

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[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: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/2/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10681091]
2.	Birth Date:	(b) (6) 1951
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: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/2/2020
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: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[osteopenia]	
	Start Date:	Aug/1/2018	
	Ongoing:	YES	
1.b	Line/MH Number:	[2]	Comments
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[recurrent cold sores]	Comments
	Start Date:	UNK/UNK/1960	Comments
	Ongoing:	YES	Comments
1.c	Line/MH Number:	[3]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[menopause syndrome]	
	Start Date:	Jan/28/2018	
	Ongoing:	NO End Date: Jun/22/2018	

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/2/2020
2.	Weight:	[57.47]
3.	Unit:	kg
4.	Height:	[164.5]
5.	Unit:	cm
6.	Body Mass Index:	[21.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/2/2020
2.	Randomization Number:	[249490]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/2/2020
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	[BNZPJR]
5.b	Sample ID	[BNZPJP]
5.c	Sample ID	[BNZPJN]
5.d	Sample ID	[BPHSFC]
5.e	Sample ID	[BPHSFD]

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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/2/2020 12:09
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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/23/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
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	[BNZPSN]
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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/23/2020 17:14
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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/22/2020
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	[BNZP7H]
5.b	Sample ID	[BNVXHM]
5.c	Sample ID	[BNVXGY]

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681091 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19 **Form Status:** Not Started

Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681091 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52 **Form Status:** Not Started

Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681091 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Unplanned Assessments

1.	Assessments	
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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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/22/2020
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: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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 **Form:** DATE OF VISIT - REPEAT SWAB
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Left Hip Fracture	Jan/20/2021 12:22	YES	Repeating Pages
2.	ADVERSE EVENT	2	Fall	Jan/20/2021 12:22	NO End Date Time: Jan/20/2021 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Syncopal Episode	Jan/22/2021 UNK:UNK	NO End Date Time: Jan/22/2021 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	orthostatic hypotension	Jan/22/2021 10:00	NO End Date Time: Jan/22/2021 10:00	Repeating Pages

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left Hip Fracture]
4.	Start Date Time:	Jan/20/2021 12:22
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	4
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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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: [incidental, caused by fall on ice]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021051305]

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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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)	[Fall]
4.	Start Date Time:	Jan/20/2021 12:22
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/20/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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: [icy conditions caused fall]

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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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)	[Syncope Episode]
4.	Start Date Time:	Jan/22/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [cause unknown]

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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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)	[orthostatic hypotension]
4.	Start Date Time:	Jan/22/2021 10:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 10:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [cause unknown]

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

#	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: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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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	[]

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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Concomitant Medications

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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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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?	

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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:	

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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?	

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/27/2021
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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/27/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/29/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/29/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/29/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/29/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
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	[BNZPCY]
5.b	Sample ID	[BNVX4J]
5.c	Sample ID	[BNVX4K]

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
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	[BNZPCW]
-----	-----------	----------

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/29/2021 15:57
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[Form Comments](#)

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1CD4]
-----	-----------	----------

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/19/2021 15:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/22/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Andrew Gentry	Approved	Mar-10-2021 07:38:47 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, AndrewGentry, 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.

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Sep-03-2020 08:51:59 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[Back to Form](#)

Item	Date	User	Comment
1.b	Sep-03-2020 08:54:25 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	episodic outbreaks. typically <2 outbreaks / year.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[Back to Form](#)

Item	Date	User	Comment
1.b	Sep-03-2020 08:54:25 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	episodic outbreaks. typically <2 outbreaks / year.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
1.b	Sep-03-2020 08:54:25 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	episodic outbreaks. typically <2 outbreaks / year.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
1.b	Sep-03-2020 08:54:25 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	episodic outbreaks. typically <2 outbreaks / year.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	menopause <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
1	Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	menopause _____ Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
2	Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer	menopause
		(b) (4)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
3	Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer	menopause
		(b) (4)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
4	Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer	menopause
		(b) (4)	Not Applicable

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
5	Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	menopause _____ Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer	menopause
		(b) (4)	Not Applicable

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer	menopause
		(b) (4)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer	menopause
		(b) (4)	Not Applicable

