

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: COHORT_SELECTION

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](#)

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/31/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10681079]
2.	Birth Date:	(b) (6)/1955
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: 10681079

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	Aug/31/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1068

Subject No: 10681079

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

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	Aug/31/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

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](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[rectovaginal fistula]
	Start Date:	Mar/9/2020
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[mixed hyperlipidemia]
	Start Date:	Feb/18/2020
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Crohn's Disease]
	Start Date:	UNK/UNK/1969
	Ongoing:	YES

090177e196ae2fdf\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: 10681079

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:	Aug/31/2020
2.	Weight:	[74.8]
3.	Unit:	kg
4.	Height:	[164.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.8]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2fdf\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: 10681079

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

090177e196ae2fdf\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: 10681079

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 :	Aug/31/2020
2.	Randomization Number:	[247855]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_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: 10681079

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: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1D1R]
5.b	Sample ID	[BP1D1S]
5.c	Sample ID	[BP1D1T]
5.d	Sample ID	[BPHS93]
5.e	Sample ID	[BPHS94]

090177e196ae2fdf\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: 10681079

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: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1D1N]
-----	-----------	----------

090177e196ae2fdf\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: 10681079

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:	Aug/31/2020 16:37
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

090177e196ae2fdf\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: 10681079

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
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681079

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/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1068

Subject No: 10681079

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/21/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[99.1]
	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: 10681079

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

090177e196ae2fdf\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: 10681079

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNZPS0]
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090177e196ae2fdf\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: 10681079

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/21/2020 17:04
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

090177e196ae2fdf\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: 10681079

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/19/2020
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: 10681079

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/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNZP57]
5.b	Sample ID	[BNZP58]
5.c	Sample ID	[BNZP59]
5.d	Sample ID	[BNVXDW]
5.e	Sample ID	[BNVXDX]

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681079

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: V4_MONTH6_L

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: 10681079

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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090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681079

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: V5_MONTH12_L

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: 10681079

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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090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681079

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: V6_MONTH24_L

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: 10681079

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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090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: DATE OF VISIT - ILLNESS ONSET

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: 10681079

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/12/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Oct/12/2020
2.	Date of First Symptom Started:	Oct/6/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Oct/14/2020

Symptoms

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.	Symptoms - Other Text:	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Oct/13/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Oct/13/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[Aptima SARS-COV-2 Assay]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

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: 10681079

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	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Oct/12/2020
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	[RW83697]
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090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 10681079

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	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[self swab was collected and shipped, subject was not seen on site.]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Health Care Utilization

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

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
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090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Lab Chemistry Details

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

Lab Result

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Laboratory Data Hematology

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

Lab Result

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Vital Signs

1.	Date:	//
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Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO ₂	FiO ₂ (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

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: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled

Form: IMAGING

Visit on Oct/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Imaging

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: DATE OF VISIT - ILLNESS ONSET

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: 10681079

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	Feb/1/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Feb/1/2021
2.	Date of First Symptom Started:	Jan/31/2021
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Feb/1/2021

Symptoms

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.	Symptoms - Other Text:	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

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: 10681079

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	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/1/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[RW83669]
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090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 10681079

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	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[self swab done so not required]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021**Form:** HEALTH CARE UTILIZATION**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681079**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Lab Chemistry Details

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

Lab Result

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Laboratory Data Hematology

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

Lab Result

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO ₂	FiO ₂ (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

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: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Imaging

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/09/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

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	Nov/9/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/09/2020

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

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: 10681079

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: Nov/9/2020
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	[BNZP89]
5.b	Sample ID	[BNVXK6]
5.c	Sample ID	[BNVXK7]

090177e196ae2fdf\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: 10681079

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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

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/19/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1068

Subject No: 10681079

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: 10681079

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 **Form:** ELECTRONIC SAMPLE TRACKING - 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: 10681079

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

090177e196ae2fdf\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: 10681079

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	Muscle aches	Sep/21/2020 23:00	NO End Date Time: Sep/22/2020 12:00	Repeating Pages
2.	ADVERSE EVENT	2	Headache	Sep/22/2020 10:30	NO End Date Time: Sep/22/2020 12:00	Repeating Pages
3.	ADVERSE EVENT	3	Suspected bacterial meningitis	Feb/6/2021 08:54	NO End Date Time: Feb/20/2021 UNK:UNK	Repeating Pages

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Muscle aches]
4.	Start Date Time:	Sep/21/2020 23:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/22/2020 12:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Sep/22/2020 10:30
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/22/2020 12:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, 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	[]

