

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/25/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10481032]
2.	Birth Date:	(b) (6)/1974
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/25/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/25/2020
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: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[gastritis]
	Start Date:	May/UNK/2020
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hiatal hernia]
	Start Date:	May/UNK/2020
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[post menopausal]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[muscle spasms]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[degenerative disc disease]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bipolar disorder]
	Start Date:	UNK/UNK/2001
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypothyroidism]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[sleep apnea]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[difficulty with sleeping]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tardive Diskinesia]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[akathisia]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[obesity]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/25/2020
2.	Weight:	[180.0]
3.	Unit:	LB
4.	Height:	[65.0]
5.	Unit:	in
6.	Body Mass Index:	[30.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[99.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Lab Urinalysis

1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	[]	
5.	Specimen Type:		

Lab Result

6.a	Sponsor ID:	[113]	Comments
	Test:	Choriogonadotropin Beta_PX113	
	Result:		Comments
	Not Done:	NOT DONE	Comments

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/25/2020
2.	Randomization Number:	[64823]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/25/2020
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	[BP3LC2]
5.b	Sample ID	[BP3LC1]
5.c	Sample ID	[BP3LC0]
5.d	Sample ID	[BPL2RB]
5.e	Sample ID	[BPL2R9]

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/25/2020
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	[BP3LC3]
-----	-----------	----------

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/25/2020 15:15
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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/15/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/15/2020
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	[BP3LT0]
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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/15/2020 12:00
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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/15/2020
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	[BPVSHR]
5.b	Sample ID	[BS696H]
5.c	Sample ID	[BS696J]

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Dec/07/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/7/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Dec/07/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Dec/7/2020
2.	Date of First Symptom Started:	Dec/5/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/17/2020

Symptoms

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Dec/07/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Symptoms - Other

5.a	Symptoms - Other Text:	[FATIGUE]
5.b	Symptoms - Other Text:	[HEADACHE]
5.c	Symptoms - Other Text:	[NASAL CONGESTION]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings/Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Dec/07/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Dec/07/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/7/2020
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	[BRJ85W]
-----	-----------	----------

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Dec/07/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Respiratory Treatment

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Dec/07/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [upper respiratory infection] Date of Diagnosis: Dec/5/2020
3.	Toxicity Grade:	1

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Dec/07/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/07/2020

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Lab Chemistry Details

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

Lab Result

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Dec/07/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date:	Vital Signs Details			Form Instance
1.	Dec/7/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	121	77	

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Dec/07/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

1.	Date:	Dec/7/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[121]
	Diastolic:	[77]
	Respiratory Rate in respirations/minute:	[16]
	Heart Rate in beats/minute:	[83]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Dec/07/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Dec/07/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Dec/07/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Jan/27/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Date of Visit

1.	Date of Visit	Jan/27/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B
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Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Jan/27/2021**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Not Complete**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Signs and Symptoms**

1.	Date of Assessment:	Jan/27/2021
2.	Date of First Symptom Started:	Jan/27/2021
3.	Symptoms Ongoing?	YES

Symptoms

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

Symptoms - Other

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Jan/27/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a	Symptoms - Other Text:	[sore throat]
5.b	Symptoms - Other Text:	[tightening in the chest]
5.c	Symptoms - Other Text:	[Headache]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jan/27/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Jan/27/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Microbiology Specimen

1.	Actual Date of Collection:	Jan/27/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[unknown]

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Jan/27/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
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	[CV58599]
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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Jan/27/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Jan/27/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
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Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Jan/27/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Jan/27/2021

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/27/2021

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Lab Chemistry Details

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

Lab Result

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/27/2021

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Jan/27/2021

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Jan/27/2021

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Jan/27/2021

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Jan/27/2021

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** IMAGING
on Jan/27/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/25/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/25/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/25/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPVSMZ]
5.b	Sample ID	[BS69CK]
5.c	Sample ID	[BS69CJ]