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Sep-24-2020 13:31:10 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Post menopause
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
1	Sep-24-2020 13:31:10 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Post menopause ----- Not Applicable

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
2	Sep-24-2020 13:31:10 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Post menopause Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
3	Sep-24-2020 13:31:10 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Post menopause
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[Back to Form](#)

Item	Date	User	Comment
4	Sep-24-2020 13:31:10 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Post menopause ----- Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
5	Sep-24-2020 13:31:10 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Post menopause Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Sep-24-2020 13:31:10 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Post menopause Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Sep-24-2020 13:31:10 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Post menopause Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Sep-24-2020 13:31:10 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Post menopause Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Jan-29-2021 15:35:42 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	Not Applicable

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
1	Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	Not Done

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
2	Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
3	Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	Not Done

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
4	Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
5	Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	Not Done

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	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, Signed, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Andrew Gentry	Approved	Mar-10-2021 07:38:47 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, AndrewGentry, 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.

Michaela ODonoghue	N/A	Jan-27-2021 10:04:01 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Andrew Gentry	Approved	Jan-26-2021 17:25:18 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, AndrewGentry, 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.

Michaela ODonoghue	N/A	Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (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, Signed, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Andrew Gentry	Approved	Jan-22-2021 11:52:22 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, AndrewGentry, 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.

Michaela ODonoghue	N/A	Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Andrew Gentry	Approved	Oct-26-2020 15:50:37 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, AndrewGentry, 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.

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-03-2020 08:50:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 08:50:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-03-2020 08:51:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: OBTAINED Date Written Consent Obtai ned Sep/2/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Subject ID

Date	Location	User	Value	Reason
Sep-03-2020 08:50:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10681091	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-03-2020 08:50:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1951	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-03-2020 08:51:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-03-2020 08:51:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 08:51:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: WHITE	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 08:51:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sep/2/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-03-2020 08:52:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sep/2/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-03-2020 08:52:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-03-2020 08:52:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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I.a

Date	Location	User	Value	Reason
Sep-03-2020 08:53:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: osteopenia Start Date: Aug/1/2018 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 08:53:42 (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
Sep-03-2020 08:53:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: osteopenia	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 08:53:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Aug/1/2018	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 08:53:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

I.b

Date	Location	User	Value	Reason
Sep-03-2020 08:54:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History: recurrent cold Term: sores Start Date: UNK/UNK/1 960 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 08:54:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 08:54:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: recurrent cold sores	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 08:54:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: UNK/UNK/1960	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 08:54:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES	Initial Entry

I.c

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date	Location	User	Value	Reason
Sep-03-2020 08:56:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 3 ber: Medical Histor menopause syn y Term: drome Start Date: Jan/28/2018 Ongoing: NO End Date: Jun/22/2018	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 08:56:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 08:56:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: menopause syndrome	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 08:56:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Jan/28/2018	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-09-2020 08:44:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-09-2020 07:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-09-2020 07:47:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	confirm if menopause is considered ongoing
Sep-03-2020 08:56:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO End Date: Jun/22/2018	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date:

Date	Location	User	Value	Reason
Sep-03-2020 08:57:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> Sep/2/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-03-2020 08:57:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> 57.47	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 08:57:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-03-2020 08:57:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> 164.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 08:57:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Sep-03-2020 08:57:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21.2	Initial Entry
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7.a

Date	Location	User	Value	Reason
Sep-03-2020 08:57:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Record Identifier 1 :: Temperature: 98.6 Temperature Uni F t: Temperature Loc FOREHE ation:: AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 08:57:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 08:57:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: 98.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 08:57:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Sep-03-2020 08:57:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: FOREHEAD	Initial Entry
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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:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681091**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sponsor-Defined Identifier: Test:: Result:: Not Done::	Initial Entry Not Appli cable Not Appli cable Not Appli cable Not Appli cable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-03-2020 09:23:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-03-2020 09:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sep/2/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-03-2020 09:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: 249490	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (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:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681091**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-03-2020 09:24:46 (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-03-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 14:09:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 09:24:46 (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-03-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES Date of Collection: Sep/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 14:09:50	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

(UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Sample ID: BNZPJR
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 14:09:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNZPJR	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 14:10:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNZPJP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 14:10:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNZPJP	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 14:10:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNZPJP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 14:10:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNZPJP	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Oct-21-2020 14:51:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BPHSFC	Initial Entry
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5.d Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 14:51:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BPHSFC	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-21-2020 14:51:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BPHSFD	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 14:51:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BPHSFD	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681091**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-03-2020 09:27:31 (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-03-2020 09:27:31 (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-03-2020 14:11:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 09:27:31 (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-03-2020 09:27:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES Date of Collection: Sep/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 14:11:22	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

(UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Sample ID: BNZPJL
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 14:11:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNZPJL	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-03-2020 09:28:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 09:28:05 (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-03-2020 09:28:05 (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-03-2020 09:28:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sep/2/2020 12:09	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 09:28:05 (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
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Sep-03-2020 09:28:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 09:28:05 (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-03-2020 09:28:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-03-2020 09:28:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-03-2020 09:28:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO - REACTOGENICITY E- DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-24-2020 13:30:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date:

Date	Location	User	Value	Reason
Sep-24-2020 13:30:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-24-2020 13:30:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 :: Temperature: 97.0 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-24-2020 13:30:47 (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-24-2020 13:30:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-24-2020 13:30:47 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Time (US & Canada)	(b) (4), (b) (6)
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2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-24-2020 13:30:47 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-24-2020 13:31:10 (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-24-2020 13:31:10 (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-24-2020 13:31:10 (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-24-2020 13:31:10 (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-24-2020 13:31:10 (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
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Sep-24-2020 13:31:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined I Not Appli dentifier: cable Test:: Not Appli cable Result:: Not Appli cable Not Done:: Not Appli cable	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-24-2020 13:31:10 (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-24-2020 13:31:10 (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-24-2020 13:31:10 (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-24-2020 13:31:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Data Origin

Date	Location	User	Value	Reason
Sep-24-2020 13:31:30 (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-24-2020 13:31:30 (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-25-2020 10:45:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-25-2020 01:46:18 (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.
Sep-24-2020 13:31:30 (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-24-2020 13:31:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/23/2020	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

5.a

Date	Location	User	Value	Reason
Sep-25-2020 10:45:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNZPSN	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 10:45:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNZPSN	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-24-2020 13:31:54 (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-24-2020 13:31:54 (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-24-2020 13:31:54 (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-24-2020 13:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020 17:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-24-2020 13:31:54 (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
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Sep-24-2020 13:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Sep-24-2020 13:31:54 (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-24-2020 13:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-24-2020 13:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-22-2020 16:53:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Oct/22/2020	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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 16:54:00 (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-22-2020 16:54:00 (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-26-2020 09:53:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-24-2020 02:40:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-22-2020 16:54:00 (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-22-2020 16:54:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

			Oct/22/2020	
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5.a

Date	Location	User	Value	Reason
Oct-26-2020 09:53:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BNZP7H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 09:53:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BNZP7H	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-26-2020 10:00:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BNVXHM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 10:00:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BNVXHM	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-26-2020 10:00:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BNVXGY	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

5.c Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 10:00:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BNVXGY	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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-23-2020 13:20:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Oct/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-23-2020 13:20:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-23-2020 13:20:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Date	Location	User	Value	Reason
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Date	Location	User	Value	Reason
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Form Created	

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Date	Location	User	Value	Reason
Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Date	Location	User	Value	Reason
Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Form Created	

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Category:

Date	Location	User	Value	Reason
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-08-2021 20:33:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-08-2021 16:43:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 1: Answered	Changed data per query
Feb-07-2021 12:04:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	per discharge summary subject had a syncopal event on 1/22/21 during the hospital stay, please revisit and update.
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-28-2021 18:49:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Feb-25-2021 08:23:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 2: Answered	added in updated report as sent
Feb-23-2021 12:40:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical Please add FALL information in the SAE Narrative, as causing the SAE (not in the SAE Event term section), as a SAE safety update
Feb-08-2021 15:25:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 2: Answered	Changed data per query
Feb-04-2021 09:50:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - please add fall information to SAE narrative, as causative for the Hip Fx SAE, in a SAE safety update
Feb-04-2021 09:49:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-29-2021 09:53:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 1: Answered	Changed data per query
Jan-25-2021 09:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please submit SAE safety update to report clinical course including any surgery (include date) performed; any prior medications; any

