

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: COHORT SELECTION

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: C4591001	Form: MAIN INFORMED CONSENT
Visit: COHORT_SELECTION	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1221) Center for American Indian Health - Gallup
Site No: 1221	Subject Initials: ---
Subject No: 12211007	Generated Time (GMT): 29-Mar-2021 13:11
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/15/2020

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Oct/16/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Seasonal allergies]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Uveitis]
	Start Date:	Jan/UNK/2006
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Chronic intermittent back pain]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Foot fracture]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: Jun/UNK/2014
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Syphilis]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Syphilis]
	Start Date:	Mar/UNK/2020
	Ongoing:	NO End Date: Mar/10/2020
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	Jun/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2018
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Surgical revision of scar tissue in foot]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: Jun/UNK/2014

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/16/2020
2.	Weight:	[118.4]
3.	Unit:	kg
4.	Height:	[180.0]
5.	Unit:	cm
6.	Body Mass Index:	[36.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[99.0]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1221
Subject No: 12211007
Generated By: (b) (4)

Form: RANDOMIZATION
Form Status: Data Complete, Frozen, Verified
Site Name: (1221) Center for American Indian Health - Gallup
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Oct/16/2020
2.	Randomization Number:	[109338]
3.	Randomization Group:	[]

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8BPD]
5.b	Sample ID	[BS71YW]
5.c	Sample ID	[BS71YX]

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8BPC]
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[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:	Oct/16/2020 15:56
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

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

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

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Dec/7/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/7/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8BXJ]
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090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001
Visit: V2_VAX2_L **Form:** VACCINATION
Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified
Site No: 1221 **Site Name:** (1221) Center for American Indian Health - Gallup
Subject No: 12211007 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/7/2020 13:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

Date of Visit			
1.	Date of Visit	Not Done _____ //	Comments
2.	Erroneous Visit	Not Done _____	Comments

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ []
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090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Health Care Utilization

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

Health Care Utilization Other

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

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

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Illness Details

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

Header Text: C4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Abscess in left jaw	Oct/31/2020 UNK:UNK	NO End Date Time: Dec/2/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Meningitis Bacterial	Nov/10/2020 UNK:UNK	NO End Date Time: Dec/2/2020 UNK:UNK	Repeating Pages
3. DELETED	ADVERSE EVENT	3	Pain radiating from left temple/jaw to neck and shoulder	Oct/27/2020 UNK:UNK	YES	Repeating Pages
4.	ADVERSE EVENT	4	STD Exposure	Nov/6/2020 UNK:UNK	NO End Date Time: Nov/6/2020 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	Left Otitis Externa	Nov/6/2020 UNK:UNK	NO End Date Time: Nov/18/2020 UNK:UNK	Repeating Pages

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Abscess in left jaw]
4.	Start Date Time:	Oct/31/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/2/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Inflammation vs. infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Meningitis Bacterial]
4.	Start Date Time:	Nov/10/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/2/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Bacterial infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

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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	[2020449668]

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pain radiating from left temple/jaw to neck and shoulder]
4.	Start Date Time:	Oct/27/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Etiology: unknown, possibly to dental work on Left upper molar.]
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?:	NOT RECOVERED/NOT RESOLVED

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

14.	Did the adverse event cause the subject to be discontinued from the study?	<input checked="" type="radio"/>
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Adverse Event Report

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

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

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Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

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14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left Otitis Externa]
4.	Start Date Time:	Nov/6/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/18/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Ear infection]
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

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Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1221
Subject No: 12211007
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete, Frozen
Site Name: (1221) Center for American Indian Health - Gallup
Subject Initials: ---
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14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Medication Error

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

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Concomitant Medications

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

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Concomitant Medications

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

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Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	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: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Radiation Treatment

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

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

Header Text: C4591001	Form: TRANSFUSIONS
Visit: Logs - Unscheduled	Form Status: Not Started
Form Version: 22-Apr-2020 21:03	Site Name: (1221) Center for American Indian Health - Gallup
Site No: 1221	Subject Initials: ---
Subject No: 12211007	Generated Time (GMT): 29-Mar-2021 13:11
Generated By: (b) (4)	

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

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (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: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Unplanned Assessments

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 20-Feb-2021 02:16

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Not Started

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Vital Signs

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

Vital Signs Details

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Dec-2020 02:26

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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?	