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled
Visit on Feb/25/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/25/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled
Visit on Feb/25/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPVSBW]
5.b	Sample ID	[]
5.c	Sample ID	[]

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/15/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	PAIN AT INJECTION SITE	Aug/26/2020 UNK:UNK	NO End Date Time: Aug/30/2020 UNK: UNK	Repeating Pages
2.	ADVERSE EVENT	2	Fatigue	Sep/16/2020 09:00	NO End Date Time: Sep/17/2020 18:00	Repeating Pages
3. DELETED	ADVERSE EVENT	3	UPPER RESPIRATORY INFECTION	Dec/5/2020 UNK:UNK	NO End Date Time: Dec/17/2020 UNK: UNK	Repeating Pages
4.	ADVERSE EVENT	4	Worsening of degenerative disc disease	Jan/11/2021 UNK:UNK	YES	Repeating Pages
5.	ADVERSE EVENT	5	Worsening of gastritis	Feb/14/2021 08:00	NO End Date Time: Feb/17/2021 UNK: UNK	Repeating Pages
6.	ADVERSE EVENT	6	Worsening of gastropar esis	Feb/14/2021 08:00	NO End Date Time: Feb/17/2021 UNK: UNK	Repeating Pages

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[PAIN AT INJECTION SITE]
4.	Start Date Time:	Aug/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/30/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Sep/16/2020 09:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/17/2020 18:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Not Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[UPPER RESPIRATORY INFECTION]
4.	Start Date Time:	Dec/5/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/17/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [VIRUS]

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Not Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of degenerative disc disease]
4.	Start Date Time:	Jan/11/2021 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: [Natural progression of the disease]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of gastritis]
4.	Start Date Time:	Feb/14/2021 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/17/2021 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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: [Progression of disease]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021218841]

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of gastroparesis]
4.	Start Date Time:	Feb/14/2021 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/17/2021 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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: [Progression of disease]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021218841]

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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	[]

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Influenza vaccine	Oct/27/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza vaccine]
5.	Date:	Oct/27/2020

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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?	

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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?	

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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:	

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Informed Consent - Asymptomatic Surveillance

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/5/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Mar/5/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/15/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Aug-26-2020 12:50:02 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	not a SF Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Aug-26-2020 13:02:00 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	not done as subject is post menopausal

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Sep-10-2020 13:53:33 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Sep-10-2020 14:26:35 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Sep-10-2020 14:26:35 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Sep-10-2020 14:26:35 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
5	Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
5	Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6	Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
7	Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
8	Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
9	Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Jan-19-2021 13:42:22 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	
Form	Dec-08-2020 08:46:35 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Jan-19-2021 13:42:22 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	
1	Dec-08-2020 08:46:35 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Jan-19-2021 13:42:22 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	
2	Dec-08-2020 08:46:35 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Jan-19-2021 13:42:22 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	
3	Dec-08-2020 08:46:35 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Jan-19-2021 13:42:22 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	
4	Dec-08-2020 08:46:35 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Jan-25-2021 18:19:39 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Abram Burgher	Approved	Jan-20-2021 15:51:40 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Jan-19-2021 13:42:22 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Abram Burgher	Approved	Dec-11-2020 11:24:36 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, AbramBurgher, 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.

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(b) (6)	N/A	Dec-08-2020 07:53:25 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Abram Burgher	Approved	Oct-21-2020 20:45:02 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, AbramBurgher, 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.

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-26-2020 12:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 12:48:57 (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: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-26-2020 12:49:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/25/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject ID

Date	Location	User	Value	Reason
Aug-26-2020 12:48:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10481032	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:48:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1974	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-26-2020 12:49:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-26-2020 12:49:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 12:49:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-26-2020 12:49:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-26-2020 12:50:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-26-2020 12:50:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-26-2020 12:50:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I.a

