

Poster presentation

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P06-08. Building an African HIV preventive trial network

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Background

Africa is a crucial setting for preventive HIV clinical trials. We present our experience of setting up a collaborative network of African clinical research centers (CRC).

Methods

IAVI supports nine CRCs in Africa: Kilifi and Nairobi, Kenya; Masaka and Entebbe, Uganda; Kigali, Rwanda; Lusaka and Ndola, Zambia; and Cape Town and Rustenburg, South Africa. The aim of the network is to support capacity and research on HIV epidemiology and immunology relevant for HIV preventive clinical trials, and to conduct these trials from phase I to efficacy. All CRCs provide VCT, and at-risk volunteers are offered enrollment into prospective HIV epidemiology and incidence studies. The populations vary by CRC and include HIV-discordant couples, commercial sex workers, and men who have sex with men. Volunteers who become HIV infected are enrolled into an early HIV infection study. Lower-risk, HIV-uninfected volunteers may be referred to phase I and/or II vaccine trials. Laboratory facilities at each CRC participate in external, independent quality assurance programs to ensure standardization and comparability of data across CRCs.

Results

Since its inception in 2001, this network has provided VCT for over 105,000 individuals, over 19,000 (18%) of

whom have enrolled into research studies. This includes eight phase I & II HIV vaccine clinical trials in Kenya, Zambia, Rwanda, Uganda and South Africa. Locally-appropriate laboratory reference intervals have been established across the network. The HIV incidence among higher-risk volunteers varies by CRC, from 2.8–7.7 cases/100 PY with over 10,000 PY accumulated. 420 incident infections have been diagnosed and are being followed up.

Conclusion

Network CRCs have conducted phase I & II trials according to GCP and/or large-scale epidemiology studies involving thousands of volunteers. The network has provided opportunities for multicenter clinical trials and access to populations with variable risk for HIV under standardized data, laboratory, and clinical operations.