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 1

Form Status: Not Started

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Contact Outcome

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

Header Text: C4591001
Visit: Unplanned Vaccination - Unscheduled
Form Version: 10-Oct-2020 16:01
Site No: 1221
Subject No: 12211007
Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 6
Form Status: Not Started
Site Name: (1221) Center for American Indian Health - Gallup
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:11

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

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Dec/17/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	OTHER
4.	Specify Status:	[Cross over to V101]

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: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/16/2020
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

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Disposition - Follow-Up

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/17/2020
2.	Erroneous Visit	

Header Text: C4591001	Form: INFORMED CONSENT - FURTHER VACCINATION
Visit: V101_VAX3	Form Status: Data Complete, Frozen, Verified
Form Version: 10-Dec-2020 02:31	Site Name: (1221) Center for American Indian Health - Gallup
Site No: 1221	Subject Initials: ---
Subject No: 12211007	Generated Time (GMT): 29-Mar-2021 13:11
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination							
1.	<table border="0"> <tr> <td>Consent Was:</td> <td>OBTAINED</td> </tr> <tr> <td></td> <td>Date Written Consent Obtained</td> </tr> <tr> <td></td> <td>Dec/17/2020</td> </tr> </table>	Consent Was:	OBTAINED		Date Written Consent Obtained		Dec/17/2020
Consent Was:	OBTAINED						
	Date Written Consent Obtained						
	Dec/17/2020						

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Dec/17/2020
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/17/2020
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	[BR8BZS]
5.b	Sample ID	[BS724W]
5.c	Sample ID	[BS724X]

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/17/2020
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	[BR8BZR]
-----	-----------	----------

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/17/2020 12:47
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/16/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001		Form: WITHDRAWAL OF CONSENT
Visit: Disposition - Unscheduled		Form Status: Not Started
Form Version: 22-Apr-2020 21:03		Site Name: (1221) Center for American Indian Health - Gallup
Site No: 1221		Subject Initials: ---
Subject No: 12211007		Generated Time (GMT): 29-Mar-2021 13:11
Generated By: (b) (4)		
Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRJ3ZX]
-----	-----------	----------

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/8/2021 11:35
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Contact Outcome		
1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/5/2021
3.	Comments:	[]

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001
Visit: V104_MONTH6
Form Version: 22-Apr-2020 21:04
Site No: 1221
Subject No: 12211007
Generated By: (b) (4)

Form: CONTACT OUTCOME
Form Status: Not Started
Site Name: (1221) Center for American Indian Health - Gallup
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:11

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

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001
Visit: V105_MONTH18
Form Version: 22-Apr-2020 21:04
Site No: 1221
Subject No: 12211007
Generated By: (b) (4)

Form: CONTACT OUTCOME
Form Status: Not Started
Site Name: (1221) Center for American Indian Health - Gallup
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:11

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

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Feb/5/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Dec/17/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[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: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jane Halpern	Approved	Mar-10-2021 14:25:01 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, JaneHalpern, 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.

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Oct-16-2020 15:41:41 (UTC-07:00) Mountain Time (US & Canada)	Dan VandeRiet (b) (4)	Not Applicable

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Dec-09-2020 11:01:47 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Subject was on vaccination temporary delay due to SAE (illness). Subject was medically cleared to received vaccination dose 2 on 07 Dec 2020.

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-22-2021 18:27:31 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Crossed-over to V101. Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Jan-22-2021 18:27:31 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Crossed-over to V101. Not Done

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Jan-22-2021 18:27:31 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Crossed-over to V101. Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Jan-22-2021 18:28:32 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Crossed-over to V101. Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Jan-22-2021 18:28:32 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Crossed-over to V101. Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Jan-22-2021 18:28:32 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Crossed-over to V101. Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
3	Jan-22-2021 18:28:32 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Crossed-over to V101. Not Done

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
4	Jan-22-2021 18:28:32 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Crossed-over to V101. Not Done

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Dec-17-2020 13:32:30 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Jane Halpern	Approved	Mar-10-2021 14:25:01 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, JaneHalpern, 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 Version: 10-Oct-2020 16:01

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-16-2020 15:39:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (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
Oct-16-2020 15:39:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Consent Was:

Date	Location	User	Value	Reason
Oct-19-2020 00:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query.
Oct-16-2020 16:50:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Query 1: Answered	Dates are correct. Consent/screening took place on 15 Oct; dosing on 16 Oct.
Oct-16-2020 15:41:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Oct-16-2020 15:40:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Oct/15/2020	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-16-2020 15:39:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 12211007	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Dec-10-2020 09:55:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [Redacted]	<u>Data Entry:</u> (b) (6) 1983	Transcription Error
Oct-16-2020 15:39:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6) 1983	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-16-2020 15:40:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	<u>Data Entry:</u> MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-16-2020 15:40:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 15:40:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	<u>Data Entry:</u> AMERICAN INDIAN OR ALASKA NATIVE	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-16-2020 15:41:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: Oct/16/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-16-2020 15:42:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: Oct/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-16-2020 15:42:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-16-2020 15:42:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I.a

Date	Location	User	Value	Reason
Oct-16-2020 15:54:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Seasonal allergies Start Date: UNK/UNK/2012 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 15:54:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 15:54:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: Seasonal allergies	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 15:54:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: UNK/UNK/2012	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 15:54:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-16-2020 16:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Uveitis	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

			Start Date:	Jan/UNK/2006
			Ongoing:	YES

I.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 16:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 16:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: Uveitis	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 16:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: Jan/UNK/2006	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 16:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-16-2020 16:16:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History: Chronic intermittent back pain Term: Start Date: UNK/UNK/2012 Ongoing: YES	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 16:16:45 (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
Oct-16-2020 16:16:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: Chronic intermittent back pain	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 16:16:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: UNK/UNK/2012	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 16:16:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-18-2020 15:21:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Line/MH Number: 4 Medical History Term: Foot fracture Start Date: UNK/UNK/2014 Ongoing: NO End Date: Jun/UNK/2014	Changed Information
Oct-16-2020 16:17:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Scar tissue in foot from broken bones Start Date: UNK/UNK/2014	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001		Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History	
Visit: V1_DAY1_VAX1_L		Form Status: Data Complete, Frozen, Verified	
Form Version: 22-Apr-2020 21:03		Site Name: (1221) Center for American Indian Health - Gallup	
Site No: 1221		Subject Initials: ---	
Subject No: 12211007		Generated Time (GMT): 29-Mar-2021 13:11	
Generated By: (b) (4)			
		Ongoing:	NO
			End Date:
			Jun/UNK/2014

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

I.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 16:17:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-18-2020 15:59:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Oct-18-2020 15:21:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-18-2020 15:21:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Foot fracture	Changed Information
Oct-17-2020 08:23:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term SCAR TISSUE IN FOOT FROM BROKEN BONES. Please split the term into SCAR TISSUE IN FOOT and FOOT BROKEN BONES and submit separately. Thank you.
Oct-16-2020 16:17:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: Scar tissue in foot fro m broken bones	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 16:17:20	ACV0PFEINFP6000	Dan VandeRiet	Data Entry:	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

(UTC-07:00) Mountain Time (US & Canada)		(b) (4)	UNK/UNK/2014	
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I.d Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 16:17:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: NO End Date: Jun/UNK/2014	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-18-2020 14:51:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Line/MH Number: 5 Medical History Term: Syphilis Start Date: UNK/UNK/2013 Ongoing: NO End Date: UNK/UNK/2013	Changed Information
Oct-16-2020 16:30:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Syphilis Start Date: UNK/UNK/2013 Ongoing: NO End Date: UNK/UNK/2013	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 16:30:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-18-2020 15:59:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Oct-18-2020 14:51:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-18-2020 14:51:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Syphilis	Changed Information
Oct-16-2020 19:58:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify SYPHILLIS as follows...Should spelling be SYPHILIS? If so edit as such, otherwise clarify. Thank you.
Oct-16-2020 16:30:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: Syphillis	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 16:30:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: UNK/UNK/2013	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
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090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Oct-16-2020 16:30:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: NO End Date: UNK/UNK/2013	Initial Entry
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If

Date	Location	User	Value	Reason
Oct-18-2020 14:51:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Line/MH Number: 6 Medical History Term Syphilis : Start Date: Mar/UNK/2020 Ongoing: NO End Date: Mar/10/2020	Changed Information
Oct-16-2020 16:31:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term Syphilis : Start Date: Mar/UNK/2020 Ongoing: NO End Date: Mar/10/2020	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

If Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 16:31:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Oct-18-2020 15:59:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Oct-18-2020 14:51:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-18-2020 14:51:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Syphilis	Changed Information
Oct-16-2020 19:58:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify SYPHILLIS as follows...Should spelling be SYPHILIS? If so edit as such, otherwise clarify. Thank you.
Oct-16-2020 16:31:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: Syphillis	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 16:31:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: Mar/UNK/2020	Initial Entry

If Ongoing:

Date	Location	User	Value	Reason
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090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Oct-16-2020 16:31:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: NO End Date: Mar/10/2020	Initial Entry
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I.g

Date	Location	User	Value	Reason
Oct-16-2020 16:33:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Anxiety Start Date: Jun/UNK/2016 Ongoing: NO End Date: UNK/UNK/2018	Initial Entry

I.g Line/MH Number:

Date	Location	User	Value	Reason
Oct-16-2020 16:33:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 16:33:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: Anxiety	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Oct-16-2020 16:33:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: Jun/UNK/2016	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Oct-16-2020 16:33:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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<i>I.h</i>				
Date	Location	User	Value	Reason
Oct-18-2020 15:23:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 8 mber: Medical History Term: Surgical revision of scar tissue in foot Start Date: UNK/UNK/2014 Ongoing: NO End Date: Jun/UNK/2014	Initial Entry

<i>I.h Line/MH Number:</i>				
Date	Location	User	Value	Reason
Oct-18-2020 15:23:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

<i>I.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Oct-18-2020 15:23:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [Redacted]	Data Entry: Surgical revision of scar tissue in foot	Initial Entry

<i>I.h Start Date:</i>				
Date	Location	User	Value	Reason
Oct-18-2020 15:23:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [Redacted]	Data Entry: UNK/UNK/2014	Initial Entry

<i>I.h Ongoing:</i>				
Date	Location	User	Value	Reason
Oct-18-2020 15:23:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [Redacted]	Data Entry: NO End Date: Jun/UNK/2014	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date:

Date	Location	User	Value	Reason
Oct-16-2020 16:32:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: Oct/16/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-16-2020 16:32:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: 118.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-16-2020 16:32:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-16-2020 16:32:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: 180.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-16-2020 16:32:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-16-2020 16:32:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 36.5	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Oct-16-2020 16:32:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: Record Identifier:: 1 Temperature: 99.0 Temperature Unit: F Temperature Location: FOREHEA :	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-16-2020 16:32:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-16-2020 16:32:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: 99.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-16-2020 16:32:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-16-2020 16:32:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Randomization Date :

Date	Location	User	Value	Reason
Oct-18-2020 15:02:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-18-2020 15:02:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Oct/16/2020	Transcription Error
Oct-18-2020 14:59:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Randomization Date 10/Oct/2020 is before or more than 1 day after corresponding Date of Visit 16/Oct/2020. Please review and update as appropriate.
Oct-18-2020 14:59:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Oct/10/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-18-2020 14:59:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: 109338	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (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, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Oct-18-2020 15:00:08 (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-18-2020 15:00:08 (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-18-2020 15:01:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-18-2020 15:00:08 (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-18-2020 15:00:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES Date of Collection: Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-18-2020 15:01:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Sample ID: BR8BPD	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-18-2020 15:01:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: BR8BPD	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (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, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.b

Date	Location	User	Value	Reason
Oct-18-2020 15:01:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Sample ID: BS71YW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-18-2020 15:01:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: BS71YW	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-18-2020 15:02:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Sample ID: BS71YX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-18-2020 15:02:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: BS71YX	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (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, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211007**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-18-2020 15:02:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-18-2020 15:02:55 (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-18-2020 15:03:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-18-2020 15:02:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-18-2020 15:02:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES Date of Collection: Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-18-2020 15:03:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Sample ID: BR8BPC	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-18-2020 15:03:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: BR8BPC	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-18-2020 15:04:15 (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
Oct-18-2020 15:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-18-2020 15:04:15 (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
Oct-18-2020 15:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Oct/16/2020 15:56	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-18-2020 15:04:15 (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
Oct-18-2020 15:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Oct-18-2020 15:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-18-2020 15:04:15 (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
Oct-18-2020 15:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: YES	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-18-2020 15:04:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-11-2020 00:46:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	Closed per SITE response - added to PD tracker for Clinical review
Dec-09-2020 11:02:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	Subject was on vaccination temporary delay due to SAE (illness). Subject was medically cleared to received vaccination dose 2 on 07 Dec 2020.
Dec-08-2020 23:11:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Opened	PDQ RQ1: As per your response, V2 was delayed for acute illness. Thus, please confirm whether corresponding temp. delay details can be updated on Vaccination form as appropriate. Else clarify.
Dec-08-2020 22:50:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Closed per SITE response, added to PD tracker for Clinical Review
Dec-08-2020 07:57:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 1: Answered	V2 was delayed for acute illness. (See SAE report). He was hospitalized with meningitis.
Dec-07-2020 23:56:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at V2_VAX2_L is out of window for 29 days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in

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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

				query response appropriately. (b) (4)
Dec-07-2020 15:01:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Dec/7/2020	New Information
Nov-11-2020 08:56:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: Nov/4/2020	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date:

Date	Location	User	Value	Reason
Dec-07-2020 15:17:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Dec/7/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-07-2020 15:17:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 98.3 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-07-2020 15:17:33 (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
Dec-07-2020 15:17:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Dec-07-2020 15:17:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Dec-07-2020 15:17:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Dec-07-2020 15:17:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-07-2020 15:17:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-07-2020 15:18:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-07-2020 15:17:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-07-2020 15:17:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Dec/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-07-2020 15:18:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BR8BXJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 15:18:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BR8BXJ	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-07-2020 14:29:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO	New Information
Nov-11-2020 08:56:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: YES Date of First Delay: Nov/4/2020 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-07-2020 14:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-07-2020 14:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-07-2020 15:01:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-07-2020 14:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Dose Date is not equal to Date of Visit 04/Nov/2020 of the corresponding Visit. Please review and update as appropriate.
Dec-07-2020 14:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Dec/7/2020 13:00	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-07-2020 14:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-07-2020 14:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Dec-07-2020 14:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-07-2020 14:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 14:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-29-2021 11:03:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Jan-29-2021 10:54:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Changed data per query
Jan-29-2021 04:57:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: It appears V3 did not take place because V101 occurred within 28d of Vax2. If so, please complete first EOT page as status OTHER with specify status field explaining: subject proceeded to open label prior to V3 in the blinded Rx phase
Jan-22-2021 18:27:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Jan-22-2021 18:27:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Not Done	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (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, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Jan-22-2021 18:28:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-22-2021 18:28:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-22-2021 18:28:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 18:28:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Not Done	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

Header Text: C4591001

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

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Date	Location	User	Value	Reason
Nov-12-2020 12:19:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Form Deleted	New Information
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

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Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

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Date	Location	User	Value	Reason
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

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Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-04-2020 17:28:39 (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
Nov-04-2020 17:28:39 (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
Nov-17-2020 11:23:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Nov-17-2020 08:35:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 2: Answered	Date of diagnosis was 6 Nov. not 7 Nov. Updated AE log.
Nov-15-2020 10:00:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Per case narrative, other additional event were reported, Use of antibiotics for "left otitis externa and associated facial cellulitis from 07Nov2020" Please revise and update AE log accordingly.
Nov-12-2020 12:27:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	Data Entry: Abscess in left jaw	Information from patient, waiting for official medical records
Nov-06-2020 14:56:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-06-2020 12:41:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 1: Answered	Dx by ED doctor was "inflammation", based on CT scan showing temporalis muscle asymetry and ?inflammation vs infection. Headache is

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				over the area of temple that was tender and slightly swollen. Will f/u when he returns. could be dental or TMJ
Nov-06-2020 09:58:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	clinical: Has a more specific dx been made? What are the results of any evaluation/testing? Is this soft tissue swelling? Does the pt have a hx of prior episodes or prior hx temporal headache?
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: Left temporal/facial swelling	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: Oct/31/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-18-2020 07:18:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Dec-14-2020 19:05:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-14-2020 19:05:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO End Date Time: Dec/2/2020 UNK:UNK	New Information
Dec-11-2020 08:37:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: please confirm if this AE is still ongoing
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

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Date	Location	User	Value	Reason
Nov-12-2020 12:28:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<u>Data Entry:</u> 3	New Information
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<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
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<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
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Inflammation vs. infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-14-2020 19:06:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-14-2020 19:06:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: RECOVERED/RESOLVED	New Information
Dec-14-2020 19:05:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Abscess in left jaw: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-19-2020 12:35:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: RECOVERING/RESOLVING	New Information
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NOT RECOVERED/NOT RESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 17:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-04-2020 17:32:02 (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
Nov-04-2020 17:32:02 (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
Nov-17-2020 11:21:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Nov-17-2020 08:35:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 2: Answered	Changed data per query
Nov-15-2020 10:11:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Per case narrative, ""subject was treated for potential sexually transmitted diseases (STDs)". As this is potential additional event, please revise and update AE log accordingly. Thank you.
Nov-14-2020 08:15:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020 17:57:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Meningitis Bacterial	Transcription Error
Nov-13-2020 14:09:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-13-2020 14:09:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Bacterial Meningitis	Changed Information

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Nov-13-2020 05:25:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	SAE RECON:AER#2020449668, the term in AE CRF was reported as Meningitis' while recorded as Bacterial meningitis in Safety database . Please confirm correct term. If safety update is required, please submit a follow-up form.
Nov-12-2020 12:22:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: Meningitis	Spoke with subject who said that he had been admitted to a hospital with meningitis
Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: Headache, Left temporal area	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-12-2020 12:23:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: Nov/10/2020 UNK:UNK	New Information
Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: Oct/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-16-2020 14:02:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO End Date Time: Dec/2/2020 UNK:UNK	New Information
Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-12-2020 12:23:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: 3	New Information
Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: 1	Initial Entry

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(US & Canada)

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
Nov-13-2020 05:24:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-12-2020 12:24:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Meningitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-12-2020 12:24:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Data Entry: YES Is this serious event associated with c ongenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prol ong hospitalization? YES Did this serious event result in persist ent or significant disability/incapacity ? NO Is this serious event life threatening? YES Other medically important serious ev ent NO	New Information

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Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-12-2020 12:25:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER <i>If Other, specify:</i> Bacterial infection	Subject states he was admitted with "bacterial meningitis". We do not yet have medical records to confirm this.
Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER <i>If Other, specify:</i> L temporal/Facial inflammation	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: YES	Initial Entry

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 03:11:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	Response satisfies query
Dec-16-2020 22:00:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Closed	Response satisfies query
Dec-16-2020 14:03:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 3: Answered	Changed data per query
Dec-15-2020 02:01:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW6461436:Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Dec-14-2020 19:07:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-14-2020 19:07:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: : RECOVERED/RESOLVED	New Information

