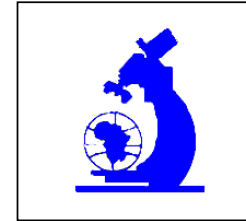




Challenges of setting up an HIV vaccine trial site in Zambia



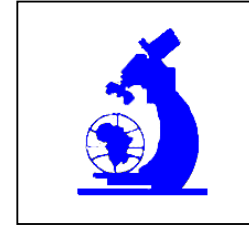
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Gates Foundation
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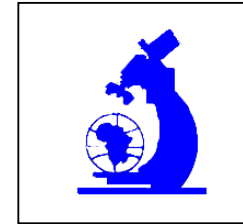
Objectives



- Organize a multi-disciplinary HIV prevention team to prepare for HIV vaccine works in Zambia.
- To define cohorts of 15-45 year old subjects for eventual enrolment in HIV vaccine trials
- Train Zambian personnel and build infrastructure capacity in the laboratory and trial wards for Vaccine trials
- Characterize HIV primary isolate strains in Zambia,



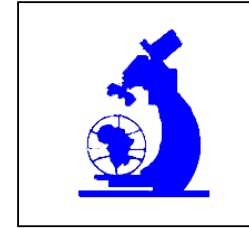
Methods (1)



- Conducted sociological survey (KAP)
- Secondary data from HIV Sentinel Surveillance for HIV prevalence
- Screening for STI in the cohorts, during visit at enrolment
- Blood draw for immunology, hematology and clinical chemistry measurements in HIV-infected and non infected subjects.



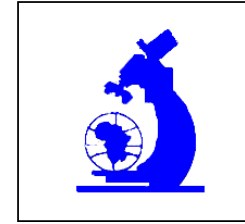
Methods (2)



- Duke University, US offered a course in Biostatistics and clinical trial design and training for PBMCS separation. Administrators at Duke consulted with Zambian administrators to teach NIH grant administration skills and NIH IRB and informed consent compliance regulations.
- cloning and sequencing up to 150 HIV isolates, involve serum testing from each HIV+ donor to determine the ability of sera to broadly neutralise HIV primary isolates



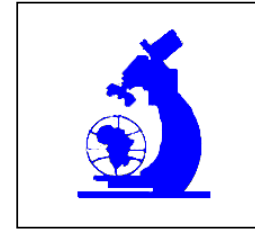
Results (1)



- Formation of the CAB
- KAP study revealed sufficient knowledge about HIV and Vaccine and willingness of the popu to participate
- Able to establish “normal”/reference values of immune system



Results (2)

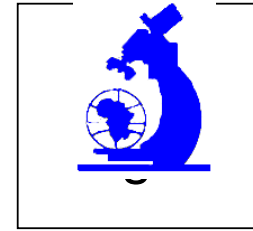


If needed

- Training in biostatistics and clinical study design
- Training in PBMCs separation
- Training in NIH/Other US grants management and monitoring
- Preliminary results on viral diversity already published/presented
- Neutralizing antibody studies continuing



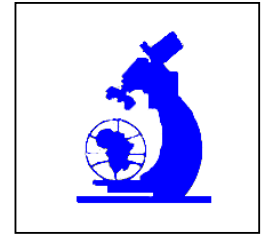
Discussion & Conclusions



- Financial: Fluctuation of local currency
- Human resource: the anticipated benefits versus loss of expertise during training
- Collaboration/Networks: limited collaboration, need to expand
- Leadership/Institutional support: difficult to anticipate problems and coordinate the project activities in the most cost-effective manner; beauraucratic system
- lacked prior knowledge of the standard format for SOPs



Future perspectives



- Collaboration with other institutions in Africa and also Europe under the EDCTP umbrella
- Infrastructure capacity development
- Staff development and retention