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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 Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

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				in-hospital medications
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Left Hip Fracture	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Jan/20/2021 12:22	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 18:55:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Mar-05-2021 12:34:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 4: Answered	hip fracture not resolved yet. will continue to follow and update end date at time of resolution based on PI designation.
Mar-04-2021 18:14:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical Please review for End date on this event, which continues at grade 4 severity
Feb-25-2021 08:26:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES	Changed Information
Feb-08-2021 20:34:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Canada)				
Feb-08-2021 16:43:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Feb-08-2021 16:43:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO End Date Time: Jan/23/2021 10:17	New Information
Feb-07-2021 11:59:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Discharge summary indicate subject was discharged from hospital on 1/23/21 at 1:17 am, please revisit and update as needed
Feb-07-2021 11:50:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-01-2021 09:14:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 2: Answered	will upload
Jan-29-2021 17:00:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Source unable in e-Chart for verification, please revisit and upload the hospital discharge summary, AE worksheet with PI determination ans a copy of the SAE submission to safety in the eSouce as needed.

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (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 Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Jan-27-2021 13:28:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Jan-27-2021 10:04:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 1: Answered	Changed data per query
Jan-22-2021 16:39:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Fall is a one-day event, please review if an end date can be applied to this entry
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-02-2021 10:26:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-01-2021 14:37:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-01-2021 14:37:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: 4	Transcription Error
Feb-26-2021 10:35:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: Please confirm that the AE has a toxicity grade of 2, given that it is

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				recorded as serious, or update accordingly.
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-04-2021 18:05:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-04-2021 15:45:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 2: Answered	pyelonephritis unrelated to this participants SAE, not in participant's medical history. Please clarify. Thanks!
Mar-04-2021 10:30:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Open ed	CLINICAL - Thank you. Indication for ceftriaxone and cefuroxime in SAE con meds section is 'INFECTION'; as this infection was pyelonephritis that was ongoing prior to HOSP, please update the indication for both to 'PYELONEPHRITIS'

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Jan-29-2021 09:53:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 2: Answered	Changed data per query
Jan-25-2021 09:33:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021051305] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-25-2021 09:33:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021051305] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-21-2021 03:44:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Left Hip Fracture: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/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>	Initial Entry
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-22-2021 16:38:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Jan-22-2021 14:52:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 1: Answered	Changed data per query
Jan-22-2021 10:04:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Per CRF completion guidelines, 'Fall' should be added as a separate line entry
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> incidental, caused by fall on ice	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-22-2021 15:47:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES	Transcription Error
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 08:26:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Close d	Close Auto Query
Feb-25-2021 08:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Open ed	For AE Left Hip Fracture: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-25-2021 08:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: RECOVERIN G/RESOLVIN G	Changed Information

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Feb-16-2021 23:01:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	SDB UPDATED. ISSUE RESOLVED
Feb-12-2021 08:51:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	pending SDB update
Feb-11-2021 14:13:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 1: Answered	confirm updated SAE form submitted
Feb-11-2021 11:33:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	SAE RECON 1: Thanks for the response. Outcome on CRF has not been updated. If SAE follow up form has been submitted, please confirm.
Feb-10-2021 17:11:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 1: Answered	Changed data per query
Feb-10-2021 02:40:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021051305, outcome was reported as Recovering/Resolving to Safety DB however, recorded as RECOVERED/RESOLVED WITH SEQUELAE on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-08-2021 16:38:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: RECOVERED /RESOLVED WITH SEQUELAE	New Information

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Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NOT RECOV ERED/NOT R ESOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-20-2021 17:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-21-2021 03:44:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021051305	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Jan-22-2021 14:50:42 (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-22-2021 14:50:42 (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-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Fall	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Jan/20/2021 12:22	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-27-2021 13:28:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Jan-27-2021 10:04:01 (UTC-07:00) Mountain Time (US &	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

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Canada)				
Jan-27-2021 10:04:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO End Date Time: Jan/20/2021 UNK:UNK	Transcription Error
Jan-25-2021 07:58:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Falls are one day events - please review for end date
Jan-22-2021 14:51:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES	Transcription Error
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO End Date Time: Jan/20/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-04-2021 09:45:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	hip fx SAE caused hospitalization

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Jan-28-2021 08:15:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-27-2021 10:04:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Jan-27-2021 10:04:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Jan-27-2021 10:04:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Changed Information
Jan-25-2021 09:32:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical Please clarify if event of 'fall' caused Hospitalization or if event of 'Lt hip fracture' caused Hospitalization. Only one responsible event is required.
Jan-25-2021 06:19:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: Fall is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Jan-25-2021 06:19:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Query can be addressed internally

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Jan-22-2021 14:51:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Transcription Error
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Fall: Response to "Is the adverse event serious?" is 'Yes' but "Serious

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				Adverse Event Number" is blank.
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	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? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening?	Initial Entry

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			NO	
			Other medically important serious event	
			NO	

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

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

Date	Location	User	Value	Reason
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: icy conditions caused f all	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-22-2021 14:50:42	ACV0PFEINFP6000	Michaela	Data Entry:	Initial Entry

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(UTC-07:00) Mountain Time (US & Canada)		ODonoghue (b) (4)	NO	
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-27-2021 10:04:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-27-2021 10:04:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: RECOVERED/RESOLVE D	Transcription Error
Jan-27-2021 10:04:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Fall: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Jan-22-2021 14:51:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Fall: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

				End Date/Time is present.
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 14:50:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Category:

Date	Location	User	Value	Reason
Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-08-2021 16:42:09 (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-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Syncopal Episode	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Jan/22/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO End Date Time: Jan/22/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date	Location	User	Value	Reason
Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-24-2021 09:21:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2 : Closed	The response to If Other, specify is updated to "cause unknown".
Feb-23-2021 15:08:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2 : Answered	syncopal episode related to orthostatic hypotension listed as additional AE

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

<p>Feb-23-2021 15:08:55 (UTC-07:00) Mountain Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Michaela ODonoghue (b) (4)</p>	<p>Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> cause</p>	<p>syncopal episode related to orthostatic hypotension listed as additional AE</p>
<p>Feb-14-2021 23:30:21 (UTC-07:00) Mountain Time (US & Canada)</p>	<p>ACV0PFEINFP6000.InFormAdapter.Discrepancy</p>	<p>PFE SDQ PROD (b) (4)</p>	<p>Query 2 : Opened</p>	<p>Please review "If not related to study treatment other" field, the following text was indicated in the comment field</p>

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

				[orthostatic hypotension]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)
Feb-11-2021 07:33:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Closed	Response satisfies query
Feb-10-2021 15:44:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Answered	New Information
Feb-10-2021 15:44:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	New Information

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

			<i>If Oth er, spe cify :</i>	
			or th os ta ti c h y p ot e ns io n	
Feb-10-2021 08:26:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Opened	clinical: pls advise as to nature of non drug treatment that caused the syncope. Thanks
Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NOT R ELATE D If Not Relate d to st udy tr eatme nt(s), t his ev ent is due to:	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

				CON CO MIT ANT NO N-D RUG TRE ATM ENT
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	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
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Feb-08-2021 16:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Category:

Date	Location	User	Value	Reason
Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-23-2021 15:13:58 (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
Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: orthostatic hypotension	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Jan/22/2021 10:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO End Date Time: Jan/22/2021 10:00	Initial Entry

6. Toxicity Grade:

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date	Location	User	Value	Reason
Mar-03-2021 14:35:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	verified
Mar-02-2021 01:04:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	unable to verify please upload source with the PI determination with toxicity grading and causality as needed.
Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> cause unknown	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	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
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Feb-23-2021 15:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry
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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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-29-2021 15:34:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Jan/27/2021	Initial Entry

