

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[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

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/10/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12461131]
2.	Birth Date:	UNK/UNK/1986
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/10/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**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 _____
----	--	-------------------------

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Oct/10/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Endometriosis uterus]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Endometriosis left ovary]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** HIV STATUS

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[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:** 15-Sep-2020 21:56

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/10/2020
2.	Weight:	[79.8]
3.	Unit:	kg
4.	Height:	[171.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.3]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

6.a	Sponsor ID:	[113]	<a href="#">Comments</a>
	Test:	Choriogonadotropin Beta_PX113	
	Result:		<a href="#">Comments</a>
	Not Done:	NOT DONE	<a href="#">Comments</a>

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Oct/10/2020
2.	Randomization Number:	[105789]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/10/2020
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	[BM9HKV]
5.b	Sample ID	[BRSSX6]
5.c	Sample ID	[BRSSX5]

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/10/2020
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	[BM9HKL]
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/10/2020 08:50
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

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[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:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/31/2020
2.	Erroneous Visit	

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/31/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 15-Sep-2020 21:51**Site No:** 1246**Subject No:** 12461131**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1246) Jongaie Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

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

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BM9DW5]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/31/2020 08:24
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

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246 **Site Name:** (1246) Jongaie Research

**Subject No:** 12461131 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/28/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246 **Site Name:** (1246) Jongaie Research

**Subject No:** 12461131 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/28/2020
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	[BM9DZR]
5.b	Sample ID	[BRYC2D]
5.c	Sample ID	[BRYC2C]

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form Version:** 20-Feb-2021 02:17

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Status:** Not Started

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**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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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Health Care Utilization**

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

**Health Care Utilization Other**

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

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started

**Site No:** 1246 **Site Name:** (1246) Jongaie Research

**Subject No:** 12461131 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

**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	[ ]
----	-----------	-----

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled **Form:** DATE OF VISIT  
Visit

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1246    **Site Name:** (1246) Jongaie Research

**Subject No:** 12461131    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 19:09

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Worsening of Endometriosis left ovary	Jan/6/2021 UNK:UNK	NO End Date Time:  Jan/20/2021 10: 31	<a href="#">Repeating Pages</a>

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of Endometriosis left ovary]
4.	Start Date Time:	Jan/6/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/20/2021 10:31
6.	Toxicity Grade:	3

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1246**Subject No:** 12461131**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1246) Jongaie Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [Unknown]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021063190]

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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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	[ ]

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	<p>Medication:</p> <p>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).</p>	[ ]
5.	Date:	//

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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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?	

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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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?	

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Nov/28/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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?	

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT  
Unscheduled

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246      **Site Name:** (1246) Jongaie Research

**Subject No:** 12461131      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION  
Unscheduled

**Form Version:** 10-Dec-2020 02:25      **Form Status:** Data Complete, Frozen

**Site No:** 1246      **Site Name:** (1246) Jongaie Research

**Subject No:** 12461131      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3  Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	---

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Treatment Unblinded**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

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

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/27/2021
----	--------------	--



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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 _____
----	--	-------------------------

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Feb/27/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/27/2021
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	[BRST42]
5.b	Sample ID	[BRST41]
5.c	Sample ID	[BR7N78]

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/27/2021
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	[BR7N77]
-----	-----------	----------

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/27/2021 08:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Not Started

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.a	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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	[ ]
----	-----------	-----

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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?	

