

# Building capacity for leading complex clinical trials in Africa through partnership: The PrEPVacc Consortium

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# Background

The PrEPVacc Consortium was funded by EDCTP in 2017 (Reference: RIA2016V-1644).

Goal was to implement a prophylactic HIV vaccine trial led by African partners with technical support from international partners.

Two components

- Recruiting a registration cohort of HIV-negative volunteers at risk of HIV acquisition for participation in an HIV preventive vaccine trial across five sites
- Assessing the safety and efficacy of two combinations of HIV vaccine regimens and comparing Descovy with Truvada PrEP in a phase IIB trial

## Coordinating partners

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# Methods (1)

## **MRC Uganda (Coordination centre)**

- Site readiness, protocol development, trial integrity and participant safety
- Social Science lead
- Laboratory endpoint assays
- Data management and statistical analyses.

## **The MRC-CTU at UCL (Technical support)**

- Protocol development
- Statistical support
- Safety monitoring
- Regulatory reporting

# Methods (2)

## **International AIDS Vaccine Initiative (Technical support)**

- Monitoring
- Capacity strengthening: local/on-site Monitor training
- Assay development, transfer & validation

## **Imperial College London (Technical support)**

- Sponsor
- IMP management
- Project management

## **EuroVacc Foundation, GSID, Gilead, MHRP, Imperial College London**

- IMP supply

# Results

Supported and participated in the recruitment of 4,172 participants in the registration cohort (2018-2022).

Established trial management/oversight structures, assessed and qualified study sites, developed and registered the protocol.

Provided sites with technical support to obtain required ethical and regulatory approvals.

Developed study documents, trial databases, maintained the trial master file, and standardized immunological endpoint assays.

Trial was initiated in December 2020 and recruited 1,513 participants by March 2023.

Participant follow-up is ongoing with completion anticipated in July 2024.

# Conclusions

Multi-country HIV vaccine efficacy trials can be coordinated in the African region/continent.

The capacity and expertise built can be applied to any large-scale international trials.

African investigators can conduct studies that are most relevant to their population/community.

**Thank you**