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1068**Subject No:** 10681091**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1068) Bozeman Health Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Feb-10-2021 11:09:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	noted and confirmed
Feb-09-2021 13:39:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Query 1: Answered	in Florence, under source folder titled "Form1"
Feb-07-2021 12:09:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	unable to verify please upload completed Form # 1
Jan-29-2021 15:35:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and con firmed to have received on ly placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-29-2021 15:33:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Jan/27/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-29-2021 15:33:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-29-2021 15:35:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-29-2021 15:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtai ned Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-29-2021 15:36:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Jan/29/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-29-2021 15:36:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-29-2021 15:36:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-29-2021 16:40:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-29-2021 16:40:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-29-2021 16:40:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Jan/29/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-29-2021 16:40:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-29-2021 16:40:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Jan-29-2021 16:40:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier : 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-29-2021 16:40:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-29-2021 16:40:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Choriogonadotropin Beta_PX 113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-29-2021 16:40:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NOT DONE	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681091**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 16:41:10 (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-29-2021 16:41:10 (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-29-2021 16:41:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 16:41:10 (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-29-2021 16:41:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-29-2021 16:41:23	ACV0PFEINFP6000	Emily	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

(UTC-07:00) Mountain
Time (US & Canada)

Anglemyer
(b) (4)

Sample ID: BNZPCY

5.a Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:41:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> BNZPCY	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-29-2021 16:48:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> Sample ID: BNVX4J	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:48:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> BNVX4J	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-29-2021 16:48:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> Sample ID: BNVX4K	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:48:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> BNVX4K	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681091**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 16:42:14 (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 16:42:14 (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 16:57:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 16:42:14 (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 16:42:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-29-2021 16:57:53	ACV0PFEINFP6000	Emily	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

(UTC-07:00) Mountain Time (US & Canada)	Anglemyer (b) (4)	Sample ID: BNZPCW
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5.a Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 16:57:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BNZPCW	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-29-2021 16:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-29-2021 16:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-29-2021 16:42:44 (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
Jan-29-2021 16:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Jan/29/2021 15:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-29-2021 16:42:44 (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
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Jan-29-2021 16:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Jan-29-2021 16:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-29-2021 16:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-29-2021 16:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-29-2021 16:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 16:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 14:39:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	verified
Mar-03-2021 08:24:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Query 1: Answered	Changed data per query
Mar-02-2021 00:38:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Unable to verify, please upload source as needed
Feb-19-2021 16:06:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Feb/19/2021	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> Not Done	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> Not Done	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> Not Done	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	<u>Data Entry:</u> Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sponsor-Defined Id Not Do entifier: ne Test:: Not Do ne Result:: Not Do ne Not Done:: Not Do ne	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Done	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Done	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Done	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-19-2021 16:07:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Done	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681091**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-19-2021 16:12:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-19-2021 16:12:10 (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
Feb-19-2021 16:28:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-19-2021 16:12:10 (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.
Feb-19-2021 16:12:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES Date of Collection: Feb/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-19-2021 16:28:24	ACV0PFEINFP6000	Emily	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

(UTC-07:00) Mountain Time (US & Canada)

Anglemyer
(b) (4)

Sample ID: BP1CD4

5.a Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 16:28:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BP1CD4	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-19-2021 16:28:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-19-2021 16:28:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-19-2021 16:28:08 (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
Feb-19-2021 16:28:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Feb/19/2021 15:40	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-19-2021 16:28:08 (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
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090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Feb-19-2021 16:28:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Feb-19-2021 16:28:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-19-2021 16:28:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-19-2021 16:28:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-19-2021 16:28:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 16:28:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681091

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Subject Status

Date	Location	User	Value	Reason
Oct-23-2020 13:20:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-03-2020 09:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-03-2020 08:52:23 (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
Oct-23-2020 13:20:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/22/2020	Initial Entry
Sep-03-2020 09:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/2/2020	Initial Entry
Sep-03-2020 08:52:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/2/2020	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (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, Signed, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-26-2020 15:49:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Andrew Gentry (b) (4)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae2fdd\Final\Final On: 01-Apr-2021 03:54 (GMT)