Date	Location	User	Value	Reason
Aug-26-2020 12:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Te gastritis rm: Start Date: May/UNK/20 20 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 12:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 12:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: gastritis	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/UNK/2020	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 12:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-26-2020 12:51:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Te Hiatal hernia rm: Start Date: May/UNK/20 20 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 12:51:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 12:51:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hiatal hernia	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:51:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/UNK/2020	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 12:51:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-26-2020 12:52:56 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)			Medical History Term: post menopausal Start Date: UNK/UNK/2018 Ongoing: YES
--------------------	--	--	--

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 12:52:56 (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
Aug-26-2020 12:52:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: post menopausal	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:52:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 12:52:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-26-2020 12:53:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: muscle spasms	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Start Date:	UNK/UNK/2015	
			Ongoing:	YES	

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 12:53:23 (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
Aug-26-2020 12:53:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: muscle spasms	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:53:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 12:53:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-26-2020 12:53:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: degenerative disc disease Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 12:53:44 (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
Aug-26-2020 12:53:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: degenerative disc disease	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:53:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 12:53:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-26-2020 12:54:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: bipolar disorder Start Date: UNK/UNK/2001 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 12:54:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 12:54:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bipolar disorder	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:54:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2001	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 12:54:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-26-2020 12:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: hypothyroidism Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 12:54:24 (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
Aug-26-2020 12:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypothyroidism	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:54:24 (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
Aug-26-2020 12:54:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-26-2020 12:54:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: sleep apnea Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 12:54:38 (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
Aug-26-2020 12:54:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sleep apnea	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:54:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 12:54:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Aug-26-2020 12:55:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: difficulty with sleeping Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 12:55:13 (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
Aug-26-2020 12:55:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: difficulty with sleeping	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:55:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 12:55:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Aug-26-2020 12:55:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 10 : Medical History T Tardive Diskin erm: esia Start Date: UNK/UNK/20 15 Ongoing: YES	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 12:55:40 (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
Aug-26-2020 12:55:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tardive Diskinesia	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:55:40 (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
Aug-26-2020 12:55:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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<i>I.k</i>				
Date	Location	User	Value	Reason
Aug-26-2020 12:59:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 11 : Medical History T akathisia erm: Start Date: UNK/UNK/2 015 Ongoing: YES	Initial Entry
<i>I.k Line/MH Number:</i>				
Date	Location	User	Value	Reason
Aug-26-2020 12:59:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry
<i>I.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Aug-26-2020 12:59:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: akathisia	Initial Entry
<i>I.k Start Date:</i>				
Date	Location	User	Value	Reason
Aug-26-2020 12:59:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry
<i>I.k Ongoing:</i>				
Date	Location	User	Value	Reason
Aug-26-2020 12:59:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
<i>I.l</i>				

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-26-2020 12:59:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 12 : Medical History Term: obesity Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 12:59:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 12:59:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: obesity	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:59:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 12:59:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Aug-26-2020 13:01:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-26-2020 13:01:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 180.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-26-2020 13:01:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-26-2020 13:01:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 65.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-26-2020 13:01:39 (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
Aug-26-2020 13:01:39 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Aug-26-2020 13:01:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 : Temperature: 99.7 Temperature Uni F t: Temperature Loc ORAL CAV ation:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-26-2020 13:01:39 (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
Aug-27-2020 00:22:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation
Aug-26-2020 13:02:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-26-2020 13:01:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 99.7 F is outside of Normal Range 97 - 99.5 F.
Aug-26-2020 13:01:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 99.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-26-2020 13:01:39	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-07:00) Mountain Time (US & Canada)		(b) (4), (b) (6)	F	
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7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-26-2020 13:01:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-10-2020 13:53:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-26-2020 13:01:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin in Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-26-2020 13:01:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-26-2020 13:01:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-26-2020 13:01:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-26-2020 13:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-26-2020 13:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 64823	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-28-2020 08:51:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 08:51:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-28-2020 08:51:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 08:51:33 (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.
Aug-28-2020 08:51:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 08:51:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3LC2	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 08:51:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3LC2	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-28-2020 08:52:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3LC1	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 08:52:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3LC1	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 08:52:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3LC0	Transcription Error
Aug-28-2020 08:52:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3LC0T	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 08:52:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-28-2020 08:52:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3LC0	Transcription Error
Aug-28-2020 08:52:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Aug-28-2020 08:52:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3LC0T	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-28-2020 08:53:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPL2RB	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 08:53:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPL2RB	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-28-2020 08:53:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPL2R9	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.e Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 08:53:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPL2R9	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-28-2020 08:54:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 08:54:02 (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
Aug-28-2020 08:54:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 08:54:02 (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.
Aug-28-2020 08:54:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 08:54:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3LC3	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 08:54:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3LC3	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-26-2020 13:03:10 (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
Aug-26-2020 13:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-26-2020 13:03:10 (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
Aug-26-2020 13:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 15:15	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-26-2020 13:03:10 (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
Aug-26-2020 13:03:10 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)

