Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	ZIMCoVVAR
Scientific Title	COVID 19 vaccine effectiveness and SARS CoV-2 variants in Zimbabwe:Test negative case control study, Genetic Sequencing and Serology

Primary Sponsor Details

Sponsors *	Coalition for Epidemic Preparedness Innovations (CEPI)

Secondary Sponsor Details

Contact for Public Queries

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Affiliation	Mutala Research

Countries of Recruitment *

Zimbabwe

Source of Funds	Coalition for Epidemic Preparedness Innovations (CEPI)
Health Condition(s) or Problem(s) Studied *	Respiratory symptoms
Medicine Name *	N/A
Quantity of medicine required *	None

7.0 PRINCIPAL INCLUSION CRITERIA *

Inclusion Criteria

1. All vaccine eligible (as per national vaccination strategy) adults (age ≥18 years) presenting with COVID-19 like symptoms who agree to COVID-19 testing by PCR tests
2. Individuals willing and able to provide informed consent
3. Individuals willing and able to comply with all study requirements

7.1 PRINCIPAL EXCLUSION CRITERIA *

Exclusion criteria

1. Individuals unwilling or unable to give written informed consent to participate in the study

2 . Individuals who have documented vaccination with vaccine other than inactivated vaccines (primarily Sinopharm and Sinovac)

3. Individuals aged <18 years at the time of possible inclusion into the study

4. Any other significant concern which, in the opinion of the Investigator, would compromise the participant's ability to participate in the study.

7.2 PRIMARY END POINTS *

Primary Endpoints

1. Comparison of COVID-19 vaccination status in patients presenting with symptoms consistent with COVID-19 who test PCR positive for COVID-19 compared with those who test PCR negative

9.0 DESIGN OF THE TRIAL

Type of trial *	Controlled
If controlled	
Randomised	No
Single Blind	No
Double Blind	No
Parallel group	No
Cross over	No
Other	Yes
If yes to other, specify	N/A this is a non interventional observational study, none of these categories apply, it is not open or controlled study its an observational case: control cohort study with no drug provided
If controlled, specify the comparator	Case control observational study
Other medicinal product(s)	No
Placebo	No
Other	No
If yes to other, specify	There is no study drug
Other	Yes

Expected Number of participants in Zimbabwe *	5690
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	5-2000

Total participants worldwide *	5690

Time period for the trial * 12 months