

**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:** 12461070

**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

090177e196ae302d\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:** 12461070

**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/3/2020
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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:** 12461070

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12461070]
2.	Birth Date:	UNK/UNK/1998
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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**Header Text:** c4591001

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

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

**Site No:** 1246

**Subject No:** 12461070

**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/3/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1246

**Subject No:** 12461070

**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 _____
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**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e196ae302d\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:** 12461070

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

**Header Text:** c4591001

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

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** GENERAL MEDICAL HISTORY

**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](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Obese]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1246

**Subject No:** 12461070

**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:** 12461070

**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/3/2020
2.	Weight:	[113.0]
3.	Unit:	kg
4.	Height:	[172.0]
5.	Unit:	cm
6.	Body Mass Index:	[38.2]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

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

**Site No:** 1246

**Subject No:** 12461070

**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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/3/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae302d\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:** 12461070

**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/3/2020
2.	Randomization Number:	[103401]
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:** 12461070

**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/3/2020
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	[BM9HGH]
5.b	Sample ID	[BRSSSH]
5.c	Sample ID	[BRSSSJ]

090177e196ae302d\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:** 12461070

**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/3/2020
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	[BM9HGB]
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090177e196ae302d\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:** 12461070

**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/3/2020 10:20
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

090177e196ae302d\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:** 12461070

**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	YES - REACTOGENICITY E-DIARY 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:** 12461070

**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/24/2020
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/24/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1246

**Subject No:** 12461070

**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

**eCRF Audit Trail History**

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/24/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**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:** 12461070

**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/24/2020
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	[BM9HNL]
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090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**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:** 12461070

**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/24/2020 08:20
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

090177e196ae302d\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:** 12461070 **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/21/2020
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 12461070 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 12461070 **Subject Initials:** ---

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

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 12461070 **Subject Initials:** ---

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

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**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:** 12461070 **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/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BM9DXT]
5.b	Sample ID	[BRYBY7]
5.c	Sample ID	[BRYBY6]

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1246

**Subject No:** 12461070

**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:** V4\_MONTH6\_L

**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:** 12461070

**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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090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1246

**Subject No:** 12461070

**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:** V5\_MONTH12\_L

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

**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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090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1246

**Subject No:** 12461070

**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:** V6\_MONTH24\_L

**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:** 12461070

**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 1 -  
Unscheduled Visit on Jan/19/2021

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

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**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	Jan/19/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Jan/19/2021
2.	Date of First Symptom Started:	Jan/18/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/19/2021

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	YES
<b>Symptoms - Other</b>		
5.a	Symptoms - Other Text:	[Nausea]

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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[eCRF Audit Trail History](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Not Done _____ //	<a href="#">Comments</a>
2.	Specimen Type:	Not Done _____	<a href="#">Comments</a>
3.	Specimen Collection Location:	Not Done _____	<a href="#">Comments</a>
4.	Assay Code and Description:	Not Done _____	<a href="#">Comments</a>
5.	Device Type:	Not Done _____	<a href="#">Comments</a>
6.	Trade Name:	Not Done _____	<a href="#">Comments</a>
7.	Test Result:	Not Done _____	<a href="#">Comments</a>
8.	Comments/Findings /Details:	Not Done _____ [ ]	<a href="#">Comments</a>
9.	Trade Name Other, Specify:	Not Done _____ [ ]	<a href="#">Comments</a>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1246**Subject No:** 12461070**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1246) Jongaie Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Not done, don't want to selfswab]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

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

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

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

**Subject Initials:** ---

**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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Patient can't attend site due to work circumstances.]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Health Care Utilization**

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

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Respiratory Treatment**

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

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** ILLNESS DETAILS

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [gastritis]  Date of Diagnosis: Jan/19/2021
3.	Toxicity Grade:	1

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Illness Details**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

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

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Lab Chemistry Details**

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

**Lab Result**

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

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Category f or Lab Tes t	Vendor Nam e (DERIVED )	Collecti on Date :	Specim en Type	Lab Result			Form Instan ce
1.					Sponsor-Defi ned Identifie r	Te st:	Res ult:	<a href="#">Repeating Pages</a>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

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

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Laboratory Data Hematology**

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

**Lab Result**

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

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		Not Done	Not Done	Not Done	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - COVID

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Not Done _____ //	<a href="#">Comments</a>
----	-------	-------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Not Done _____ 1	
	Systolic:	Not Done _____ [ ]	<a href="#">Comments</a>
	Diastolic:	Not Done _____ [ ]	<a href="#">Comments</a>
	Respiratory Rate in respirations/minute:	Not Done _____ [ ]	<a href="#">Comments</a>
	Heart Rate in beats/minute:	Not Done _____ [ ]	<a href="#">Comments</a>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Done	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Not Done	Not Done	