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

7. Route:

Date	Location	User	Value	Reason
Aug-26-2020 13:03:10 (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
Aug-26-2020 13:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 13:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-26-2020 13:03:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-15-2020 14:06:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Sep-15-2020 14:07:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-15-2020 14:07:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 : Temperature: 98.2 Temperature Uni F t: Temperature Loc ORAL CAV ation:: ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-15-2020 14:07:14 (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
Sep-15-2020 14:07:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-15-2020 14:07:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-15-2020 14:07:14 (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: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-15-2020 14:07:21	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-07:00) Mountain Time (US & Canada)		(b) (4), (b) (6)	Sponsor-Defined Identifier:	Not Applicable
			Test::	Not Applicable
			Result::	Not Applicable
			Not Done::	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-15-2020 14:07:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-15-2020 12:59:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-15-2020 12:59:11 (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
Sep-15-2020 12:59:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-15-2020 12:59:11 (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.
Sep-15-2020 12:59:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-15-2020 12:59:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3LT0	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Sep-15-2020 12:59:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3LT0	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-15-2020 14:26:01 (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
Sep-15-2020 14:26:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-15-2020 14:26:01 (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
Sep-15-2020 14:26:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020 12:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-15-2020 14:26:01 (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
Sep-15-2020 14:26:01 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)	(b) (4), (b) (6)
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7. Route:

Date	Location	User	Value	Reason
Sep-15-2020 14:26:01 (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
Sep-15-2020 14:26:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 14:26:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 12:22:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-16-2020 15:46:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-16-2020 15:46:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-16-2020 15:46:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-16-2020 15:46:47 (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.
Oct-16-2020 15:46:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 15:46:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVSHR	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 15:46:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVSHR	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-16-2020 15:47:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS696H	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 15:47:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS696H	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-16-2020 15:47:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS696J	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 15:47:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS696J	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Dec/07/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-19-2021 22:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-19-2021 13:43:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Dec-09-2020 09:59:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Microbiology Specimen Illness Details form' at this visit. Thank you.
Dec-08-2020 07:57:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-08-2020 07:53:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-08-2020 07:53:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Dec/07/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Dec-08-2020 07:53:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry
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3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-08-2020 07:53:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Assessment:

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-01-2021 09:48:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-29-2021 11:26:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Jan-29-2021 06:22:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: UPPER RESPIRATORY INFECTION is reported on AE CRF from 05DEC20 which overlaps with COVID ILL visit symptom date. Was diagnosis made? Enter diagnosis of event if available on ILL POTEN CRF even if diagnosis is not COVID-19/respiratory related.
Jan-28-2021 09:24:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLINQUERY: UPPER RESPIRATORY INFECTION is reported on AE CRF from 05DEC20