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Suspected bacterial meningitis]
4.	Start Date Time:	Feb/6/2021 08:54
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/20/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

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: [suspected secondary to pyelonephritis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021132870]

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	Medication Error	Start Date	Is the medication error or Still Ongoing	Study Medication Errors Action	Form Instance
1.	MEDICATION ERROR	administered incorrect dosage at vaccination 1	Aug/31/2020	NO End Date: Aug/31/2020	NO ACTION TAKEN	Repeating Pages

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 17-Jul-2020 21:54
Site No: 1068
Subject No: 10681079
Generated By: (b) (4)

Form: MEDICATION ERROR
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](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Medication Error

1.	Category:	MEDICATION ERROR
2.	Medication Error (Type of Medication Error):	[administered incorrect dosage at vaccination 1]
3.	Start Date:	Aug/31/2020
4.	Is the medication error still ongoing?	NO End Date: Aug/31/2020
5.	Latest Action Taken with Study Treatment:	NO ACTION TAKEN
6.	Was a Concomitant Medication given?	NO
7.	Was a Non-Drug Treatment given?	NO
8.	Did the Medication Error cause the subject to be discontinued from the study?	NO
9.	Was this medication error associated with any adverse events?	NO
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae2fdf\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: 10681079

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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

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: 10681079

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

090177e196ae2fdf\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: 10681079

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2fdf\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: 10681079

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681079

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

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

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

[Back to Form](#)

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: 10681079 **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: 10681079

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: 10-Oct-2020 15:58

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

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:	

090177e196ae2fdf\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: 10681079

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?	

090177e196ae2fdf\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: 10681079

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: 10681079 **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: V201_SURVEIL_CONSENT -
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: 10681079

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: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

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

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

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	Dec/17/2020
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: 10681079

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 and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/17/2020
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: 10681079

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: 10681079

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: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

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/19/2020

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: 10681079

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: 10681079

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 07:35:10 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1068

Subject No: 10681079

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-01-2020 16:54:44 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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
Form	Sep-01-2020 16:58:46 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	post menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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
1	Sep-01-2020 16:58:46 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	post menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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
2	Sep-01-2020 16:58:46 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	post menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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
3	Sep-01-2020 16:58:46 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	post menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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-01-2020 16:58:46 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	post menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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
5	Sep-01-2020 16:58:46 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	post menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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-01-2020 16:58:46 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	post menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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-01-2020 16:58:46 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	post menopausal <hr/> Not Applicable

090177e196ae2fdf\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: 10681079

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-01-2020 16:58:46 (UTC-07:00) Mountain Time (US & Canada)	Emily Anglemyer (b) (4)	post menopausal <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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
Form	Sep-22-2020 10:30:19 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	post menopause since 2007 <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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
1	Sep-22-2020 10:30:19 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	post menopause since 2007 <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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
2	Sep-22-2020 10:30:19 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	post menopause since 2007 <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

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Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Sep-22-2020 10:30:19 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	post menopause since 2007 <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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-22-2020 10:30:19 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	post menopause since 2007 <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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
5	Sep-22-2020 10:30:19 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	post menopause since 2007 <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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-22-2020 10:30:19 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	post menopause since 2007 <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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-22-2020 10:30:19 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	post menopause since 2007 <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681079

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-22-2020 10:30:19 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	post menopause since 2007
			Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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 07:35:10 (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	Feb-08-2021 15:42:06 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Andrew Gentry	Approved	Jan-22-2021 12:05:46 (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.

Emily Anglemyer	N/A	Dec-17-2020 16:02:39 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae2fdf\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:** 10681079**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05**Affidavit:**

N/A

Andrew Gentry	Approved	Nov-09-2020 18:03:39 (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	Nov-09-2020 11:34:36 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Andrew Gentry	Approved	Oct-29-2020 18:04:37 (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.

Michaela ODonoghue	N/A	Oct-29-2020 18:03:32 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Andrew Gentry	Approved	Oct-26-2020 15:34:25 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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	Oct-20-2020 12:05:22 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Andrew Gentry	Approved	Oct-16-2020 20:17:36 (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	Oct-16-2020 09:08:12 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Andrew Gentry	Approved	Oct-15-2020 15:01:38 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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090177e196ae2fdf\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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

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.

