

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Nov/18/2020
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Header Text: C4591001
Visit: COHORT_SELECTION **Form:** DEMOGRAPHY
Form Version: 15-Sep-2020 21:54 **Form Status:** Data Complete, Frozen, Verified
Site No: 1220 **Site Name:** (1220) Shiprock Center for American Indian Health
Subject No: 12201052 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12201052]
2.	Birth Date:	(b) (6) 1985
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/18/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Nov/18/2020
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: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

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/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[acne]
	Start Date:	UNK/UNK/1999
	Ongoing:	NO End Date: UNK/UNK/2002

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001	Form: HIV STATUS
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Frozen, Verified
Form Version: 15-Sep-2020 21:57	Site Name: (1220) Shiprock Center for American Indian Health
Site No: 1220	Subject Initials: ---
Subject No: 12201052	Generated Time (GMT): 29-Mar-2021 13:11
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/18/2020
2.	Weight:	[190.2]
3.	Unit:	LB
4.	Height:	[69.0]
5.	Unit:	in
6.	Body Mass Index:	[28.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Nov/18/2020
2.	Randomization Number:	[116356]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

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: Nov/18/2020
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	[BR8P6H]
5.b	Sample ID	[BS70J3]
5.c	Sample ID	[BS70JL]

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

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: Nov/18/2020
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	[BR8P9X]
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090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

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:	Nov/18/2020 16:28
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

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001	Form: REACTOGENICITY DIARY
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Frozen, Verified
Form Version: 06-Jul-2020 21:53	Site Name: (1220) Shiprock Center for American Indian Health
Site No: 1220	Subject Initials: ---
Subject No: 12201052	Generated Time (GMT): 29-Mar-2021 13:11
Generated By: (b) (4)	

[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: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/8/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Dec/8/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

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/8/2020
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	[BR8PDT]
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090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

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:	Dec/8/2020 15:05
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

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/11/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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: Jan/11/2021
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	[BR8P7Y]	Comments
5.b	Sample ID	[BS70XW]	Comments
5.c	Sample ID	[BS70ZM]	Comments

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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:	
----	-------------------------	--

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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:	[]
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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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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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090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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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090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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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090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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	Soreness at injection site	Nov/19/2020 08:00	NO End Date Time: Nov/19/2020 22:00	Repeating Pages
2.	ADVERSE EVENT	2	Chills	Dec/8/2020 18:05	NO End Date Time: Dec/9/2020 08:00	Repeating Pages
3.	ADVERSE EVENT	3	Soreness at injection site	Dec/8/2020 18:05	NO End Date Time: Dec/9/2020 08:00	Repeating Pages
4.	ADVERSE EVENT	4	headache	Dec/9/2020 07:00	NO End Date Time: Dec/10/2020 07:00	Repeating Pages
5.	ADVERSE EVENT	5	Malaise	Dec/9/2020 07:00	NO End Date Time: Dec/10/2020 07:00	Repeating Pages
6.	ADVERSE EVENT	6	Lymphadenopathy Left axillary	Dec/9/2020 06:00	NO End Date Time: Dec/14/2020 07:00	Repeating Pages

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

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)	[Soreness at injection site]
4.	Start Date Time:	Nov/19/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/19/2020 22:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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	[]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

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)	[Chills]
4.	Start Date Time:	Dec/8/2020 18:05
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/9/2020 08:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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	[]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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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)	[Soreness at injection site]
4.	Start Date Time:	Dec/8/2020 18:05
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/9/2020 08:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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	[]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

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)	[headache]
4.	Start Date Time:	Dec/9/2020 07:00
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/10/2020 07:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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	[]

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

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)	[Malaise]
4.	Start Date Time:	Dec/9/2020 07:00
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/10/2020 07:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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	[]

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Lymphadenopathy Left axillary]
4.	Start Date Time:	Dec/9/2020 06:00
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/14/2020 07:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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	[]

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

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	[]

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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:	//

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

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?	

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

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?	

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Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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?	

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Jan/11/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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/23/2020
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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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 and NOT 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: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

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: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/23/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1220) Shiprock Center for American Indian Health

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: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Jan/11/2021

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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
(b) (6)	Approved	Mar-11-2021 11:35:45 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Nov-18-2020 15:48:18 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

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, Frozen, Verified

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.a	Jan-12-2021 08:26:43 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Serum-Send

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, Frozen, Verified

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Jan-12-2021 08:27:15 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Serum-Retain

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, Frozen, Verified

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.c	Jan-12-2021 08:30:15 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Serum-Retain

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-11-2021 11:35:45 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Feb-19-2021 13:25:38 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Laura Hammit	Approved	Jan-23-2021 08:07:12 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Jan-11-2021 10:32:43 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Laura Hammit	Approved	Jan-11-2021 09:57:26 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

(b) (6)	N/A	Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Laura Hammit	Approved	Dec-04-2020 23:00:38 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, LauraHammit, 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.

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

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
Nov-18-2020 15:46:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-18-2020 15:46:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Nov-18-2020 15:46:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Nov/18/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Nov-18-2020 15:45:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12201052	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Nov-18-2020 15:45:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1985	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Nov-18-2020 15:46:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Nov-18-2020 15:46:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-18-2020 15:46:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: WHITE	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-18-2020 15:47:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Nov/18/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

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
Nov-18-2020 15:48:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Nov/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-18-2020 15:48:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-18-2020 15:48:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1.a

Date	Location	User	Value	Reason
Nov-18-2020 16:01:30 (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/2005 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Nov-18-2020 16:01:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Nov-18-2020 16:01:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: seasonal allergies	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Nov-18-2020 16:01:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2005	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Nov-18-2020 16:01:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

1.b

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

Date	Location	User	Value	Reason
Nov-18-2020 16:02:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History acne Term: Start Date: UNK/UNK/1999 Ongoing: NO End Date: UNK/UNK/ 2002	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Nov-18-2020 16:02:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Nov-18-2020 16:02:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: acne	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Nov-18-2020 16:02:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/1999	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Nov-18-2020 16:02:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date: UNK/UNK/2002	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-18-2020 15:48:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Nov-18-2020 15:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Nov/18/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Nov-18-2020 15:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 190.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Nov-18-2020 15:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Nov-18-2020 15:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 69.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Nov-18-2020 15:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Nov-18-2020 15:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28.1	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

7.a

Date	Location	User	Value	Reason
Nov-18-2020 15:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Locati on:: FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Nov-18-2020 15:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Nov-18-2020 15:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 97.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Nov-18-2020 15:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Nov-18-2020 15:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Nov-18-2020 16:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Nov/18/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Nov-18-2020 16:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 116356	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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
Nov-18-2020 15:49:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-18-2020 15:49:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-19-2020 09:38:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-19-2020 02:37:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-18-2020 15:49:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-18-2020 15:49:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Nov/18/2020	Initial Entry

5.a

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-19-2020 09:38:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BR8P6H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 09:38:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BR8P6H	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-19-2020 09:39:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BS70J3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 09:39:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BS70J3	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-19-2020 09:40:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BS70JL	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 09:40:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BS70JL	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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
Nov-18-2020 15:50:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-18-2020 15:50:04 (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
Nov-19-2020 09:37:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-19-2020 02:37:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-18-2020 15:50:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-18-2020 15:50:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Nov/18/2020	Initial Entry

5.a

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-19-2020 09:37:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Sample ID: BR8P9X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 09:37:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: BR8P9X	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

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
Nov-18-2020 16:39:55 (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
Nov-18-2020 16:39:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-18-2020 16:39:55 (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
Nov-18-2020 16:39:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Nov/18/2020 16:28	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-18-2020 16:39:55 (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
Nov-18-2020 16:39:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: LEFT	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Nov-18-2020 16:39:55 (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
Nov-18-2020 16:39:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-18-2020 16:39:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Nov-18-2020 15:50:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-08-2020 15:51:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/8/2020	Initial Entry

Header Text: C4591001**Visit:** V2_VAX2_L**Form Version:** 10-Oct-2020 16:01**Site No:** 1220**Subject No:** 12201052**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1220) Shiprock Center for American Indian Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Dec-08-2020 15:51:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-08-2020 15:51:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Record Identifier: 1 : Temperature: 97.7 Temperature Unit F : Temperature Loc FOREHE ation:: AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-08-2020 15:51:41 (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-08-2020 15:51:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 97.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Dec-08-2020 15:51:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: F	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Dec-08-2020 15:51:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: FOREHEAD	Initial Entry

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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-08-2020 15:51:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-08-2020 15:51:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-08-2020 16:18:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-08-2020 15:51:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-08-2020 15:51:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Dec/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-08-2020 16:18:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR8PDT	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-08-2020 16:18:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BR8PDT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

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-08-2020 15:52:08 (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-08-2020 15:52:08 (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-08-2020 15:52:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-08-2020 15:52:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/8/2020 15:05	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-08-2020 15:52:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-08-2020 15:52:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: LEFT	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Dec-08-2020 15:52:08 (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-08-2020 15:52:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Dec-08-2020 15:52:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-11-2021 10:32:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/11/2021	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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-11-2021 10:33:05 (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-11-2021 10:33:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-12-2021 08:26:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 10:33:05 (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-11-2021 10:33:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Jan/11/2021	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-12-2021 08:27:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry:	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (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, Frozen, Verified**Site No:** 1220**Site Name:** (1220) Shiprock Center for American Indian Health**Subject No:** 12201052**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**5.a**

Date	Location	User	Value	Reason
Jan-12-2021 08:26:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR8P7Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 08:26:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BR8P7Y	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-12-2021 08:27:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BS70XW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 08:27:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BS70XW	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-12-2021 08:30:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BS70ZM	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 08:30:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BS70ZM	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Dec-11-2020 16:04:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Dec-08-2020 15:24:34 (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
Dec-08-2020 15:24:34 (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
Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Soreness at injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Nov/19/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Nov/19/2020 22:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-08-2020 15:24:34 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

Time (US & Canada)	(b) (4)
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-08-2020 15:24:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Dec-11-2020 16:04:55 (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
Dec-11-2020 16:04:55 (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
Dec-11-2020 16:04:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Chills	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-11-2020 16:04:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/8/2020 18:05	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-11-2020 16:04:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Dec/9/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Dec-11-2020 16:04:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-11-2020 16:04:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-11-2020 16:04:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-11-2020 16:04:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-11-2020 16:04:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-11-2020 16:04:55 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (6)	Data Entry: NO	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4)
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-11-2020 16:04:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-11-2020 16:04:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-11-2020 16:04:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (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
Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Soreness at injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/8/2020 18:05	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Dec/9/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (6)	Data Entry: NO	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

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Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

Time (US & Canada)	(b) (4)
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-11-2020 16:06:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/9/2020 07:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-11-2021 10:49:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Dec/10/2020 07:00	Transcription Error
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time:	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

Dec/9/2020 07:00

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-11-2021 10:50:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 10:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (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
Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Malaise	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/9/2020 07:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Dec/10/2020 07:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4)
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 10:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-11-2021 14:21:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Lymphadenopathy Left axillary	Transcription Error
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Lymphadenopathy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/9/2020 06:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Dec/14/2020 07:00	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 10:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

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-11-2021 10:34:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/11/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-11-2021 10:34:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-11-2021 10:34:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-19-2021 13:25:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/23/2020	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Mar-09-2021 16:10:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Mar-09-2021 15:34:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-09-2021 15:34:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirme d to have received only pla cebo at Vaccination 1/2	Transcription Error
Mar-09-2021 08:33:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	CLINQUERY: Please review if correct selection has been made here. Treatment Unblind performed ('Assess for Additional Vax'). Therefore, was the subject willing to participate in revax and eligible for unblind? (NB eligible is not related to Rx arm)
Mar-08-2021 10:51:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candidate	CLINQUERY: Please review if correct selection has been made here. Treatment Unblind performed ('Assess for Additional Vax'). Therefore,

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

				was the subject willing to participate in revax and eligible for unblind? (NB eligible is not related to Rx arm)
Feb-19-2021 13:25:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-26-2021 12:55:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Dec/23/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-10-2021 10:39:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Clo sed	Response satisfies query
Mar-09-2021 15:37:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: An swere d	Participant was unblinded 23 DEC 2020. Pt. is willing to return, eligible and NOT confirmed to have received placebo. Information is confirmed.
Mar-04-2021 23:16:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 3: Rei ssued: Open ed	DM: Please update selection on this form OR confirm 1) If the Unblinding occurred before the participant was determined to be willing/eligible for Vaccination 3, or 2) If the participant later decided to continue in the study and not proceed with VAX3.
Mar-04-2021 16:04:46 (UTC-07:00) Mountain Time (US &	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: An swere d	All participants were contacted when eligible locally to receive vaccine and were asked if they wanted

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

Canada)				unblinded
Mar-04-2021 01:44:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Rei ssued: Opene d	DM: Please update selection on this form OR confirm 1) participant was assigned to placebo and returned to safety FUP or 2) treatment unblinded before subject contacted to confirm willingness/eligibility to proceed with Vax 3. Thank you.
Mar-03-2021 16:28:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 4: Clo sed	new query issued
Mar-03-2021 08:37:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: An swere d	Participant is NOT eligible or willing to return for vaccine. Date Entry Guidelines 8.66 FAQ#3
Mar-03-2021 08:36:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 4: An swere d	Participant is NOT eligible or willing to return for vaccine. Date Entry Guidelines 8.66 FAQ#3
Mar-03-2021 02:42:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Clo sed	Closed per data updated by site.
Mar-03-2021 02:40:24 (UTC-07:00) Mountain Time (US &	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Rei ssued: Opene d	As Subject is NOT willing to return for Vax 3, please confirm if participant was assigned to placebo and

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

Canada)				returned to safety FUP or treatment Unblinded before subject contacted to confirm willingness/eligibility to proceed with Vax 3, Else, clarify.
Mar-02-2021 22:21:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 4: Opened	DMW7580036;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Mar-02-2021 16:33:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Mar-02-2021 16:33:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Mar-02-2021 16:33:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry</u> : ASSESS ELIGIBILITY FOR ADDITIONAL V	Changed Information

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

			ACCI NATI ON	
Mar-02-2021 07:06:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 3: Op ened	DM RQ1: As per response provided- Vaccine Recipient, please verify eCCG section 8.66 FAQ#3 and update the data in database accordingly. Else clarify.
Mar-02-2021 02:53:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_35
Mar-02-2021 00:08:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Op ened	IVRS Reconciliation: Other is selected as the primary reason for unblinding but matching blind break is not captured in IRT. Please correct primary reason in Inform or confirm as correct".
Mar-01-2021 12:46:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Changed Information
Mar-01-2021 12:46:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry : OTH ER <i>If ot her, spec ify:</i> Va cci	Changed Information

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

			ne Re cip ien t	
Feb-26-2021 23:13:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7482250;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Feb-26-2021 12:55:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry : ASSE SS EL IGIBI LITY FOR ADDI TION AL V ACCI NATI ON	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1220

Subject No: 12201052

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1220) Shiprock Center for American Indian Health

Subject Initials: ---

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

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1. Subject Status

Date	Location	User	Value	Reason
Jan-11-2021 10:34:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Nov-18-2020 16:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Nov-18-2020 15:48:35 (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-11-2021 10:34:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/11/2021	Initial Entry
Nov-18-2020 16:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/18/2020	Initial Entry
Nov-18-2020 15:48:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/18/2020	Initial Entry

090177e196ae30d0\Final\Final On: 01-Apr-2021 04:17 (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: 1220

Site Name: (1220) Shiprock Center for American Indian Health

Subject No: 12201052

Subject Initials: ---

Generated By: (b) (4)

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Dec-03-2020 15:47:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Click Here to Enable	Initial Entry