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

				which overlaps with COVID ILL visit symptom date. Was diagnosis made? Enter diagnosis of event if available on ILL POTEN CRF even if diagnosis is not COVID-19/respiratory related.
Jan-28-2021 09:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-27-2021 14:06:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: UPPER RESPIRATORY INFECTION is reported on AE CRF from 05DEC20 which overlaps with COVID ILL visit symptom date. Was diagnosis made? Enter diagnosis of event if available on ILL POTEN CRF even if diagnosis is not COVID-19/respiratory related.
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/5/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-11-2021 23:16:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Feb-11-2021 15:04:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-11-2021 15:04:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Dec/17/2020	Changed Information
Feb-11-2021 15:03:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Last Symptom Resolved date is a future date compared to when it was entered. Please correct.
Feb-11-2021 15:03:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-11-2021 15:03:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Dec/17/2021	New Information
Feb-01-2021 00:33:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Next visit should be entered only if all the symptoms at this visit resolved. If resolved, please review and update the date of last symptom resolved as appropriate. If not, please move details from next visit into this visit. Thank you.
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

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Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

4.a

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREA : SED COUGH Symptom Present: YES	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present: YES	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

4.f

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: DIARRHE A Symptom Present NO :	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)	Symptoms: VOMITIN G Symptom Present NO :	
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4.i Symptoms:

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-08-2020 07:55:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-08-2020 07:55:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: FATIGUE	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-08-2020 07:55:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-08-2020 07:56:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: HEADACHE	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-08-2020 07:56:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-08-2020 07:57:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: NASAL CONGESTION	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-08-2020 07:57:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASAL CONGESTION	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-19-2021 13:43:39	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-07:00) Mountain Time (US & Canada)		(b) (4), (b) (6)	Not Done	
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7. Test Result:

Date	Location	User	Value	Reason
Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-19-2021 13:43:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Jan-19-2021 13:42:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Jan-19-2021 13:42:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-08-2020 08:46:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 13:42:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry
Jan-19-2021 13:42:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-08-2020 08:46:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-19-2021 19:24:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_07
Jan-19-2021 13:42:49 (UTC-07:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1048**Subject No:** 10481032**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1048) The Pain Center of Arizona**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

Mountain Time (US & Canada)				
Jan-19-2021 13:42:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Jan-19-2021 13:42:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-19-2021 13:42:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : NO	Initial Entry
Jan-19-2021 13:42:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> :	Initial Entry
Dec-08-2020 23:30:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6400349;Sample Collected is not expected to be Not Done. Please review and update appropriately or clarify
Dec-08-2020 08:46:35 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : Not D	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)			one	
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4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Jan-19-2021 13:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-19-2021 13:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: pfe	Changed Information
Jan-19-2021 13:42:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Jan-19-2021 13:42:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PFE	Initial Entry
Jan-19-2021 13:42:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-08-2020 08:46:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Dec/07/2020**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:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-08-2020 07:57:45 (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-08-2020 07:57:45 (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-08-2020 08:47:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-08-2020 07:57:45 (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-08-2020 07:57:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-08-2020 08:47:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ85W	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

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: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Dec-08-2020 08:47:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRJ85W	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/07/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I.a

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/07/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/07/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-02-2021 16:26:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-25-2021 15:51:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-22-2021 12:40:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	please check and correct
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/07/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/07/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-08-2020 07:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Dec/07/2020**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Jan-29-2021 11:25:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jan-29-2021 11:26:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-29-2021 11:26:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> upper respiratory infection Date of Diagnosis: Dec/5/2020	Transcription Error
Jan-29-2021 11:25:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date entered is in the future compared to today's date. Please correct.
Jan-29-2021 11:25:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> upper respiratory infection Date of Diagnosis: Dec/5/2021	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Dec/07/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Feb-08-2021 13:10:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021 09:16:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-04-2021 09:16:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Transcription Error
Feb-01-2021 13:47:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source = 1. Please verify
Jan-29-2021 11:25:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Dec/07/2020

Form Version: 21-Aug-2020 02:50

Form Status:

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Dec-08-2020 08:00:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Dec/07/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Dec-08-2020 08:00:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-08-2020 08:00:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 12 1 Diastolic:: 77 Respiratory Rate in respir 16 ations/minute: Heart Rate in beats/minute 83 :	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-08-2020 08:00:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-26-2021 07:36:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-25-2021 15:52:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	scanned into Florence with the convalescent visit
Jan-22-2021 12:42:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	please upload sd with vital signes