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:**  
FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Not Started

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/28/2020

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Dany Musungaie	Approved	Mar-02-2021 18:10:37 (UTC+02:00) Harare, Pretoria	BOOK	Signed

**Affidavit:**

By my dated signature below, I, DanyMusungaie, 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:** INCLUSION/EXCLUSION CRITERIA -  
Comments

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
Form	Oct-10-2020 11:48:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-10-2020 12:51:44 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	N/A had hysterectomy
Form	Oct-10-2020 12:51:29 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	N? had hysterectomy

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
3	Oct-10-2020 12:52:16 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
6.a	Oct-10-2020 12:53:00 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	n/a had hysterectomy



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
6.a	Oct-10-2020 12:53:00 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	n/a had hysterectomy

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
6.a	Oct-10-2020 12:53:00 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	n/a had hysterectomy

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
Form	Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
1	Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Hysterectomy
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
2	Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

Item	Date	User	Comment
3	Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

Item	Date	User	Comment
4	Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

Item	Date	User	Comment
5	Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Hysterectomy
			Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
6.a	Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Hysterectomy
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
6.a	Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Hysterectomy
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
6.a	Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Hysterectomy
			Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
Form	Feb-27-2021 09:07:38 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
Form	Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
1	Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
2	Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

Item	Date	User	Comment
3	Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
4	Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
5	Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

Item	Date	User	Comment
6.a	Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

Item	Date	User	Comment
6.a	Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
6.a	Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Dany Musungaie	Approved	Mar-02-2021 18:10:37 (UTC+02:00) Harare, Pretoria	BOOK	Signed

**Affidavit:**

By my dated signature below, I, DanyMusungaie, 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	Mar-01-2021 15:41:53 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Feb-27-2021 11:35:33 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Affidavit:**

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

(b) (6)	N/A	Feb-27-2021 09:06:40 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Feb-08-2021 19:27:07 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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**Affidavit:**

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

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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

(b) (6)	N/A	Feb-08-2021 12:20:14 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Jan-28-2021 14:35:34 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, DanyMusungaie, 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-28-2021 10:08:30 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Jan-27-2021 19:30:59 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Affidavit:**

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

(b) (6)	N/A	Jan-27-2021 07:42:41 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Jan-25-2021 19:34:02 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, DanyMusungaie, 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.

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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

(b) (6)	N/A	Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Dec-02-2020 07:25:02 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, DanyMusungaie, 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	Nov-28-2020 09:47:50 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Nov-18-2020 11:55:58 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Affidavit:**

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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.

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Oct-10-2020 11:47:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-10-2020 11:47:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Consent Was:**

Date	Location	User	Value	Reason
Oct-10-2020 11:47:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Oct/10/2020	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Subject ID**

Date	Location	User	Value	Reason
Oct-10-2020 11:47:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12461131	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-10-2020 11:47:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> UNK/UNK/1986	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-10-2020 11:48:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Oct-10-2020 11:48:00 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Harare, Pretoria

SPANISH ORIGIN

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

Date	Location	User	Value	Reason
Oct-10-2020 11:48:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLACK OR AFRICA N AMERICAN	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-10-2020 11:48:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/10/2020	Initial Entry



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Oct-10-2020 11:48:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/10/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-10-2020 11:48:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-10-2020 11:48:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1.a*

Date	Location	User	Value	Reason
Oct-10-2020 11:52:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 1 <b>Number:</b> <b>Medical History Term:</b> Hysterectomy <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> NO End Date:  UNK/UNK/2017	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Oct-10-2020 11:52:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Oct-10-2020 11:52:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hysterectomy	Initial Entry
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**1.a Start Date:**

Date	Location	User	Value	Reason
Oct-10-2020 11:52:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Oct-10-2020 11:52:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2017	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Jan-27-2021 07:42:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 2 <b>Number:</b> <b>Medical History Term:</b> Endometriosis uterus	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Start Date</b> UNK/UN : K/2017 <b>Ongoing:</b> NO End Date : UNK/U NK/201 7	
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Jan-27-2021 07:42:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Jan-27-2021 07:42:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Endometriosis uterus	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Jan-27-2021 07:42:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Jan-27-2021 07:42:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2017	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

*I.c*

Date	Location	User	Value	Reason
Jan-27-2021 07:45:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 3 <b>Number:</b> <b>Medical History Term:</b> Endometriosis left ovary <b>Start Date:</b> UNK/UNK /2017 <b>Ongoing:</b> NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

***1.c Line/MH Number:***

Date	Location	User	Value	Reason
Jan-27-2021 07:45:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