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Dec-11-2020 04:08:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Op ened	SAE RECON:AER#2020449668,outcome was updated to Recovered/Resolved on Safety database while retained as RECOVERING/RESOLVING in AE CRF.Please confirm correct outcome.If safety update is required,please submit a follow-up form
Nov-20-2020 01:36:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Clo sed	Response satisfies query
Nov-19-2020 12:13:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	New Information
Nov-19-2020 12:13:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry : RECO VERI NG/R ESOL VING	New Information
Nov-19-2020 04:29:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Op ened	SAE RECON:AER#2020449668,outcome was updated to RECOVERING/RESOLVING on Safety database while reported as Not Recovered/Not Resolved in AE CRF.Please confirm correct outcome.If safety update is required,please submit a follow-up form
Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry : NOT RECO VERE D/NO T RE SOLV	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 17:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-13-2020 05:24:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: 2020449668	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

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1. Category:

Date	Location	User	Value	Reason
Nov-11-2020 10:28:03 (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
Nov-11-2020 10:28:03 (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
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: Pain radiating from left temple/jaw to neck and shoulder	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: Oct/27/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

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
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<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
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Etiology: unknown, possibly to dental work on Left upper molar.	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> YES	Initial Entry

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Header Text: C4591001

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Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> 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
Nov-11-2020 10:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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1. Category:

Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-17-2020 13:40:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Nov-17-2020 11:43:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	The prophylaxis is not an AE. It is the treatment he received for the exposure.
Nov-17-2020 11:43:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: STD Exposure	The prophylaxis is not an AE. It is the treatment he received for the exposure.
Nov-17-2020 10:33:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term STD EXPOSURE/PROPHYLAXIS. Split the term into STD EXPOSURE and STD PROPHYLAXIS and report as separate entries. Thank you.
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: STD Exposure /prophylaxis	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

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4. Start Date Time:

Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: Nov/6/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-17-2020 09:54:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO End Date Time: Nov/6/2020 UNK:UNK	New Information
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

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Header Text: C4591001

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Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unprotected sex with a male	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-17-2020 08:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

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Generated By: (b) (4)

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Form Status: Data Complete, Frozen

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1. Category:

Date	Location	User	Value	Reason
Nov-17-2020 08:33:39 (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
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-19-2020 05:38:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-17-2020 11:45:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Removed cellulitis. It was a result of the left jaw abscess.
Nov-17-2020 11:45:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: Left Otitis Externa	Removed cellulitis. It was a result of the left jaw abscess.
Nov-17-2020 10:35:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Please split the term LEFT OTITIS EXTERNA WITH CELLULITIS into LEFT OTITIS EXTERNA and the term CELLULITIS.Thank you.
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: Left Otitis Externa with cellulitis	Initial Entry

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Header Text: C4591001

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Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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(US & Canada)

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: Nov/6/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-18-2020 07:17:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Dec-14-2020 19:07:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-14-2020 19:07:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: NO End Date Time: Nov/18/2020 UNK:UNK	New Information
Dec-11-2020 09:07:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please confirm if AE is still ongoing
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

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Form Status: Data Complete, Frozen

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Subject Initials: ---

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(US & Canada)

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
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Ear infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-14-2020 19:08:10	ACV0PFEINFP6000	auto query	Query 1: Closed	Close Auto Query

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

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Generated By: (b) (4)

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(UTC-07:00) Mountain Time (US & Canada)		(autoquery)		
Dec-14-2020 19:08:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: RECOVERED/RESOLVED	New Information
Dec-14-2020 19:07:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Left Otitis Externa: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-17-2020 08:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Data Entry: NO	Initial Entry

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Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-29-2021 10:56:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Dec/17/2020	Changed Information
Jan-29-2021 10:54:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Jan/7/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-29-2021 10:54:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-29-2021 10:54:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: OTHER	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Jan-29-2021 10:54:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Cross over to V101	Initial Entry

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Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

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Generated By: (b) (4)

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-17-2020 13:31:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Dec/16/2020	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

Date	Location	User	Value	Reason
Dec-18-2020 11:36:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-18-2020 03:12:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-17-2020 13:31:57 (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 13:31:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-17-2020 13:32:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Dec/17/2020	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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I. Consent Was:

Date	Location	User	Value	Reason
Dec-17-2020 13:32:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Dec/17/2020	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-17-2020 13:32:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Dec/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-17-2020 13:32:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-17-2020 13:32:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Dec-17-2020 14:03:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-17-2020 14:03:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-17-2020 14:03:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 14:03:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-17-2020 14:03:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Dec/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-17-2020 14:03:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BR8BZS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 14:03:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BR8BZS	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.b

Date	Location	User	Value	Reason
Dec-17-2020 14:04:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BS724W	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 14:04:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BS724W	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-17-2020 14:04:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BS724X	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 14:04:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BS724X	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Dec-17-2020 13:33:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-17-2020 13:33:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-17-2020 13:33:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 13:33:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-17-2020 13:33:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Dec/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-17-2020 13:33:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BR8BZR	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 13:33:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BR8BZR	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-17-2020 14:05:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-17-2020 14:05:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-17-2020 14:05:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-17-2020 14:05:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Dec/17/2020 12:47	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-17-2020 14:05:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-17-2020 14:05:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Dec-17-2020 14:05:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Dec-17-2020 14:05:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Dec-17-2020 14:05:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-17-2020 14:05:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 14:05:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-18-2020 11:36:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	Data Entry: Dec/16/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-18-2020 11:36:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	Data Entry: ASSESS ELIGIBILITY FOR ADDITI ONAL VACCINATION	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-08-2021 12:01:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/8/2021	Initial Entry

Header Text: C4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211007**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-08-2021 12:02:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-08-2021 12:02:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-08-2021 12:02:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 12:02:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-08-2021 12:02:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Jan/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-08-2021 12:02:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BRJ3ZX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-08-2021 12:02:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BRJ3ZX	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-08-2021 12:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-08-2021 12:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-08-2021 12:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-08-2021 12:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jan/8/2021 11:35	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-08-2021 12:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-08-2021 12:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Jan-08-2021 12:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Jan-08-2021 12:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-08-2021 12:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-08-2021 12:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 12:03:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-05-2021 15:52:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	Data Entry: Feb/5/2021	Initial Entry

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Contact Type:

Date	Location	User	Value	Reason
Feb-05-2021 15:53:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-05-2021 15:53:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	Data Entry: YES Date of Contact: Feb/5/2021	Initial Entry

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-09-2021 09:11:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Feb/5/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-09-2021 09:11:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-09-2021 22:24:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Feb-09-2021 16:32:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Original value is correct
Feb-09-2021 16:30:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-09-2021 16:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is COMPLETED but "Specify Status" is Provided.
Feb-09-2021 14:07:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7210764;Status on the Disposition - Treatment form is COMPLETED, but Visit 3 Date is missing. Please review and update as appropriate.

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211007

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Feb-09-2021 09:11:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: COMPLETED	Initial Entry
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4. Specify Status:

Date	Location	User	Value	Reason
Feb-09-2021 16:30:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry:	Changed Information
Feb-09-2021 16:29:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Visit 3 not done due to crossover to V101	Initial Entry

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211007

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Subject Status

Date	Location	User	Value	Reason
Jan-29-2021 10:54:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-18-2020 15:02:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Transcription Error
Oct-18-2020 14:59:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-16-2020 15:42:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jan-29-2021 10:56:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/17/2020	Changed Information
Jan-29-2021 10:54:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/7/2021	Initial Entry
Oct-18-2020 15:02:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/16/2020	Transcription Error
Oct-18-2020 14:59:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/10/2020	Initial Entry
Oct-16-2020 15:42:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/16/2020	Initial Entry

090177e196ae4041\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

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