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Dec/07/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Dec-08-2020 08:00:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 121	Initial Entry
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2.a Diastolic:

Date	Location	User	Value	Reason
Dec-08-2020 08:00:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 77	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Dec-08-2020 08:00:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Dec-08-2020 08:00:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 83	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/27/2021**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)***1. Date of Visit***

Date	Location	User	Value	Reason
Jan-29-2021 11:31:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-29-2021 11:27:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-29-2021 11:27:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-29-2021 11:27:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-29-2021 11:27:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit
on Jan/27/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Not Complete**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-15-2021 12:33:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 15:05:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated covid a
Feb-01-2021 10:33:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: COVID_B visit is conducted while symptoms from 1st visit is ongoing, please clarify. If the subject develops new symptoms while any of the symptoms from 1st visit ongoing, new symptoms should be added to 1st visit. please clarify.
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/27/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)	(b) (4), (b) (6)
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4.a

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREASED COUGH Symptom Present: YES	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Jan/27/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1048**Subject No:** 10481032**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Not Complete**Site Name:** (1048) The Pain Center of Arizona**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44**4.b Symptoms:**

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/27/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREAS s: ED MUSCLE PAIN Symptom YES Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSC LE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/27/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

4.f

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-19-2021 16:03:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom YES Present:	Transcription Error
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Jan/27/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1048**Subject No:** 10481032**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Not Complete**Site Name:** (1048) The Pain Center of Arizona**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44**4.g Symptoms:**

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-19-2021 16:03:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA A Symptom Present NO :	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/27/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present NO :	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 11:29:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-19-2021 16:04:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other sore throa :	Transcription Error (DELETED)
Jan-29-2021 11:29:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other sore throa :	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-22-2021 07:19:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-19-2021 16:04:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sore throat	Transcription Error (DELETED)

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Jan/27/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Not Complete**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Feb-19-2021 16:04:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-15-2021 12:32:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Please clarify? One of the pre-printed symptoms is NEW OR INCREASED SORE THROAT. And it is marked as NO. Please review and update CRF appropriately.
Feb-11-2021 15:11:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	new sore throat
Feb-01-2021 10:35:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Is the term 'sore throat' consistent with one of the pre-printed symptoms (e.g. new or increased sore throat)? Please review and update CRF if appropriate or else clarify.
Jan-29-2021 11:29:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sore throat	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-29-2021 11:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - O tightening in th ther: e chest	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/27/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Not Complete

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Mar-04-2021 14:41:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-27-2021 15:08:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-24-2021 10:05:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	please add also headache
Jan-29-2021 11:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: tightening in the chest	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-27-2021 15:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: Headache	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-27-2021 15:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headache	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Jan/27/2021

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Jan-29-2021 11:31:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/27/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-29-2021 11:31:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-29-2021 11:31:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-29-2021 11:31:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-29-2021 11:31:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jan-29-2021 11:31:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-29-2021 11:31:21 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/27/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)	(b) (4), (b) (6)
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7. Test Result:

Date	Location	User	Value	Reason
Jan-29-2021 11:31:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-29-2021 11:31:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: unknown	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit
on Jan/27/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1048**Subject No:** 10481032**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1048) The Pain Center of Arizona**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 11:31:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 11:31:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-29-2021 11:32:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 11:31:37 (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-29-2021 11:31:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-29-2021 11:32:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV58599	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/27/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 11:32:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV58599	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/27/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Jan-29-2021 11:32:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 11:32:12 (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
Jan-29-2021 11:32:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Jan-29-2021 11:32:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: selfswab	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/27/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I.a

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIA LIST Occurrence of Visits NO or Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitio EMERGEN ner: CY ROOM Occurrence of Vi NO sits or Contacts:	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/27/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/27/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.d

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/27/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry
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I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/27/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 11:33:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/25/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-25-2021 18:19:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-25-2021 18:19:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/25/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-25-2021 18:20:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-25-2021 18:20:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-26-2021 12:59:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-25-2021 20:02:25 (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-25-2021 18:20:10 (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-25-2021 18:20:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/25/2021	Initial Entry

5.a

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/25/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-26-2021 12:59:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVSMZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 12:59:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVSMZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-26-2021 13:00:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS69CK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 13:00:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS69CK	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-26-2021 13:00:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS69CJ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 13:00:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS69CJ	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit on Feb/25/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 07:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/25/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Mar-02-2021 07:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_B1	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit on Feb/25/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Mar-02-2021 07:51:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-02-2021 07:51:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-05-2021 14:09:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-03-2021 04:44:59 (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.
Mar-02-2021 07:51:55 (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.
Mar-02-2021 07:51:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/25/2021	Initial Entry

5.a

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit on Feb/25/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-05-2021 14:09:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPVSBW	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 14:09:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVSBW	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-15-2020 12:22:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-15-2020 12:22:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-15-2020 12:22:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-15-2020 14:19:31 (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: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Jan-25-2021 20:11:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-11-2021 15:13:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Jan-26-2021 14:36:27 (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: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-02-2021 08:08:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Mar-02-2021 08:24:30 (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: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Mar-02-2021 08:30:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Sep-15-2020 14:19:31 (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
Sep-15-2020 14:19:31 (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
Sep-15-2020 14:19:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-15-2020 14:19:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-15-2020 14:19:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/30/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-15-2020 14:19:31 (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
Sep-15-2020 14:19:31 (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
Sep-15-2020 14:19:31 (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
Sep-15-2020 14:19:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-15-2020 14:19:50 (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
Sep-15-2020 14:19:31 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)

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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-15-2020 14:19:31 (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
Sep-15-2020 14:19:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 14:19:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Jan-25-2021 20:11:42 (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-25-2021 20:11:42 (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-25-2021 20:11:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fatigue	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-25-2021 20:11:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020 09:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-25-2021 20:11:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/17/2020 18:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Jan-25-2021 20:11:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-25-2021 20:11:42 (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
Jan-25-2021 20:11:42 (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
Jan-25-2021 20:11:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-27-2021 13:44:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_AE001_32
Jan-27-2021 09:44:25	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answer	Transcription Error

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1048**Subject No:** 10481032**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1048) The Pain Center of Arizona**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-07:00) Mountain Time (US & Canada)			ed	
Jan-27-2021 09:44:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Transcription Error
Jan-27-2021 00:25:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6999759;The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Disposition-Treatment Form Status is not DEATH OR ADVERSE EVENT. Please review and update as appropriate.
Jan-25-2021 20:11:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-25-2021 20:11:42 (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
Jan-25-2021 20:11:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Jan-25-2021 20:11:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 20:11:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Not Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jan-26-2021 14:36:27 (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-26-2021 14:36:27 (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-15-2021 12:27:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-11-2021 15:13:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-02-2021 06:44:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Upper Respiratory Infection is now already documented under the COVID Illness ILL POTEN CRF. PP Section 8.37, events consistent with the clinical endpoint definition are not to then also be recorded as AEs. Update AE CRF as appropriate.

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1048**Subject No:** 10481032**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Deleted, Not Verified**Site Name:** (1048) The Pain Center of Arizona**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44***** THIS REPEATING FORM HAS BEEN DELETED *****

Feb-01-2021 09:48:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Feb-01-2021 09:48:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLINQUERY: Upper Respiratory Infection is now already documented under the COVID Illness ILL POTEN CRF. PP Section 8.37, events consistent with the clinical endpoint definition are not to then also be recorded as AEs. Update AE CRF as appropriate.
Feb-01-2021 09:47:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Upper Respiratory Infection is now already documented under the COVID Illness SOD CRF. PP Section 8.37, events consistent with the clinical endpoint definition are not to then also be recorded as AEs. Update AE CRF as appropriate.
Jan-26-2021 14:36:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UPPER RESPIRATORY INFE CTION	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-26-2021 14:36:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/5/2020 UNK:UNK	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Not Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-26-2021 14:36:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date Time: Dec/17/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-26-2021 14:36:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-26-2021 14:36:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-26-2021 14:36:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-26-2021 14:36:27 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Not Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Time (US & Canada)		(b) (4), (b) (6)	If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> VIRUS
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-26-2021 14:36:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-26-2021 14:36:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-26-2021 14:36:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-26-2021 14:36:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-26-2021 14:36:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Not Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Time (US & Canada)