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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-01-2020 16:53:23 (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-01-2020 16:53:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae2fdf\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: 10681079

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Sep-01-2020 16:53:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-01-2020 16:53:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10681079	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-01-2020 16:53:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1955	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-01-2020 16:53:51 (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-01-2020 16:53:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NOT HISPANIC OR LATI NO(A) OR OF SPANISH O RIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:53:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: WHITE	Initial Entry

090177e196ae2fdf\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: 10681079

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 16:54:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - 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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-01-2020 16:55:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Aug/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-01-2020 16:55:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-01-2020 16:55:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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.a

Date	Location	User	Value	Reason
Sep-01-2020 16:56:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History rectovaginal fistula Term: Start Date: Mar/9/2020 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 16:56:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:56:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: rectovaginal fistula	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 16:56:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Mar/9/2020	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
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090177e196ae2fdf\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: 10681079
Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Sep-04-2020 12:29:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-04-2020 11:59:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Query 1: Answered	only slight indication that this is happening. there has been no change in therapy, hospitalization, or change in condition.
Sep-02-2020 09:09:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: Please confirm that rectovaginal fistula is ongoing since 2020/03/09 and that disease did not require significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrolment.
Sep-01-2020 16:56:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-01-2020 16:56:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 ber: Medical Histor mixed hyperli y Term: pidemia Start Date: Feb/18/2020 Ongoing: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 16:56:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Feb-16-2021 17:03:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 11:17:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 1: Answered	Changed data per query
Feb-11-2021 14:12:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical On review of the SAE report for Meningitis, Med Hx of Crohn's disease (from 1969) was reported, yet it does not appear on CRF. Please review for clinical relevance to SAE safety event (infection) & report on Med Hx CRF.
Feb-10-2021 20:22:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	Clinical On review of the SAE report for Meningitis, Med Hx of Crohn's disease (from

090177e196ae2fdf\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: 10681079
Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

				1969) was reported, yet it does not appear on CRF. Please review for clinical relevance to SAE safety event (infection) & report on Med Hx CRF.
Sep-01-2020 16:56:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: mixed hyperlipidemia	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 16:56:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Feb/18/2020	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 16:56:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Feb-17-2021 07:55:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Line/MH Number: 3 Medical History Term: Crohn's Disease	Transcription Error

090177e196ae2fdf\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: 10681079
Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			Start Date: UNK/UNK/1969 Ongoing: YES	
Feb-16-2021 17:48:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Line/MH Number: 3 Medical History Term: Chron's Disease Start Date: UNK/UNK/1969 Ongoing: YES	Transcription Error
Feb-16-2021 11:17:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Chron's Disease Start Date: UNK/UNK/1969 Ongoing: YES	Initial Entry

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Feb-16-2021 11:17:37 (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
Feb-17-2021 14:30:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-17-2021 07:55:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-17-2021 07:55:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Crohn's Disease	Transcription Error
Feb-17-2021 07:25:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical please update typo for CROHN's disease
Feb-16-2021 19:45:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.

090177e196ae2fdf\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:** 10681079**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - 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

Canada)				
Feb-16-2021 17:48:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Feb-16-2021 17:48:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Crhon's Disease	Transcription Error
Feb-16-2021 13:56:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Open ed	Clarify CHRON'S DISEASE as follows...Should the spelling be CROHN'S DISEASE? If so, edit. Otherwise clarify. Thank you.
Feb-16-2021 11:17:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Chron's Disease	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Feb-16-2021 11:17:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: UNK/UNK/1969	Initial Entry

I.c Ongoing:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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
Feb-16-2021 11:17:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-01-2020 16:58:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Aug/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-01-2020 16:58:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: 74.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 16:58:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-01-2020 16:58:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: 164.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 16:58:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: cm	Initial Entry

090177e196ae2fdf\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: 10681079
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

Canada)				
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6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-01-2020 16:58:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27.8	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-01-2020 16:58:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Record Identifier: Temperature: 98.4 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 16:58:01 (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-01-2020 16:58:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: 98.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
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090177e196ae2fdf\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: 10681079

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-01-2020 16:58:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: F	Initial Entry
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7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-01-2020 16:58:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

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-01-2020 16:58:46 (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-01-2020 16:58:46 (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-01-2020 16:58:46 (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-01-2020 16:58:46 (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-01-2020 16:58:46 (UTC-07:00)	ACV0PFEINFP6000	Emily Anglemyer	Data Entry: Not Applicable	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

Mountain Time (US & Canada)

(b) (4)

6.a

Date	Location	User	Value	Reason
Sep-01-2020 16:58:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-01-2020 16:58:46 (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-01-2020 16:58:46 (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-01-2020 16:58:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