***1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Jan-27-2021 07:45:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Endometriosis left ova ry	Initial Entry

***1.c Start Date:***

Date	Location	User	Value	Reason
Jan-27-2021 07:45:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

***1.c Ongoing:***

Date	Location	User	Value	Reason
Jan-27-2021 07:45:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2017	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** HIV STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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

Date	Location	User	Value	Reason
Oct-10-2020 11:52:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:56

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Oct-10-2020 11:54:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/10/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-10-2020 11:54:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 79.8	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Oct-10-2020 11:54:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Oct-10-2020 11:54:30	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 171.0	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

(UTC+02:00)  
Harare, Pretoria

5. Unit:

Date	Location	User	Value	Reason
Oct-10-2020 11:54:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-10-2020 11:54:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 27.3	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-10-2020 11:54:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.6 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVIT <b>::</b> Y	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-10-2020 11:54:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-10-2020 11:54:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-10-2020 11:54:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-10-2020 11:54:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-10-2020 12:29:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-10-2020 11:54:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-10-2020 12:29:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-10-2020 11:54:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-10-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1246**Site Name:** (1246) Jongaie Research**Subject No:** 12461131**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09

12:52:16 (UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	Not Applicable	
Oct-10-2020 12:29:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-10-2020 12:29:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Oct-10-2020 12:29:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of collection is reported, but result is missing. Please review and update as appropriate.
Oct-10-2020 11:54:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/10/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-10-2020 12:29:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Oct-10-2020 11:54:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry
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**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-10-2020 12:29:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-10-2020 11:54:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Oct-10-2020 12:29:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined</b> <b>Identifie</b> <b>r:</b> <b>Test::</b> Choriogon adotropin Beta_PX1 13 <b>Result::</b>	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Not Done:</b> NOT DONE	
Oct-10-2020 12:29:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX1 13 <b>Result::</b> <b>Not Done:</b>	Transcription Error
Oct-10-2020 11:54:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogon adotropin Beta_PX1 13 <b>Result::</b> NEGATIVE <b>Not Done:</b>	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1246**Site Name:** (1246) Jongaie Research**Subject No:** 12461131**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09

Oct-10-2020 12:29:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry
Oct-10-2020 12:29:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-10-2020 11:54:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Oct-10-2020 11:54:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Oct-10-2020 12:29:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Transcription Error
Oct-10-2020 11:54:51 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NEGATIVE	Initial Entry



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Harare, Pretoria

**6.a Not Done:**

Date	Location	User	Value	Reason
Oct-12-2020 21:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	issued in error
Oct-12-2020 21:25:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Subject is less than 60 years old and it is not clear from her medhx why a pregnancy test was not performed. Please review and update the MedHx log as appropriate else clarify. Thank you.
Oct-10-2020 12:29:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-10-2020 11:55:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Oct/10/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-10-2020 11:55:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> 105789	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-10-2020 14:20:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-10-2020 14:20:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-10-2020 14:21:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-10-2020 14:20:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

				and correct as appropriate.
Oct-10-2020 14:20:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/10/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-10-2020 14:21:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BM9HK : V	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-10-2020 14:21:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9HKV	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-10-2020 14:21:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSSX6	Initial Entry

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-10-2020 14:21:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSSX6	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-10-2020 14:22:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSSX5	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-10-2020 14:22:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSSX5	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-10-2020 14:22:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-10-2020 14:22:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-10-2020 14:23:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-10-2020 14:22:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

				and correct as appropriate.
Oct-10-2020 14:22:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/10/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-10-2020 14:23:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BM9HK : L	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-10-2020 14:23:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9HKL	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-10-2020 11:55:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-10-2020 11:55:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-10-2020 11:55:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-10-2020 11:55:52 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Oct/10/2020 08:50	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Harare, Pretoria

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-10-2020 11:55:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-10-2020 11:55:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Oct-10-2020 11:55:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-10-2020 11:55:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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

Date	Location	User	Value	Reason
Oct-10-2020 11:55:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Oct-10-2020 11:56:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-31-2020 08:41:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/31/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Oct-31-2020 08:41:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/31/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-31-2020 08:41:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 36.6 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-31-2020 08:41:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-31-2020 08:41:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.6	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-31-2020 08:41:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-31-2020 08:41:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:01	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	
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5. Specimen Type:

Date	Location	User	Value	Reason
Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defi</b> Not Ap <b>ned Identifie</b> plicabl <b>r:</b> e <b>Test::</b> Not Ap plicabl e <b>Result::</b> Not Ap plicabl e <b>Not Done::</b> Not Ap plicabl e	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**6.a Test:**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-31-2020 08:42:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				and correct as appropriate.
Oct-31-2020 08:42:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-31-2020 08:42:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BM9DW : 5	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-31-2020 08:42:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9DW5	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-31-2020 08:42:58 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/31/2020 08:24	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Harare, Pretoria

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-31-2020 08:42:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-31-2020 08:42:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-31-2020 08:42:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-31-2020 08:42:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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

Date	Location	User	Value	Reason
Oct-31-2020 09:01:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246 **Site Name:** (1246) Jongaie Research

**Subject No:** 12461131 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-28-2020 09:47:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/28/2020	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246 **Site Name:** (1246) Jongaie Research

**Subject No:** 12461131 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-28-2020 09:48:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-28-2020 09:48:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-28-2020 09:48:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-28-2020 09:48:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

				and correct as appropriate.
Nov-28-2020 09:48:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/28/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-28-2020 09:48:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BM9DZ : R	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-28-2020 09:48:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9DZR	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-28-2020 09:48:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BRYC2D :	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246 **Site Name:** (1246) Jongaie Research

**Subject No:** 12461131 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-28-2020 09:48:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRYC2D	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-28-2020 09:48:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRYC2C	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-28-2020 09:48:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRYC2C	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Category:**

Date	Location	User	Value	Reason
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-10-2021 21:49:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 3: Closed	SDB updated
Feb-05-2021 07:34:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 3: Answered	Was changed as requested

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Feb-04-2021 20:17:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Reissued: Opened	SAE RECON 1: SAE term in both Safety database and CRF is expected to match. Please review and update the appropriate database with the correct term.
Feb-02-2021 08:45:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Answered	Diagnosis changed on SAE
Feb-01-2021 19:39:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	SAE RECON:AER#2021063190, the term in AE CRF was updated to 'Worsening of Endometriosis left ovary' while retained as 'Endometriosis left ovary' in SDB. Please confirm correct term. If safety update is required, please submit a follow-up form.
Feb-01-2021 18:55:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Jan-28-2021 10:08:30 (UTC+02:00) Harare,	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Pretoria				
Jan-28-2021 10:08:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Worsening of Endometriosis left ovary	Changed Information
Jan-27-2021 21:04:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	Response satisfies query
Jan-27-2021 16:46:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Per CRF completion requirements V12 section 8.50.2.3. If the event of Endometriosis left ovary is an intermittent AE (as reported on Med Hx) the new episodes should be recorded as "worsening of...". Please update event term accordingly.
Jan-27-2021 07:45:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Added in medical history
Jan-26-2021 21:55:14 (UTC+02:00) Harare,	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Reissued: Opened	GPD Clin: MH eCRF is now unlocked. Many thanks for updating as per previous query response.

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Pretoria				
Jan-26-2021 11:28:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Thank you- waiting for MH page
Jan-25-2021 19:54:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Reissued: Opened	Thanks for confirming presence of MH item. Request to unlock MH page has been posted. Please update MH page once unlocked. Thank you
Jan-25-2021 11:26:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient had a hysterectomy 2017 due to Endometriosis. Site can't enter medical history- page is locked.
Jan-22-2021 17:48:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD CLIN: Does subject have a history of Endometriosis? If yes, please update medical history CRF. Thank you.
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Endometriosis left ovary	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021 UNK:UNK	Initial Entry
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Jan/20/2021 10:31	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Jan-25-2021 17:43:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Endometriosis left ovary: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO Did this serious event result in death?  NO Did this serious event require or prolong hospitalization?	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246**Site Name:** (1246) Jongaie Research**Subject No:** 12461131**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09

			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

**8. Is this adverse event the result of a study Medication Error?***If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Unknown	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-22-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

13:00:27 (UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	YES	
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 13:00:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Jan-25-2021 17:43:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021063190	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-30-2020 08:12:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/28/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-30-2020 08:12:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-30-2020 08:12:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246      **Site Name:** (1246) Jongaie Research

**Subject No:** 12461131      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-08-2021 12:20:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

**Site No:** 1246 **Site Name:** (1246) Jongaie Research

**Subject No:** 12461131 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

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

Date	Location	User	Value	Reason
Feb-08-2021 12:36:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 12:20:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-08-2021 12:20:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccina tion 3 Participant is:  eligible per other protocol allowan ce(s) and confirm ed to have receiv ed only placebo a	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

**Site No:** 1246 **Site Name:** (1246) Jongaie Research

**Subject No:** 12461131 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

			t Vaccination 1/2	
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**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:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-08-2021 12:36:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-08-2021 12:36:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-27-2021 09:06:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Feb/27/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Consent Was:**

Date	Location	User	Value	Reason
Feb-27-2021 09:07:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Feb/27/2021	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-27-2021 09:08:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Feb/27/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-27-2021 09:08:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENIN G 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-27-2021 09:08:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Feb-27-2021 09:11:13	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Frozen, Verified

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)		
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5. Specimen Type:

Date	Location	User	Value	Reason
Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> <b>Sponsor-Def</b> Not Applicable <b>Identified Identifier:</b> e <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**6.a Test:**

Date	Location	User	Value	Reason
Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Feb-27-2021 09:11:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-27-2021 09:37:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-27-2021 09:37:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-27-2021 09:37:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-27-2021 09:37:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)



Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461131

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				and correct as appropriate.
Feb-27-2021 09:37:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection :  Feb/27/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-27-2021 09:37:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID BRST4</b> : 2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-27-2021 09:37:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRST42	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-27-2021 09:37:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID BRST4</b> : 1	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 22-Apr-2020 21:03

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**Site No:** 1246

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**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-27-2021 09:37:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRST41	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-27-2021 09:38:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BR7N7 : 8	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-27-2021 09:38:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR7N78	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-27-2021 09:38:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-27-2021 09:38:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-01-2021 15:41:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-01-2021 12:47:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

				and correct as appropriate.
Feb-27-2021 09:38:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-27-2021 09:38:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection :  Feb/27/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-01-2021 15:41:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR7N77	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-01-2021 15:41:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR7N77	Initial Entry

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**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-27-2021 09:10:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-27-2021 09:10:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-27-2021 09:10:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-27-2021 09:10:10 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> Feb/27/2021 08:30	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Harare, Pretoria

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-27-2021 09:10:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-27-2021 09:10:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Feb-27-2021 09:10:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-27-2021 09:10:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**9. Unit:**

Date	Location	User	Value	Reason
Feb-27-2021 09:10:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-27-2021 09:10:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-27-2021 09:10:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> YES	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-30-2020 08:12:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-10-2020 11:55:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-10-2020 11:48:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-30-2020 08:12:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/28/2020	Initial Entry
Oct-10-2020 11:55:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/10/2020	Initial Entry
Oct-10-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae302c\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1246

**Site Name:** (1246) Jongaie Research

**Subject No:** 12461131

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

11:48:50  
(UTC+02:00)  
Harare, Pretoria

(autocalc) Oct/10/2020

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1246

**Subject No:** 12461131

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1246) Jongaie Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Nov-18-2020 11:32:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Click Here to Enable	Initial Entry