

MRC/UVRI and LSHTM Uganda Research Unit



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

Bernadette Kalanzi Nayiga, Eugene Ruzagira, Jennifer Serwanga, Andrew Abaasa, Sylvia Kusemererwa, Ayoub Kakande, Freddie Mukasa Kibengo, Cherry Kingsley, Julie Fox, Mary Amondi, Song Ding, Sarah Joseph, Sheena McCormack, Pontiano Kaleebu

LSHTM Trials Day
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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

PrEPVacc Partners

Coordinating partners

P Kaleebu, E Ruzagira
(MRC/UVRI & LSHTM, Uganda);

J Weber/J Fox/C Kingsley
(Imperial College, UK); S
McCormack (MRC-CTU at UCL,
UK); K Chinyenze (IAVI-Kenya);
G Pantaleo/S Ding (CHUV/EVF,
Switzerland)

Immunology

G Pantaleo (CHUV, Switzerland); P
Kaleebu/J Serwanga (MRC/UVRI &
LSHTM, Uganda); J Gilmour
(IAVI/Imperial College); C Nilsson
(Karolinska, Sweden)

Other Lab Activities

M Hoelscher (LMU, Germany); G
Doncel (CONRAD, US)

Social Science

J Seeley, R Kawuma (MRC/UVRI &
LSHTM, Uganda)



Partners with a centre

Pontiano Kaleebu (MRC/UVRI &
LSHTM, Masaka, Uganda)
Lucas Maganga (MMRC, Mbeya,
Tanzania)

Said Aboud (MUHAS, Dar es
Salaam, Tanzania)

Ilesh Jani (CISPOC, Maputo,
Mozambique)

Glenda Gray (HPRU, Durban,
South Africa)

Partners with a product

Song Ding (EVF, Switzerland)

Carter Lee (GSID, US)

(Merlin Robb) (MHRP, US)

Cherry Kingsley (Imperial, UK)

Jim Rooney (Gilead, US)

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.

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Thank you