6.a Not Done:

Date	Location	User	Value	Reason
Sep-01-2020 16:58:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-01-2020 17:00:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Aug/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:00:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: 247855	Initial Entry

090177e196ae2fdf\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: 10681079

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-01-2020 17:00:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 17:00:37 (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 04:53:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	2 serum barcodes updated.
Oct-21-2020 09:29:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	DM: Site request to update form. Do not issue query. Once updates are made form can be re-locked.
Sep-01-2020 17:00:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 17:00:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e196ae2fdf\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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

				entered. Please review and correct as appropriate.
Sep-01-2020 17:00:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 17:00:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BP1D1R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 17:00:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BP1D1R	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 17:01:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BP1D1S	Initial Entry

090177e196ae2fdf\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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 17:01:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BP1D1S	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 17:01:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BP1D1T	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 17:01:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BP1D1T	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-21-2020 14:41:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BPHS93	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 14:41:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BPHS93	Initial Entry

090177e196ae2fdf\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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

5.e

Date	Location	User	Value	Reason
Oct-21-2020 14:42:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BPHS94	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 14:42:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BPHS94	Initial Entry

090177e196ae2fdf\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: 10681079

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-01-2020 17:01:31 (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-01-2020 17:01:31 (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-01-2020 17:01:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 17:01:31 (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-01-2020 17:01:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

090177e196ae2fdf\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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-01-2020 17:01:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BP1D1N	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 17:01:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BP1D1N	Initial Entry

090177e196ae2fdf\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: 10681079

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-01-2020 17:02:17 (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-01-2020 17:02:17 (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-01-2020 17:02:17 (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-01-2020 17:02:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Aug/31/2020 16:37	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 17:02:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae2fdf\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: 10681079

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

6. Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 17:02:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 17:02:17 (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-01-2020 17:02:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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-01-2020 17:02:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES	Initial Entry

090177e196ae2fdf\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: 10681079

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-01-2020 17:02:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECT ED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681079

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 12:30:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Illness entered for 12/Oct
Oct-15-2020 06:17:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ1: Previous response states 'subject was contacted today, 12oct2020. will follow up'. Please confirm if the Covid Illness visit was done for Illness eDiary response on 06OCT2020. Please update or clarify.
Oct-13-2020 00:40:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Awaiting subject confirmation
Oct-12-2020 13:13:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Query 1: Answered	subject was contacted today, 12oct2020. will follow up.
Oct-09-2020 10:54:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per Illness diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681079

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

				the COVID-19 symptoms or diagnosis on 06OCT2020. But there is no COVID Illness visit reported in the database.
Sep-22-2020 10:24:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1068

Subject No: 10681079

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:27:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-22-2020 10:27:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 99.1 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-22-2020 10:27:48 (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-22-2020 10:27:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 99.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
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090177e196ae2fdf\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: 10681079

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

Sep-22-2020 10:27:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry
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2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-22-2020 10:27:48 (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: 10681079

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-22-2020 10:30:19 (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-22-2020 10:30:19 (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-22-2020 10:30:19 (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-22-2020 10:30:19 (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-22-2020 10:30:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

090177e196ae2fdf\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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-22-2020 10:30:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 10:30:19 (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-22-2020 10:30:19 (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-22-2020 10:30:19 (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-22-2020 10:30:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fdf\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: 10681079

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-22-2020 10:30:40 (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-22-2020 10:30:40 (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-22-2020 10:30:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 10:30:40 (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-22-2020 10:30:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae2fdf\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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

Sep-22-2020 10:30:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNZPS0	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 10:30:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNZPS0	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681079

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-22-2020 10:31:16 (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-22-2020 10:31:16 (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-22-2020 10:31:16 (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-22-2020 10:31:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020 17:04	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-22-2020 10:31:16 (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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090177e196ae2fdf\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: 10681079

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-22-2020 10:31:16 (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-22-2020 10:31:16 (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-22-2020 10:31:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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-22-2020 10:31:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fdf\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: 10681079

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-20-2020 12:05:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Oct/19/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

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
Oct-20-2020 12:08:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-20-2020 12:08:45 (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-20-2020 12:09:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 12:08:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-20-2020 12:08:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

090177e196ae2fdf\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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-20-2020 12:09:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Sample ID: BNZP57	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 12:09:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: BNZP57	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 12:09:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Sample ID: BNZP58	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 12:09:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: BNZP58	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 12:09:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Sample ID: BNZP59	Initial Entry

090177e196ae2fdf\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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 12:09:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: BNZP59	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-22-2020 10:40:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BNVXDW	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 10:40:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BNVXDW	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-22-2020 10:40:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: BNVXDX	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 10:40:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: BNVXDX	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail
History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 14:00:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-13-2020 13:58:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-13-2020 13:58:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-13-2020 13:58:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Oct/12/2020	Initial Entry

3. COVID-19 Illness Visit:

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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
Oct-13-2020 13:58:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681079**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Oct/12/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Oct/6/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Oct-15-2020 12:26:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO Date of Last Symptom R esolved: Oct/14/2020	New Information
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Symptoms: FEVE R	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020

Form Version: 10-Oct-2020 16:02

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

			Symptom Present NO	
			:	

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Symptom NEW OR INCR s: EASED COUGH Symptom NO Present:	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sympt NEW OR INCRE oms: ASSED SHORTNE SS OF BREATH Sympt YES om Pre sent:	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Symptoms: CHILL S Symptom Present NO :	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Symptom: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NEW OR INCREASED M USCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Symptom: NEW LOSS OF TASTE OR SENSE OF TASTE Symptom Present: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Symptom: NEW OR INCREASED SORE THROAT Symptom Present: YES	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NEW OR INCREASED SO RE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Symptoms: DIARRH EA Symptom Pres NO ent:	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Symptoms: VOMITI NG Symptom Present: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 14:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-15-2020 12:31:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-15-2020 12:31:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Oct/13/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-15-2020 12:31:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-15-2020 12:31:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-15-2020 12:31:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYND ROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-15-2020 12:31:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC T EST	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

6. Trade Name:

Date	Location	User	Value	Reason
Oct-15-2020 12:31:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-15-2020 12:31:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-16-2020 10:10:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-16-2020 09:08:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-16-2020 09:08:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Aptima SA RS-C OV-2 Assay	New Information

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

<p>Oct-16-2020 07:33:57 (UTC-07:00) Mountain Time (US & Canada)</p>	<p>ACV0PFEINFP6000.InFormAdapter.Discrepancy</p>	<p>PFE SDQ PROD (b) (4)</p>	<p>Query 1: Op ened</p>	<p>sars-cov-2 rna, qualitative real time rt-pcr is not indicated on the FDA-cleared (including Emergency Use Authorization) diagnostic list and is not indicated as 'CLIA- certified lab' or 'ISO 15189 accredited lab' . Please verify and update as appropriate. Otherwise, please provide clarification. (b) (4)</p>
<p>Oct-15-2020 12:31:33 (UTC-07:00) Mountain Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Michaela ODonoghue (b) (4)</p>	<p>Data Entry : SARS -COV -2 RN A, Q UALI TATI VE R EAL TIME RT-P CR</p>	<p>Initial Entry</p>

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

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
Oct-13-2020 14:00:39 (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-13-2020 14:00:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-13-2020 14:24:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 14:00:39 (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-13-2020 14:00:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: YES Date of Collection: Oct/12/2020	Initial Entry

5.a

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF - 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
Oct-13-2020 14:24:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Sample ID: RW83697	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 14:24:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: RW83697	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

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
Oct-13-2020 14:24:38 (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-13-2020 14:24:38 (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
Oct-15-2020 02:48:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-14-2020 12:35:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Oct-14-2020 04:26:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thanks for response. According to protocol 'If no sample was collected or sample was not collected', please update the reason. Else clarify.

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/12/2020
Form Version: 22-Apr-2020 21:03
Site No: 1068
Subject No: 10681079
Generated By: (b) (4)
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

Oct-13-2020 16:03:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Query 1: Answered	not collected at visit yet
Oct-13-2020 14:24:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Oct-13-2020 14:24:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-14-2020 12:35:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: self swab was collected and shipped, subject was not seen on site.	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681079**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: TELEPHONE CONSULTA TION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Type of Practitioner OTH : ER Occurrence of Visits NO or Contacts:	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

If Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: OTHER	Initial Entry

If Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 14:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/12/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLN ESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-13-2020 14:01:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-13-2020 14:01:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: 1	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail
History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681079**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**I. Date of Visit**

Date	Location	User	Value	Reason
Mar-11-2021 00:14:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	This will be checked post BLA
Mar-10-2021 07:29:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Query 3: Answered	Subject is out of state until 2Apr21. The CRA has been notified that a convalescent visit will occur on that date.
Mar-09-2021 03:32:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ: Convalescent visit is missing and 35+ days (36) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Feb-08-2021 16:33:57 (UTC-07:00) Mountain Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail
History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681079**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05

& Canada)				
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-08-2021 16:28:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-08-2021 16:28:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-08-2021 16:28:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Feb/1/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-08-2021 16:28:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681079**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Feb/1/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Jan/31/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO Date of Last Symptom Re solved: Feb/1/2021	Initial Entry

4.a

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Symptoms: FEVE R Symptom Present YES :	Initial Entry

4.a Symptoms:

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Symptoms: NEW OR INCR EASED COUGH H Symptom Present: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.b Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Symptom: NEW OR INCREASED SHORTNESSES OF BREATH Symptom Present: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.c Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NEW OR INCREASED S HORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Symptoms: CHILL S Symptom Present: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Symptoms: NEW OR INCR EASED MUSCLE PAIN Symptom Present: YES	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.e Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NEW OR INCREASED M USCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Symptom: NEW LOSS OF TASTE OR SM ELL Symptom Present: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form Version: 14-Jan-2021 02:23

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

4.f Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NEW LOSS OF TASTE O R SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Sympto NEW OR INCR ms: EASED SORE T HROAT Sympto NO m Prese nt:	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NEW OR INCREASED S ORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Symptoms: DIARRH EA Symptom Pres ent: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.h Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Symptoms: VOMITI NG Symptom Present: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

4.i Symptoms:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-08-2021 16:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-08-2021 16:33:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Feb-08-2021 16:33:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Feb/1/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-08-2021 16:33:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-08-2021 16:33:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Feb-08-2021 16:33:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYND ROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Feb-08-2021 16:33:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC T EST	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

6. Trade Name:

Date	Location	User	Value	Reason
Feb-08-2021 16:33:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Feb-08-2021 16:33:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NEGATIVE	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF - 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. Data Origin

Date	Location	User	Value	Reason
Feb-08-2021 16:33:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-08-2021 16:33:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-08-2021 16:34:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 16:33:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-08-2021 16:33:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES Date of Collection: Feb/1/2021	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF - 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

5.a

Date	Location	User	Value	Reason
Feb-08-2021 16:34:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Sample ID: RW83669	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-08-2021 16:34:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: RW83669	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

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-08-2021 16:34:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-08-2021 16:34:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-08-2021 16:34:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Feb-08-2021 16:34:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: self swab done so not requir ed	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681079**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Type of Practitioner: EMERGENCY ROOM	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

			Occurrence YES of Visits or <i>Number of</i> Contacts: <i>Visits or Co</i> <i>ntacts:</i> 1	
--	--	--	--	--

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES <i>Number of Visits or Conta</i> <i>cts:</i> 1	Initial Entry

1.c

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Type of Prac PRIMARY titioner: CARE PHY SICIAN Occurrence NO of Visits or Contacts:	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: PRIMARY CARE PHYSIC IAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Type of Pra URGENT C ctitioner: ARE Occurrence YES of Visits or <i>Number of</i> Contacts: <i>Visits or Co</i> <i>ntacts:</i> 1	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES <i>Number of Visits or Con- tacts:</i> 1	Initial Entry

I.e

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Type of Prac TELEPHON titioner: E CONSUL TATION Occurrence NO of Visits or Contacts:	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: TELEPHONE CONSULTA TION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

If Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: OTHER	Initial Entry

If Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 16:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled
Visit on Feb/01/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLN ESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Feb-08-2021 16:35:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-08-2021 16:35:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: 1	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/09/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-09-2020 11:34:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Nov/9/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-09-2020 11:34:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: COVID_A1	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/09/2020

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Nov-09-2020 11:34:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-09-2020 11:34:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-09-2020 14:52:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-09-2020 11:34:50 (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.
Nov-09-2020 11:34:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES Date of Collection: Nov/9/2020	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/09/2020

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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Nov-09-2020 15:00:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Sample ID: BNZP89	New Information
Nov-09-2020 14:52:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Sample ID: BNZP89P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 15:00:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-09-2020 15:00:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: BNZP89	New Information
Nov-09-2020 14:52:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Nov-09-2020 14:52:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: BNZP89P	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/09/2020

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

5.b

Date	Location	User	Value	Reason
Nov-09-2020 14:59:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Sample ID: BNVXK6	Transcription Error
Nov-09-2020 14:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Sample ID: BNVXK6	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/09/2020

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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 14:59:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-09-2020 14:59:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-09-2020 14:59:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: BNVXK6	Transcription Error
Nov-09-2020 14:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Nov-09-2020 14:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Nov-09-2020	ACV0PFEINFP6000	Michaela	Data Entry:	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/09/2020

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

14:59:29 (UTC-07:00) Mountain Time (US & Canada)		ODonoghue (b) (4)	BNVXK6	
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5.c

Date	Location	User	Value	Reason
Nov-09-2020 15:01:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Sample ID: BNVXK7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 15:01:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: BNVXK7	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-20-2020 12:43:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-20-2020 12:43:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-20-2020 12:43:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fdf\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: 10681079

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681079

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681079

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-08-2021 15:42:06 (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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-25-2020 11:55:58 (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
Sep-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-28-2020 11:39:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-28-2020 09:47:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-28-2020 09:47:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Muscle ac hes	Transcription Error
Sep-25-2020 13:39:49	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify MUSCLE as

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

(UTC-07:00) Mountain Time (US & Canada)				follows. The term appears incomplete. Please edit to include the condition, diagnosis, procedure or investigation. Are you reporting MUSCLE PAIN ? MUSCLE OPERATION ? MUSCLE BIOPSY ? or other? If so then edit to such, otherwise clarify. Thank you.
Sep-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Muscle	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020 23:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-25-2020 11:55:58	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

(UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	NO End Date Time: Sep/22/2020 12:00
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 11:55:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (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
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020 10:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/22/2020 12:00	Initial Entry

090177e196ae2fdf\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, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 12:21:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Feb-08-2021 15:42:06 (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 15:42:06 (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
Mar-05-2021 18:49:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Query closed; will follow for requested pyelonephritis antibiotic usage information.
Mar-05-2021 12:36:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 4: Answered	complete
Mar-04-2021 18:08:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	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

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

				the indication for both to 'PYELONEPHRITIS'
Feb-22-2021 08:18:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Clinical Thank you; however subject was receiving treatment for pyelonephritis from 01Feb21. This antibiotic is also important as CSF culture is neg and fluid was obtained 06Feb21. Please submit antibiotic Rx for pyelo to SAE
Feb-18-2021 08:16:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 3: Answered	Original value is correct
Feb-17-2021 07:42:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical Please confirm if the subject was receiving NO Con meds at time of SAE onset; e.g. what was the antibiotic subject was receiving for pyelonephritis which started 01Feb21?
Feb-17-2021 07:40:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	rewording
Feb-17-2021 07:29:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

Feb-17-2021 07:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Open ed	Clinical Thank you; please confirm if the subject was receiving NO Con meds at time of SAE onset
Feb-16-2021 17:53:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 2: Answered	Changed data per query
Feb-16-2021 17:49:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 1: Answered	pertinent CBC/diff values reported. are results within normal limits needed?
Feb-15-2021 18:58:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Open ed	Clinical Thank you; please include a CBC/diff if available.
Feb-15-2021 18:54:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Open ed	Clinical - please submit a SAE safety update with any medication for Crohn's disease, pyelonephritis, rectovaginal fistula and any other pre-hospitalization meds in the SAE Con Meds section
Feb-11-2021 14:12:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 2: Answered	per SAE instructions, medications used to treat SAE listed under narrative
Feb-10-2021 20:26:00 (UTC-07:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - Please submit a SAE safety update reporting the

090177e196ae2fdf\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:** 10681079**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1068) Bozeman Health Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:05

Mountain Time (US & Canada)				subject's Concomitant medications in the medication section.
Feb-10-2021 17:11:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 1: Answered	Changed data per query
Feb-10-2021 08:22:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please submit SAE update (#2021132870) with clinical presentation including any fever; also blood (not CSF) tests including hematology
Feb-08-2021 15:42:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Suspected bacterial meningitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-08-2021 15:42:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Feb/6/2021 08:54	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 09:23:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO End Date Time: Feb/20/2021 UNK:UNK	New Information

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

Feb-08-2021 15:42:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-09-2021 11:37:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: 3	Transcription Error
Feb-08-2021 15:42:06 (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-10-2021 19:08:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 15:42:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Suspected bacterial meningitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

				Adverse Event Number" is blank.
Feb-08-2021 15:42:06 (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

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
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090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

Feb-08-2021 15:42:06 (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
Feb-25-2021 05:39:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-23-2021 14:54:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 2: Answered	pyelonephritis occurred outside of the AE reporting window, and thus is not an additional AE.
Feb-22-2021 10:50:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	GPD CLINQUERY: Please confirm if pyelonephritis is a separate adverse event and, if so, record on a separate CRF.
Feb-22-2021 08:19:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 17:24:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-18-2021 17:24:43	ACV0PFEINFP6000	Michaela ODonoghue	Data Entry: NOT RELATED	New Information

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

(UTC-07:00) Mountain Time (US & Canada)		(b) (4)	If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> suspected secondary to pyelonephritis	
Feb-17-2021 07:43:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Other cause for 'Bact Meningitis' is UNKNOWN; however, SAE report states that meningitis developed in the setting of Pylonephritis. Please review possible etiology, and update 'other cause' if appropriate
Feb-08-2021 15:42:06 (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 presently unknown	Initial Entry

10. Latest Action Taken with Study Treatment:				
Date	Location	User	Value	Reason

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

Feb-08-2021 15:42:06 (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
Feb-08-2021 15:42:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-08-2021 15:42:06 (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
Mar-04-2021 11:33:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 09:22:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-04-2021 09:22:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: RECOVERED/RESOLVED	New Information

090177e196ae2fdf\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: 10681079

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

Mar-04-2021 02:37:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021132870,outcome was reported as RECOVERED/RESOLVED to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-08-2021 15:42:06 (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
Feb-08-2021 15:42:06 (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
Feb-10-2021 19:08:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021132870	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: MEDICATION ERROR - Audit Trail

Form Status:

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-29-2020 18:03:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: MEDICATION ERROR - 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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-29-2020 18:03:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: MEDICATION ERROR	Initial Entry

2. Medication Error (Type of Medication Error):

Date	Location	User	Value	Reason
Oct-29-2020 18:03:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: administered incorrect dose at vaccination 1	Initial Entry

3. Start Date:

Date	Location	User	Value	Reason
Oct-29-2020 18:03:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: Aug/31/2020	Initial Entry

4. Is the medication error still ongoing?

Date	Location	User	Value	Reason
Oct-29-2020 18:03:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO End Date: Aug/31/2020	Initial Entry

5. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-29-2020 18:03:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO ACTION TAKEN	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1068

Subject No: 10681079

Generated By: (b) (4)

Form: MEDICATION ERROR - 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

6. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-29-2020 18:03:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

7. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-29-2020 18:03:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

8. Did the Medication Error cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-29-2020 18:03:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

9. Was this medication error associated with any adverse events?

Date	Location	User	Value	Reason
Oct-29-2020 18:03:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Data Entry: NO	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Dec-17-2020 16:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Dec/17/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1068

Subject No: 10681079

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
Dec-17-2020 16:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 16:02:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-17-2020 16:02:49 (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 and NOT confirmed to have received on ly placebo at Vaccination 1/2	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-17-2020 16:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: Dec/17/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-17-2020 16:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Anglemyer (b) (4)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-20-2020 12:43:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-01-2020 17:00:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-01-2020 16:55:02 (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
Feb-17-2021 00:19:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	erroneous entry
Feb-16-2021 11:18:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 3: Answered	erroneous entry, no new symptoms on 08Feb2021
Feb-11-2021 23:01:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	RQ1: Thank you for response. Please confirm if subject had any new illness symptoms on 08FEB2021 or was deemed erroneous entry.

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

Feb-11-2021 14:10:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 3: Answered	participant entered yes as continuation of illness from 1Feb2021.
Feb-11-2021 04:47:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 08FEB2021. But there is no COVID Illness visit reported in the database. Please clarify.
Feb-09-2021 06:30:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-09-2021 03:16:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Added data per query
Feb-08-2021 16:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 1: Answered	Changed data per query
Feb-08-2021 16:37:38 (UTC-07:00) Mountain Time (US	ACV0PFEINFP6000	Michaela ODonoghue (b) (4)	Query 2: Answered	Changed data per query

090177e196ae2fdf\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)				
Feb-08-2021 12:50:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	HOLDS: For COVID Illness visit the lab has received nasal self swab barcode RW83669; however this barcode has not been recorded. Please review and update as appropriate. Otherwise please clarify.
Feb-08-2021 12:17:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 01FEB2021. But there is no COVID Illness visit reported in the database. Please clarify.
Oct-20-2020 12:43:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry
Sep-01-2020 17:00:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae2fdf\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: 10681079

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

Sep-01-2020 16:55:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry
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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: 10681079

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Oct-15-2020 15:01:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Andrew Gentry (b) (4)	Data Entry: Click Here to Enable	Initial Entry