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Vital Signs**

1.	Date:	Not Done _____ //	<a href="#">Comments</a>
----	-------	-------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Not Done _____ 1	
	SPO2 Pulse Oximetry %	Not Done _____ [ ]	<a href="#">Comments</a>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Oxygenation Parameters**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1246

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

**Subject No:** 12461070

**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>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Status:** Not Started

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

**Subject Initials:** ---

**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.	Start Date:	//
6.	Ongoing?	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** IMAGING

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

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Imaging**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Date of Visit**

1.	Date of Visit	Feb/3/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

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

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
<b>Symptoms - Other</b>		
5.a	Symptoms - Other Text:	[Headache]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Feb/3/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Microbiology Specimen**

1.	Actual Date of Collection:	Feb/3/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[ ]
9.	Trade Name Other, Specify:	[ISO 15189 accredited lab]

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1246**Site Name:** (1246) Jongaie Research**Subject No:** 12461070**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_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[sample done at site]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

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

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

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

**Subject Initials:** ---

**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/3/2021
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	[BM9F0S]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Health Care Utilization**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

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

**Health Care Utilization**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Respiratory Treatment**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** ILLNESS DETAILS

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [bronchitis]  Date of Diagnosis: Feb/4/2021
3.	Toxicity Grade:	2

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Illness Details**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

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

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Lab Chemistry Details**

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

**Lab Result**

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

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

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

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Laboratory Data Hematology**

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

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details			Form Instance
1.	Feb/3/2021	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	120	87	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** VITAL SIGNS - COVID

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Vital Signs**

1.	Date:	Feb/3/2021
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**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[120]
	Diastolic:	[87]
	Respiratory Rate in respirations/minute:	[16]
	Heart Rate in beats/minute:	[94]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details		Form Instance
1.	Feb/3/2021	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	97.0	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Vital Signs**

1.	Date:	Feb/3/2021
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[97.0]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Oxygenation Parameters**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1246

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

**Subject No:** 12461070

**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>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Status:** Not Started

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

**Subject Initials:** ---

**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.	Start Date:	//
6.	Ongoing?	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** IMAGING

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** IMAGING

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

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**Imaging**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/15/2021

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

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**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/15/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A1
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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/15/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

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

**Subject Initials:** ---

**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/15/2021
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	[BR7N54]
5.b	Sample ID	[BRST30]
5.c	Sample ID	[BRST31]

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 -  
Unscheduled Visit on Mar/03/2021

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

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**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	Mar/3/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_B1
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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 -  
Unscheduled Visit on Mar/03/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

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

**Subject Initials:** ---

**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: Mar/3/2021
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	[BM9F2V]
5.b	Sample ID	[BRST4C]
5.c	Sample ID	[BRST4D]

090177e196ae302d\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:** 12461070

**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:	
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**Header Text:** c4591001

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

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

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

**Subject No:** 12461070 **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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090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/28/2020

**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:** 12461070

**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/28/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
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**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/28/2020  Contact Outcome: VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY
3.	Comments:	[Did not complete, child was at hospital last night. She has no symptoms.]

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**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:** 12461070

**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	Urine tract Infection-pathogen unknown	Nov/15/2020 UNK:UNK	NO End Date Time:  Nov/18/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Worsening of depression	Dec/25/2020 UNK:UNK	NO End Date Time:  Jan/15/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Urine tract Infection-pathogen unknown]
4.	Start Date Time:	Nov/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/18/2020 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae302d\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:** 12461070

**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?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae302d\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:** 12461070

**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

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[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of depression]
4.	Start Date Time:	Dec/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/15/2021 UNK:UNK
6.	Toxicity Grade:	3



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1246

**Subject No:** 12461070

**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>	<p>NO</p>
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: [Medical history Depression- stopped conmeds]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	<p>NOT APPLICABLE</p>

090177e196ae302d\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:** 12461070

**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	[2021039621]

090177e196ae302d\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:** 12461070

**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:** 12461070

**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	[ ]

090177e196ae302d\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:** 12461070

**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:** 12461070

**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.	Date:	//

090177e196ae302d\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:** 12461070

**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>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**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:** 12461070

**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?	

090177e196ae302d\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:** 12461070

**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:** 12461070

**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?	

090177e196ae302d\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:** 12461070

**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>

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**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:** 12461070

**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:** 12461070

**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/21/2020
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:** 12461070

**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:** 12461070

**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:	

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**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:** 12461070

**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:	

090177e196ae302d\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:** 12461070

**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?	

090177e196ae302d\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:** 12461070

**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:** 12461070

**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:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT  
Unscheduled

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

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

**Subject No:** 12461070 **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:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
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**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

**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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090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1246

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

**Subject No:** 12461070

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

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**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:** 12461070

**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:** 12461070      **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:** 12461070      **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 and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	---

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**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:** 12461070

**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:** 12461070

**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:** 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:** 12461070

**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/21/2020

**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:** 12461070

**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:** 12461070

**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-03-2021 19:35:32 (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:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-03-2020 11:38:30 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2	Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
3	Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
4	Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5	Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
6	Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
7	Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
8	Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
9	Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - COVID - Comments

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - COVID - Comments

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - COVID - Comments

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - COVID - Comments

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - COVID - Comments

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - COVID - Comments

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR -  
Comments

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-25-2021 11:34:31 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR -  
Comments

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Jan-25-2021 11:34:31 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR -  
Comments

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-25-2021 11:34:31 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient can't attend site due to work circumstances. <hr/> Not Done

(

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Dany Musungaie	Approved	Mar-03-2021 19:35:32 (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-03-2021 08:15:11 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Feb-15-2021 18:18:34 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

**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	Feb-15-2021 10:48:01 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Feb-05-2021 18:31:54 (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.

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

(b) (6)	N/A	Feb-05-2021 10:57:04 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Feb-04-2021 19:39:08 (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	Feb-04-2021 07:48:02 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Feb-03-2021 21:02:31 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

**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	Feb-03-2021 11:36:22 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Jan-25-2021 19:33:34 (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.

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

(b) (6)	N/A	Jan-25-2021 11:27:13 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Jan-20-2021 16:13:33 (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-20-2021 14:20:11 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Jan-18-2021 19:56:17 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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090177e196ae302d\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:** 12461070

**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-18-2021 14:20:26 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Dec-10-2020 19:21:30 (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.

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

(b) (6)	N/A	Dec-09-2020 15:54:40 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Nov-27-2020 07:26:03 (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-21-2020 08:52:33 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Dany Musungaie	Approved	Nov-12-2020 20:05:29 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

**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:** 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:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Oct-03-2020 11:36:37 (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-03-2020 11:36:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**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:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Consent Was:**

Date	Location	User	Value	Reason
Oct-03-2020 11:36:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Oct/3/2020	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1246

**Subject No:** 12461070

**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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Oct-03-2020 11:36:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12461070	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-03-2020 11:36:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> UNK/UNK/1998	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-03-2020 11:37:17 (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-03-2020 11:37:17 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR L ATINO(A) OR OF SP	Initial Entry

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

Harare, Pretoria

ANISH ORIGIN

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

Date	Location	User	Value	Reason
Oct-03-2020 11:37:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1246

**Subject No:** 12461070

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-03-2020 11:38:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/3/2020	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:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-03-2020 11:38:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/3/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-03-2020 11:38:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-03-2020 11:38:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae302d\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, Locked, Frozen, Verified

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

*1.a*

Date	Location	User	Value	Reason
Oct-03-2020 11:39:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N umber:</b> 1 <b>Medical History Term:</b> Depression <b>Start Date:</b> UNK/UNK/2014 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Oct-03-2020 11:39:39 (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
Oct-03-2020 11:39:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Depression	Initial Entry

090177e196ae302d\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, Locked, Frozen, Verified

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

**1.a Start Date:**

Date	Location	User	Value	Reason
Oct-03-2020 11:39:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2014	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Oct-03-2020 11:39:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Oct-03-2020 11:43:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 2</b> <b>umber:</b> <b>Medical His Obese</b> <b>tory Term:</b> <b>Start Date:</b> UNK/U NK/201 4 <b>Ongoing:</b> YES	Initial Entry

090177e196ae302d\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, Locked, Frozen, Verified

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Oct-03-2020 11:43:32 (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
Oct-03-2020 11:43:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Obese	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Oct-03-2020 11:43:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2014	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Oct-03-2020 11:43:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae302d\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:** 12461070

**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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-03-2020 11:39:51 (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:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Oct-03-2020 11:41:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/3/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-03-2020 11:41:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 113.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Oct-03-2020 11:41:17 (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-03-2020 11:41:17	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 172.0	Initial Entry

090177e196ae302d\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: 12461070

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. Unit:

Date	Location	User	Value	Reason
Oct-03-2020 11:41:17 (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-03-2020 11:41:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 38.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-03-2020 11:41:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.7 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

090177e196ae302d\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: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-03-2020 11:41:17 (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-03-2020 11:41:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-03-2020 11:41:17 (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-03-2020 11:41:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-03-2020 11:43:47 (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-03-2020 11:43:47 (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-03-2020 11:43:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/3/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-03-2020 11:43:47	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

090177e196ae302d\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: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+02:00)  
Harare, Pretoria

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-03-2020 11:43:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-03-2020 11:43:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor- 113 <b>Defined Identifier:</b> Test:: Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-03-2020 11:43:47	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

(UTC+02:00)  
Harare, Pretoria

**6.a Test:**

Date	Location	User	Value	Reason
Oct-03-2020 11:43:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin B eta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Oct-03-2020 11:43:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae302d\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:** 12461070

**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-03-2020 11:45:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/3/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-03-2020 11:45:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 103401	Initial Entry

090177e196ae302d\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:** 12461070

**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-03-2020 11:45:14 (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-03-2020 11:45:14 (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-03-2020 11:48:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-03-2020 11:45:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

				and correct as appropriate.
Oct-03-2020 11:45:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/3/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-03-2020 11:48:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BM9HG : H	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-03-2020 11:48:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9HGH	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-03-2020 11:49:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSSSH	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:** 12461070

**Subject Initials:** ---

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

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

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-03-2020 11:49:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSSSH	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-03-2020 11:49:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSSSJ	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-03-2020 11:49:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSSSJ	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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-03-2020 11:50:27 (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-03-2020 11:50:27 (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-03-2020 11:50:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-03-2020 11:50:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

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**Header Text:** c4591001

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

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

				and correct as appropriate.
Oct-03-2020 11:50:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/3/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-03-2020 11:50:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BM9HG : B	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-03-2020 11:50:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9HGB	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 1246

**Subject No:** 12461070

**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-03-2020 11:51:26 (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-03-2020 11:51:26 (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-03-2020 11:51:26 (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-03-2020 11:51:26 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/3/2020 10:20	Initial Entry

090177e196ae302d\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:** 12461070

**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-03-2020 11:51:26 (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-03-2020 11:51:26 (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-03-2020 11:51:26 (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-03-2020 11:51:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

090177e196ae302d\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:** 12461070

**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?***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-03-2020 11:51:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> YES	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** REACTOGENICITY DIARY - 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 - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Oct-03-2020 11:51:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENI CITY E-DIARY COL LECTED FOR THIS S UBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1246

**Subject No:** 12461070

**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-24-2020 09:18:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/24/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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:** 12461070

**Subject Initials:** ---

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

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

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**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed? :	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
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090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry
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*2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?*

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.b*

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G U E  <b>Were fever or s N</b> <b>ystemic sympto O</b> <b>ms present on t</b> <b>he last day the</b> <b>Subject Diary</b> <b>was completed</b> <b>?:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461070

Subject Initials: ---

Generated By: (b) (4)

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2.b Symptom:

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE A D AC HE	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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:** 12461070

**Subject Initials:** ---

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

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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**2.c Symptom:**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

**2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI L	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

			L S Were fever or systemic symptoms present on the last day the Subject Diary was completed? :	
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2.d Symptom:

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom:: VO	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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:** 12461070

**Subject Initials:** ---

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

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

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	MI TI NG NO	Were fever or systemic symptoms present on the last day the Subject Diary was completed?:
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**2.e Symptom:**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI A RR HE A <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry
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**2.f Symptom:**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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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:** 12461070

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED MUS CLE P AIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED JOIN T PAI N	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
--	--	--	--	--

2.h Symptom:

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSEN ED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

Harare, Pretoria

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site</b> RE <b>Reaction::</b> D N ES S <b>Were injection</b> N <b>site reactions p</b> O <b>resent on the la<p><b>st day the Subj</b> <b>ect Diary was c</b> <b>ompleted?:</b></p></b>	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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:** 12461070

**Subject Initials:** ---

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

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

(UTC+02:00)  
Harare, Pretoria

(b) (4), (b) (6)

**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site</b> SW <b>Reaction::</b> EL LI NG <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site PAI</b> <b>Reaction::</b> N A T IN JEC TIO N SI TE	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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:** 12461070

**Subject Initials:** ---

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

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

			<b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	
--	--	--	--	--

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** VITAL SIGNS - TEMP - 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:**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/24/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> <b>Temperature Unit:</b> <b>Temperature Location:</b> <b>Y</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.0	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-24-2020 09:19:58 (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-24-2020 09:19:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae302d\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:** 12461070

**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-24-2020 09:20:13 (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-24-2020 09:20:13 (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-24-2020 09:20:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/24/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-24-2020 09:20:13	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

090177e196ae302d\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: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+02:00)  
Harare, Pretoria

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-24-2020 09:20:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-24-2020 09:20:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor- 113 <b>Defined Identifier:</b> Test:: Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-24-2020 09:20:13	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

(UTC+02:00)  
Harare, Pretoria

**6.a Test:**

Date	Location	User	Value	Reason
Oct-24-2020 09:20:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Oct-24-2020 09:20:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae302d\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:** 12461070

**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-24-2020 09:20:48 (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-24-2020 09:20:48 (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-24-2020 09:22:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-24-2020 09:20:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

				and correct as appropriate.
Oct-24-2020 09:20:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection :  Oct/24/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-24-2020 09:22:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BM9HN <b>D:</b> L	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-24-2020 09:22:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9HNL	Initial Entry

090177e196ae302d\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:** 12461070

**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-24-2020 09:23:44 (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-24-2020 09:23:44 (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-24-2020 09:23:44 (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-24-2020 09:23:44 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/24/2020 08:20	Initial Entry

090177e196ae302d\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: 12461070

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-24-2020 09:23:44 (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-24-2020 09:23:44 (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-24-2020 09:23:44 (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-24-2020 09:23:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

090177e196ae302d\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:** 12461070

**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-24-2020 09:23:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject No:** 12461070 **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-21-2020 08:52:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/21/2020	Initial Entry



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 12461070 **Subject Initials:** ---

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

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**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed? :	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
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090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 12461070 **Subject Initials:** ---

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

Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry
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**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G U E  <b>Were fever or s N</b> <b>ystemic sympto O</b> <b>ms present on t</b> <b>he last day the</b> <b>Subject Diary</b> <b>was completed</b> <b>?:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56 Form Status: Data Complete, Frozen, Verified

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

Subject No: 12461070 Subject Initials: ---

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

2.b Symptom:

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE A D AC HE	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 12461070 **Subject Initials:** ---

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

			<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	
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**2.c Symptom:**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

**2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI L	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56 Form Status: Data Complete, Frozen, Verified

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

Subject No: 12461070 Subject Initials: ---

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

			L S Were fever or systemic symptoms present on the last day the Subject Diary was completed? :	
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2.d Symptom:

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom:: VO	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56 Form Status: Data Complete, Frozen, Verified

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

Subject No: 12461070 Subject Initials: ---

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

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	MI TI NG NO	Were fever or systemic symptoms present on the last day the Subject Diary was completed?:
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2.e Symptom:

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56 Form Status: Data Complete, Frozen, Verified

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

Subject No: 12461070 Subject Initials: ---

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

Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI A RR HE A <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry
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2.f Symptom:

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 12461070 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED MUS CLE P AIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56 Form Status: Data Complete, Frozen, Verified

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

Subject No: 12461070 Subject Initials: ---

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

2.g Symptom:

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED JOIN T PAI N	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 12461070 **Subject Initials:** ---

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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**2.h Symptom:**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSEN ED JOINT PAIN	Initial Entry

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56 Form Status: Data Complete, Frozen, Verified

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

Subject No: 12461070 Subject Initials: ---

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

Harare, Pretoria

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site</b> RE <b>Reaction::</b> D N ES S <b>Were injection</b> N <b>site reactions p</b> O <b>resent on the la<p><b>st day the Subj</b> <b>ect Diary was c</b> <b>ompleted?:</b></p></b>	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 12461070 **Subject Initials:** ---

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

(UTC+02:00)  
Harare, Pretoria

(b) (4), (b) (6)

**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site</b> SW <b>Reaction::</b> EL LI NG <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56 Form Status: Data Complete, Frozen, Verified

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

Subject No: 12461070 Subject Initials: ---

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site PAI</b> <b>Reaction::</b> N A T IN JEC TIO N SI TE	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 12461070 **Subject Initials:** ---

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

			<b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae302d\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:** 12461070 **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-21-2020 08:53:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-21-2020 08:53:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae302d\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: 12461070 Subject Initials: ---

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

				and correct as appropriate.
Nov-21-2020 08:53:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection :  Nov/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-21-2020 08:53:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BM9DX <b>D:</b> T	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-21-2020 08:53:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9DXT	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-09-2020 15:54:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BRYBY7 :	Initial Entry

090177e196ae302d\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:** 12461070 **Subject Initials:** ---

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

**5.b Sample ID**

Date	Location	User	Value	Reason
Dec-09-2020 15:54:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRYBY7	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-09-2020 15:54:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BRYBY6 :	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Dec-09-2020 15:54:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRYBY6	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** DATE OF VISIT - ILLNESS ONSET - 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
Jan-25-2021 18:16:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-25-2021 11:27:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-25-2021 11:27:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

				are missing. Please review and update as appropriate.
Jan-25-2021 11:27:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 11:27:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Sympto m Resolved:  Jan/19/2021	Initial Entry

**4.a**

Date	Location	User	Value	Reason
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090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVE R <b>Symptom Pre NO</b> <b>sent:</b>	Initial Entry
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**4.a Symptoms:**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympto NEW OR IN</b> <b>ms: CREASED</b> COUGH	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

			<b>Symptom Present:</b>	
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**4.b Symptoms:**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

**4.c Symptoms:**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D SHORTNESS OF B REATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHIL LS <b>Symptom Pre NO</b> <b>sent:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

**4.d Symptoms:**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW OR IN <b>oms:</b> CREASED M USCLE PAIN  <b>Sympt</b> NO <b>om Pr</b> <b>esent:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**4.e Symptoms:**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW LOSS <b>oms:</b> OF TASTE O R SMELL  <b>Sympt</b> NO <b>om Pre</b> <b>sent:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**4.f Symptoms:**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TAST E OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW OR IN <b>oms:</b> CREASED S ORE THROA T <b>Sympt</b> NO <b>om Pr</b> <b>esent:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**4.g Symptoms:**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARR HEA <b>Symptom P</b> NO <b>resent:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**4.h Symptoms:**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMIT ING <b>Symptom P</b> YES <b>resent:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**4.i Symptoms:**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Jan-25-2021 11:27:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-25-2021 11:28:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> Nausea	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Jan-25-2021 11:28:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nausea	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Jan-25-2021 11:30:45	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**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. Device Type:**

Date	Location	User	Value	Reason
Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Jan-25-2021 11:30:45	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

(UTC+02:00)  
Harare, Pretoria

(b) (4), (b)  
(6)

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Jan-25-2021 11:30:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

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

Date	Location	User	Value	Reason
Jan-25-2021 11:31:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-25-2021 11:31:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-25-2021 11:31:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

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

11:31:23 (UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	Not done, don't want to selfswab	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

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

Date	Location	User	Value	Reason
Jan-25-2021 11:31:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-25-2021 11:31:34 (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
Jan-25-2021 11:31:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

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

11:31:34  
(UTC+02:00)  
Harare, Pretoria

(b) (4), (b)  
(6)

Patient can't attend site  
due to work circumsta  
nces.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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*1.a*

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: SPECIALIST IALIS T Occurrence of NO Visits or Contacts:	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*1.b*

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pra</b> EMERG <b>ctitioner:</b> ENCY R OOM <b>Occurrence NO</b> <b>of Visits or</b> <b>Contacts:</b>	Initial Entry

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROO M	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pr</b> PRIMAR <b>actioner:</b> Y CARE	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

Harare, Pretoria			PHYSICIAN	
			AN	
			<b>Occurrence of Visits or Contacts:</b> NO	

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

			<b>Occurrence NO of Visits or C ontacts:</b>	
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***1.d Physician or Healthcare Professional:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pr TELEPH actioner: ONE CO NSULTA TION</b>  <b>Occurren NO ce of Visit s or Conta cts:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

*I.e Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONS ULTATION	Initial Entry

*I.e Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practiti</b> OT <b>oner:</b> HE R <b>Occurrence of</b> NO <b>Visits or Conta</b> <b>cts:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 11:31:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Jan-25-2021 13:30:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID- 19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 13:30:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness D iagnosis:</i>  gastritis  Date of Diagnosis:  Jan/19/2021	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-25-2021 13:30:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**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
Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Systolic::</b> Not Done <b>Diastolic::</b> Not Done <b>Respiratory Rate in respiration s/minute:</b> Not Done <b>Heart Rate in beats/minute:</b> Not Done	Initial Entry

**2.a Record Identifier:**

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Heart Rate in beats/minute:**

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-25-2021 11:34:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**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
Jan-25-2021 11:34:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-25-2021 11:34:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Ident</b> Not D <b>ifier::</b> one <b>Oxygen Satu</b> Not D <b>ration:</b> one	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-25-2021 11:34:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
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090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/19/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

Jan-25-2021 11:34:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** DATE OF VISIT - ILLNESS ONSET - 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-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-03-2021 11:37:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 11:36:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-03-2021 11:36:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

				are missing. Please review and update as appropriate.
Feb-03-2021 11:36:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-03-2021 11:36:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_B	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/1/2021	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Mar-03-2021 10:27:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Sym ptom Resolved:  Mar/3/2021	Changed Information
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

4.a

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEV ER <b>Symptom Present:</b> NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR I NCREASE	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

Harare, Pretoria			D COUGH	
			<b>Symptom Present:</b> YES	

**4.b Symptoms:**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

			<b>Symptom Present:</b>	
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**4.c Symptoms:**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

**4.d Symptoms:**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symp</b> NEW OR I <b>toms:</b> NCREASE D MUSCLE PAIN <b>Symp</b> YES <b>tom P</b> <b>resent</b> :	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**4.e Symptoms:**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW LOSS OF TASTE OR SMELL <b>Symptom Present:</b> NO	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

**4.f Symptoms:**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> YES	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**4.g Symptoms:**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> DIARR : HEA <b>Symptom</b> NO <b>Present:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**4.h Symptoms:**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> VOMI : TING <b>Symptom</b> NO <b>Present:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1246

**Subject No:** 12461070

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

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**4.i Symptoms:**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Feb-03-2021 11:47:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-03-2021 11:48:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms -</b> Headache <b>Other:</b> che	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Feb-03-2021 11:48:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Headache	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Feb-03-2021 11:50:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Feb-03-2021 11:50:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Feb-03-2021 11:50:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATER IAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Feb-03-2021 11:50:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Feb-03-2021 11:50:15 (UTC+02:00)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RES P SYNDROME CORO	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

Harare, Pretoria			NAVIRUS 2	
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**5. Device Type:**

Date	Location	User	Value	Reason
Feb-03-2021 11:50:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Feb-03-2021 11:50:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Feb-04-2021 07:48:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Feb-03-2021 11:50:15 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ISO 15189 accredite d lab	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

Harare, Pretoria				
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

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

Date	Location	User	Value	Reason
Feb-03-2021 11:36:53 (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-03-2021 11:36:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-03-2021 11:36:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-03-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

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

11:36:53  
(UTC+02:00)  
Harare, Pretoria

(b) (4), (b) (6) sample done at site

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

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

Date	Location	User	Value	Reason
Feb-03-2021 11:37:11 (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-03-2021 11:37:11 (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
Feb-03-2021 11:38:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 11:37:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

				and correct as appropriate.
Feb-03-2021 11:37:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection :  Feb/3/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-03-2021 11:38:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BM9F0 <b>D:</b> S	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-03-2021 11:38:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9F0S	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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*1.a*

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Prac</b> SPEC <b>itioner:</b> IALI ST <b>Occurrence</b> NO <b>of Visits or</b> <b>Contacts:</b>	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*1.b*

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pr</b> EMER <b>actioner:</b> GENC Y ROO M <b>Occurrence</b> NO <b>of Visits</b> <b>or Contact</b> <b>s:</b>	Initial Entry

**1.b Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY RO OM	Initial Entry

**1.b Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Feb-03-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

11:54:11 (UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	<b>Type of P ractice er:</b> PRIMAR Y CARE PHYSIC IAN	
			<b>Occure nce of Vi sits or Co ntacts:</b> NO	

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE P HYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pra ctitioner:</b> URGE NT C ARE	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

			<b>Occurrence NO of Visits or Contacts:</b>	
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***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of P TELEPH raction ONE CO er: NSULTA TION</b> <b>Occurre NO nce of Vi sits or Co ntacts:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

*1.e Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CON SULTATION	Initial Entry

*1.e Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*1.f*

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practi</b> OT <b>tioner:</b> HE R <b>Occurrence of</b> NO <b>Visits or Cont</b> <b>acts:</b>	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-03-2021 11:54:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Feb-04-2021 07:48:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 07:48:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  bronchitis  Date of Diagnosis:  Feb/4/2021	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-04-2021 07:48:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** VITAL SIGNS - COVID - Audit Trail

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

**Form Status:**

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Feb-03-2021 11:55:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**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
Feb-03-2021 11:55:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-03-2021 11:55:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Systolic::</b> 1 2 0 <b>Diastolic::</b> 8 7 <b>Respiratory Rate in respirations /minute:</b> 1 6 <b>Heart Rate in beats/minute:</b> 9 4	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Feb-03-2021 11:55:37	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**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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**2.a Systolic:**

Date	Location	User	Value	Reason
Feb-03-2021 11:55:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 120	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Feb-03-2021 11:55:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 87	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Feb-03-2021 11:55:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 16	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Feb-03-2021 11:55:37	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 94	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

(UTC+02:00)  
Harare, Pretoria

(b) (4), (b) (6)

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit  
Trail

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

**Form Status:**

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Feb-03-2021 11:56:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1246

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

**Subject No:** 12461070

**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
Feb-03-2021 11:56:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-03-2021 11:56:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Oxygen Saturation:</b> 97.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Feb-03-2021 11:56:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Feb-03-2021 11:56:00	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.0	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Feb/03/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

(UTC+02:00)  
Harare, Pretoria

(b) (4), (b) (6)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/15/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT -  
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-15-2021 10:48:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/15/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 10:48:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/15/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - 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. Data Origin**

Date	Location	User	Value	Reason
Feb-15-2021 10:48:11 (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-15-2021 10:48:11 (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-15-2021 10:48:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-15-2021 10:48:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/15/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - 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

				and correct as appropriate.
Feb-15-2021 10:48:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/15/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-15-2021 10:48:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR7N54	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-15-2021 10:48:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR7N54	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Feb-15-2021 10:48:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRST30	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/15/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - 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

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-15-2021 10:48:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRST30	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-15-2021 10:48:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRST31	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-15-2021 10:48:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRST31	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 -  
Unscheduled Visit on Mar/03/2021

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

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**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
Mar-03-2021 08:15:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/3/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-03-2021 08:15:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_B1	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 -  
Unscheduled Visit on Mar/03/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - 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. Data Origin**

Date	Location	User	Value	Reason
Mar-03-2021 08:16:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-03-2021 08:16:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-03-2021 08:16:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 08:16:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 -  
Unscheduled Visit on Mar/03/2021

**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:** 12461070

**Subject Initials:** ---

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

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

				and correct as appropriate.
Mar-03-2021 08:16:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/3/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-03-2021 08:16:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM9F2V	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-03-2021 08:16:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9F2V	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Mar-03-2021 08:16:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRST4C	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 -  
Unscheduled Visit on Mar/03/2021

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - 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

**5.b Sample ID**

Date	Location	User	Value	Reason
Mar-03-2021 08:16:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRST4C	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Mar-03-2021 08:16:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRST4D	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Mar-03-2021 08:16:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRST4D	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/28/2020

**Form:** DATE OF VISIT - 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:** 12461070

**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
Oct-28-2020 15:28:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/28/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/28/2020

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** UNPLANNED 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. Assessments*

Date	Location	User	Value	Reason
Oct-28-2020 15:29:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 15:28:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-28-2020 15:28:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCO ME	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/28/2020

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** CONTACT OUTCOME - UNPLANNED - 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. Contact Type:**

Date	Location	User	Value	Reason
Oct-28-2020 15:29:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Oct-28-2020 15:29:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Oct/28/2020  Contact Outcome:  VISIT NOT REQU IRED, DATA ENT RY ERROR IN E- DIARY	Initial Entry

**3. Comments:**

Date	Location	User	Value	Reason
Oct-28-2020 15:29:05 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Did not complete, chil d was at hospital last ni	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/28/2020

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

**Site No:** 1246

**Subject No:** 12461070

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

**Form:** CONTACT OUTCOME - UNPLANNED - 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

Harare, Pretoria			ght. She has no sympto ms.	
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**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:** 12461070

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Nov-21-2020 08:59:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae302d\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:** 12461070

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Jan-18-2021 14:20:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**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:** 12461070

**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
Nov-21-2020 08:59:17 (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
Nov-21-2020 08:59:17 (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
Nov-23-2020 19:37:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	Response satisfies query
Nov-23-2020 15:34:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-23-2020 15:34:41	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Urine tract Infectio	Changed Information

090177e196ae302d\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:** 12461070**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	n-pathogen unknown	
Nov-23-2020 14:34:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Can you please confirm, if pathogen causing Urine tract Infection is known? Please review and update AE term as needed. Thanks
Nov-21-2020 08:59:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Urine tract Infection	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-21-2020 08:59:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/15/2020 UNK: UNK	Initial Entry

**5. Is the adverse event still ongoing?**

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:** 12461070

**Subject Initials:** ---

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

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

Nov-21-2020 08:59:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Nov/18/2020 UN K:UNK	Initial Entry
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**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-21-2020 08:59:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

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

Date	Location	User	Value	Reason
Nov-21-2020 08:59:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

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Site Name: (1246) Jongaie Research

Subject No: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-21-2020 09:00:12 (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
Nov-21-2020 08:59:17 (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

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-21-2020 08:59:17 (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
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**Header Text:** c4591001

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

Nov-21-2020 08:59:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-21-2020 08:59:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-21-2020 08:59:17 (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
Nov-21-2020 08:59:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae302d\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:** 12461070

**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-18-2021 14:20:26 (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-18-2021 14:20:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-18-2021 14:20:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Worsening of depression	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-18-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

14:20:26 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Dec/25/2020 UNK:UN K
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-18-2021 14:20:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Jan/15/2021 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-18-2021 14:20:26 (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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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

Jan-20-2021 14:20:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 14:20:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Worsening of depression: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-18-2021 14:20:26 (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

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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:** 12461070**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-18-2021 14:20:26 (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
Jan-18-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1246

Site Name: (1246) Jongaie Research

Subject No: 12461070

Subject Initials: ---

Generated By: (b) (4)

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

14:20:26 (UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Medical history Depression- stopped conmeds	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-18-2021 14:20:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-18-2021 14:20:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1246

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

**Subject No:** 12461070

**Subject Initials:** ---

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

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

Jan-18-2021 14:20:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jan-18-2021 14:20:26 (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-18-2021 14:20:26 (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-20-2021 14:20:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021039621	Initial Entry

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**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:** 12461070

**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-21-2020 08:53:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/21/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-21-2020 08:53:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae302d\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:** 12461070      **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-05-2021 10:57:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

090177e196ae302d\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:** 12461070 **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-05-2021 10:57:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 10:57:12 (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-05-2021 10:57:12 (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 and NOT confirmed to hav e received only p lacebo at Vaccina tion 1/2	Initial Entry

090177e196ae302d\Final\Final On: 01-Apr-2021 04:02 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1246

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

**Subject No:** 12461070

**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-05-2021 10:57:24 (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-05-2021 10:57:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

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**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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**Form Status:** Data Complete, Verified

**Site No:** 1246

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

**Subject No:** 12461070

**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-21-2020 08:53:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-03-2020 11:45:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-03-2020 11:38:56 (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
Jan-25-2021 23:25:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-25-2021 11:20:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Site contacted patient 19 Jan 2021. She had nausea and vomiting 18 Jan 2021. She

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**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:** 12461070

**Subject Initials:** ---

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

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

				can't attend site because she was on sick leave for 2 weeks and will not be able to attend site visit.
Jan-22-2021 18:17:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Opened	Illness ed diary: As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 18JAN2021. But corresponding COVID Illness visit not reported. Please clarify.
Nov-21-2020 08:53:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/21/2020	Initial Entry
Oct-03-2020 11:45:00	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/3/2020	Initial Entry

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**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:** 12461070

**Subject Initials:** ---

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

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

(UTC+02:00) Harare, Pretoria				
Oct-03-2020 11:38:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/3/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1246

**Subject No:** 12461070

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

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