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Mar-02-2021 08:08:01 (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
Mar-02-2021 08:08:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-02-2021 08:08:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Worsening of degenerative disc d isease	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-02-2021 08:08:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-02-2021 08:08:01 (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
Mar-02-2021 08:08:01 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)	(b) (4), (b) (6)
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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
Mar-02-2021 08:08:01 (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
Mar-02-2021 08:08:01 (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
Mar-02-2021 08:08:01 (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: Natural progression of the disease	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-02-2021 08:08:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-02-2021 08:08:01 (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
Mar-02-2021 08:08:01 (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
Mar-02-2021 08:08:01 (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
Mar-02-2021 08:08:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Mar-02-2021 08:24:30 (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
Mar-02-2021 08:24:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-02-2021 08:24:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Worsening of gastritis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-02-2021 08:24:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/14/2021 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-02-2021 08:24:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/17/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Verified, Frozen

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Mar-02-2021 08:24:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	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
Mar-03-2021 04:33:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 08:24:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Worsening of gastritis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-02-2021 08:24:30 (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? 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?	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			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
Mar-02-2021 08:24:30 (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
Mar-02-2021 08:24:30 (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: Progression of disease	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-02-2021 08:24:30 (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
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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Verified, Frozen

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Mar-02-2021 08:24:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-02-2021 08:24:30 (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
Mar-02-2021 08:24:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 08:24:30 (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
Mar-03-2021 04:33:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021218841	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Mar-02-2021 08:30:40 (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
Mar-02-2021 08:30:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-02-2021 08:30:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Worsening of gastroparesis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-02-2021 08:30:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/14/2021 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-02-2021 08:31:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/17/2021 UNK:UNK	Transcription Error
Mar-02-2021 08:30:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Feb/16/2021 UNK:UNK

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-02-2021 08:30:40 (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
Mar-03-2021 04:34:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 08:30:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Worsening of gastroparesis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-02-2021 08:30:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or bir th defect? NO Did this serious event result in death? NO Did this serious event require o r prolong hospitalization?	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			<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
Mar-02-2021 08:30:40 (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
Mar-02-2021 08:30:40 (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: Progression of disease	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Not Verified, Frozen

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Mar-02-2021 08:30:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-02-2021 08:30:40 (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
Mar-02-2021 08:30:40 (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
Mar-02-2021 08:30:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 08:30:40 (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
Mar-03-2021 04:34:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021218841	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Jan-25-2021 18:22:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-25-2021 18:22:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-25-2021 18:22:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-25-2021 18:22:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-25-2021 18:22:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Jan-25-2021 18:22:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/27/2020	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-08-2021 13:05:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/5/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Mar-08-2021 13:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-08-2021 13:06:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Mar-08-2021 13:06:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-08-2021 13:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/5/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-08-2021 13:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481032

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject Status

Date	Location	User	Value	Reason
Oct-15-2020 12:22:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-26-2020 13:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-26-2020 12:50:16 (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
Mar-03-2021 04:35:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event recorded in AE CRF
Mar-02-2021 03:20:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021218841 worsening of gastritis and gastroparesis (onset date:14Feb2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-15-2020 12:22:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/15/2020	Initial Entry
Aug-26-2020 13:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2020	Initial Entry
Aug-26-2020 12:50:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2020	Initial Entry

090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)				
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090177e196ae30a5\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481032

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Casebook Signature

Date	Location	User	Value	Reason
Sep-19-2020 13:59:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry