/has not had previous hospitalizations (prior to study enrollment) for depression/anxiety and update medhx as appropriate.
Jan-07-2021 09:29:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Worsening of Depression	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-14-2021 17:01:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-13-2021 13:55:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient was allowed out of facility to come to visit 2 in person.
Jan-11-2021 14:07:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical V2 date is 06Jan21; however, SAE report (#2021009347) states that subject was hospitalized 05Jan21. Please confirm if subject attended V2 in person (on pass?) or if not, clarify how

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

				V2 urine sample was provided.
Jan-07-2021 09:29:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 01:51:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 15:55:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-23-2021 15:55:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/18/2021 UNK:UNK	New Information
Feb-18-2021 14:23:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source documents end date is captured as 18Jan2021 and AE is resolved. Please confirm and update SAE forms with end dates.
Jan-07-2021 09:29:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-07-2021 09:29:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

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

Date	Location	User	Value	Reason
Jan-21-2021 18:57:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for requested Covid test information.
Jan-20-2021 18:19:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	it was confirmed that subject was not tested prior to admission and has not been tested since admission. SAE follow-up sent on 1/14/21.
Jan-11-2021 07:21:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021009347] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-08-2021 02:33:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-07-2021 09:29:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Worsening of Depression: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-07-2021 09:29:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

			<p>with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability /incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
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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-07-2021 09:29:24 (UTC-07:00) Mountain 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
Feb-02-2021 10:14:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-29-2021 14:26:02	ACV0PFEINFP6000	auto query	Query 2: Answered	Transcription Error

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-07:00) Mountain Time (US & Canada)		(autoquery)		
Jan-29-2021 14:26:02 (UTC-07:00) Mountain 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> Stress	Transcription Error
Jan-29-2021 12:12:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Per source documents causality is reported as stress. Please confirm or clarify.
Jan-14-2021 15:25:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-13-2021 14:02:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-13-2021 13:53:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Jan-12-2021 17:41:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Per source documents causality is reported as stress. Please confirm or clarify.
Jan-10-2021 16:14:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	For alternative causality, please indicate any precipitating events leading to worsening depression (changes in family or social situations, traumatic events, ect.)
Jan-07-2021 10:51:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Transcription Error

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Time (US & Canada)			If Not Related to study treatment (s), this event is due to: OTHER <i>If Other, specify:</i> Pre-existing conditions	
Jan-07-2021 09:29:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-21-2021 18:58:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	subject has withdrawn from treatment
Jan-21-2021 02:22:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-20-2021 18:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated EOT CRF.
Jan-11-2021 07:17:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - Subject is eligible for VAX 2 in the future if medical delay (Sect 5.5) is approved; consider if current action taken with study treatment will be delayed or withdrawn.
Jan-08-2021 06:02:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Action Taken with Study Treatment is Drug withdrawn; however, EOT CRF is not started. Please review and update the data appropriately.
Jan-07-2021 09:29:24	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04(UTC-07:00) Mountain
Time (US & Canada)

(b) (4), (b) (6)

DRUG WITHDRAWN

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-07-2021 09:29:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-07-2021 09:29:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 15:55:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-23-2021 15:55:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Feb-23-2021 15:55:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Worsening of Depression: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.

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Header Text: c4591001

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

Date	Location	User	Value	Reason
Jan-07-2021 09:29:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-07-2021 10:50:50 (UTC-07:00) Mountain 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
Jan-08-2021 02:33:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021009347	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Jan-07-2021 10:55:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-07-2021 10:55:00 (UTC-07:00) Mountain 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
Jan-07-2021 10:55:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Worsening of anxiety	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-07-2021 10:55:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 01:49:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 15:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-23-2021 15:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	New Information

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

			Jan/18/2021 UNK:UNK	
Feb-18-2021 14:23:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source documents end date is captured as 18Jan2021 and AE is resolved. Please confirm and update SAE forms with end dates.
Jan-07-2021 10:55:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-07-2021 10:55:00 (UTC-07:00) Mountain 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
Jan-08-2021 02:33:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-07-2021 10:55:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Worsening of anxiety: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-07-2021 10:55:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

			ct?	
			NO	
			Did this serious event result in death?	
			NO	
			Did this serious event require or prolong hospitalization?	
			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Jan-07-2021 10:55:00 (UTC-07:00) Mountain 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
Feb-03-2021 10:03:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-29-2021 14:26:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Time (US & Canada)				
Jan-29-2021 14:26:29 (UTC-07:00) Mountain 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> Stress	Transcription Error
Jan-29-2021 12:12:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Per source documents causality is reported as stress. Please confirm or clarify.
Jan-13-2021 13:58:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Causality is stress
Jan-12-2021 17:40:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source documents causality is reported as stress. Please confirm or clarify.
Jan-07-2021 10:55:00 (UTC-07:00) Mountain 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> Pre-existing conditions	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 01:48:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Cl osed	Response satisfies query

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-20-2021 18:13:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: A nswere	Updated EOT CRF.
Jan-11-2021 22:24:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: O pened	The Adverse Event Action Taken is DRUG WITHDRAWN but reason for treatment discontinuation is not reported as ADVERSE EVENT or DEATH. Please review and clarify. (b) (4)
Jan-07-2021 10:55:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : DRUG WI THDRAW N	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-07-2021 10:55:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-07-2021 10:55:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 15:56:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

Header Text: c4591001

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Generated By: (b) (4)

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Feb-23-2021 15:56:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Feb-23-2021 15:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Worsening of anxiety: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Jan-07-2021 10:55:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-07-2021 10:55:00 (UTC-07:00) Mountain 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
Jan-08-2021 02:33:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021009347	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Feb-09-2021 16:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-09-2021 16:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-09-2021 16:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Contusion left elbow	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-09-2021 16:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/5/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-09-2021 16:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-09-2021 16:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-09-2021 16:52:59 (UTC-07:00) Mountain 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
Feb-09-2021 16:52:59 (UTC-07:00) Mountain 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
Feb-11-2021 21:16:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 13:06:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-11-2021 13:06:25 (UTC-07:00) Mountain 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: Fall on ice	New Information
Feb-09-2021 23:34:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Is this event related to study treatment" Is

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

				reported as 'Not Related', however response for, 'Please indicate what this event is due to' is missing. Kindly review and update.
Feb-09-2021 16:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-09-2021 16:52:59 (UTC-07:00) Mountain 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
Feb-09-2021 16:52:59 (UTC-07:00) Mountain 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
Feb-09-2021 16:52:59 (UTC-07:00) Mountain 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
Feb-09-2021 16:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 16:52:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Subject No: 10061272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

Time (US & Canada)	(b) (4), (b) (6)
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-20-2021 18:13:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-20-2021 18:13:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-20-2021 18:13:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ADVERSE EVENT	Initial Entry

090177e196ae4049\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061272**Generated By:** (b) (4)**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Jan-20-2021 18:13:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Dec-22-2020 09:52:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Dec-22-2020 09:49:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jan-20-2021 18:13:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/6/2021	Initial Entry
Dec-22-2020 09:52:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/16/2020	Initial Entry
Dec-22-2020 09:49:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/16/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061272

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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I. Casebook Signature

Date	Location	User	Value	Reason
Mar-11-2021 17:14:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry