

RFA: Phase I: Strengthening Capacity for Research for HIV-Associated Malignancies in Africa

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of HIV and AIDS Malignancy (OHAM)



- New office in the Office of the Director, NCI. Works with NCI leadership, the Divisions, and other Offices to manage the portfolio of HIV/AIDS and AIDS malignancy research throughout the NCI.
- Interfaces with the NIH Office of AIDS Research (OAR) and other ICs with regard to research in HIV/AIDS and AIDS malignancies.
- Initiates and directly manages certain research programs, including the AIDS Malignancy Clinical Trials Consortium (AMC), the AIDS and Cancer Specimen Resource (ACSR), etc.

OHAM

Dr. R. Yarchoan



AIDS Malignancy Program

Dr. Kishor Bhatia (Head)
Dr. Geraldina Dominguez
Denise Jenkins

- Develops and prioritizes new scientific initiatives
- Manages certain programs (CFAR, MACS, WIHS, IeDEA, AITRP)

AIDS Clinical Cancer Program

Dr. Mostafa Nokta (Head)
Dr. Rebecca Huppi

- Manages the AIDS Malignancy Consortium (AMC) and the AIDS Cancer Specimen Resource
- Coordinates other AIDS clinical projects in the NCI

Goal of this RFA

To enhance research capacity in Africa in order to allow US investigators to develop and maintain sustainable collaborations.

Plan is for it to segue into Phase II, a follow-up RFA that, if approved, will fund specific AIDS malignancy research projects in Africa.

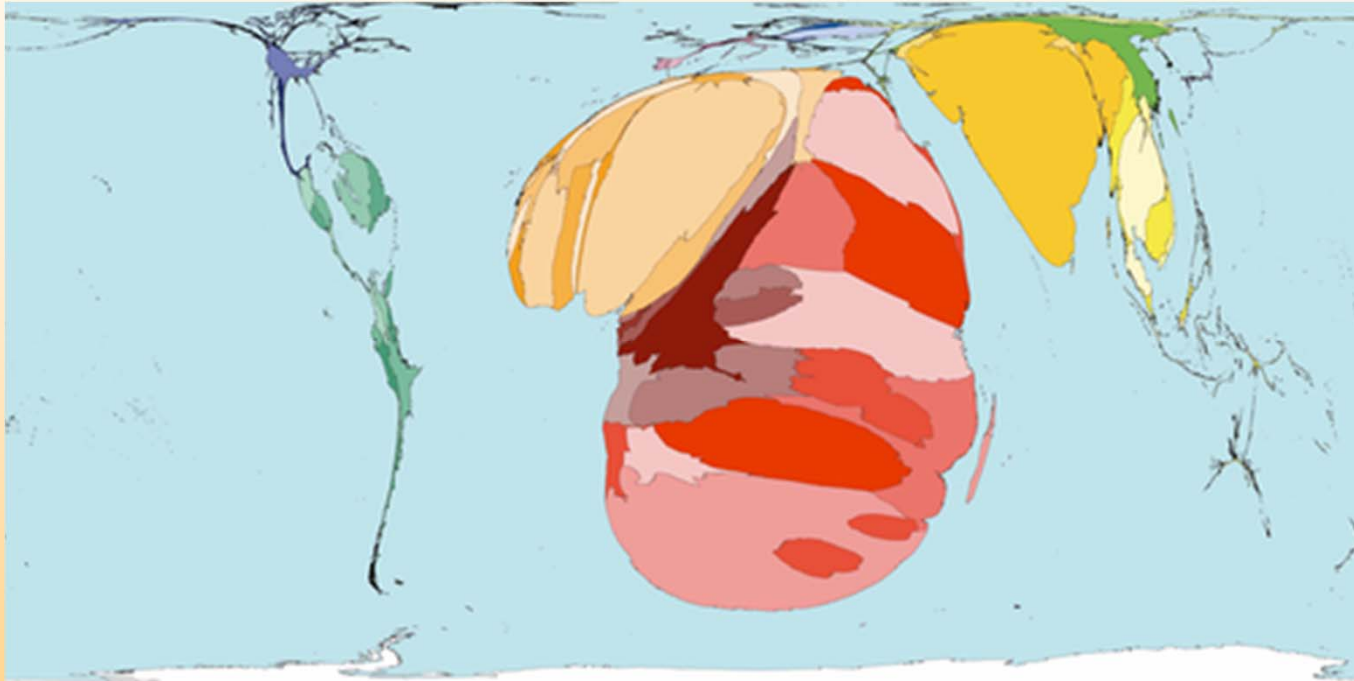
Why Africa?

- 68% of all people infected with HIV live in Africa.
- Africa is a major endemic region for Kaposi's sarcoma-associated herpesvirus (KSHV/HHV-8), the cause of KS.
- Africa was the epicenter of viral-related cancers even prior to the HIV epidemic (e.g., KS, Burkitt's lymphoma, cervical cancer, and hepatocellular carcinoma).
- Lymphoma and Kaposi's sarcoma (KS) are major causes of morbidity and mortality in sub-Saharan Africa.
 - Since the HIV epidemic the relative risk of KS has increased 30-50 fold.

Why Africa? (Cont.)

- There is a rich history of partnership between Africa and the NCI (e.g. Burkitts lymphoma studies in the Uganda Cancer Institute).
- The US has made a major effort to combat AIDS in Africa through PEPFAR (the US President's Emergency Plan for AIDS Relief). As we provide treatment for HIV, AIDS malignancies in Africa are emerging as a major problem that is not adequately addressed and requires more research.
- Studies conducted in Africa will inform our understanding of the biology of cancers in the United States (e.g. Burkitt's lymphoma).

HIV/AIDS Deaths

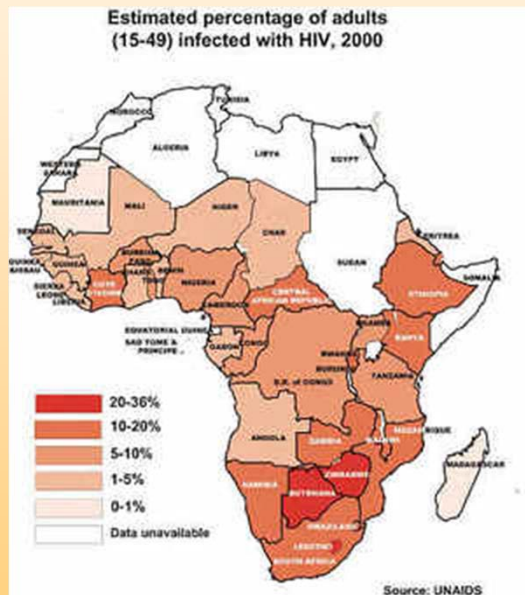


www.worldmapper.org

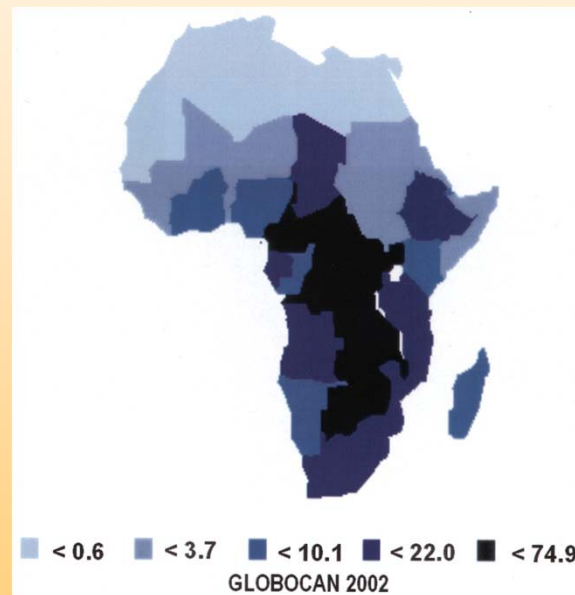
Territories are sized in proportion to the absolute number of people who died from HIV/AIDS in one year.

Dual Burden of KSHV and HIV Infection in Africa Fuel an Epidemic of Kaposi's Sarcoma (KS)

HIV



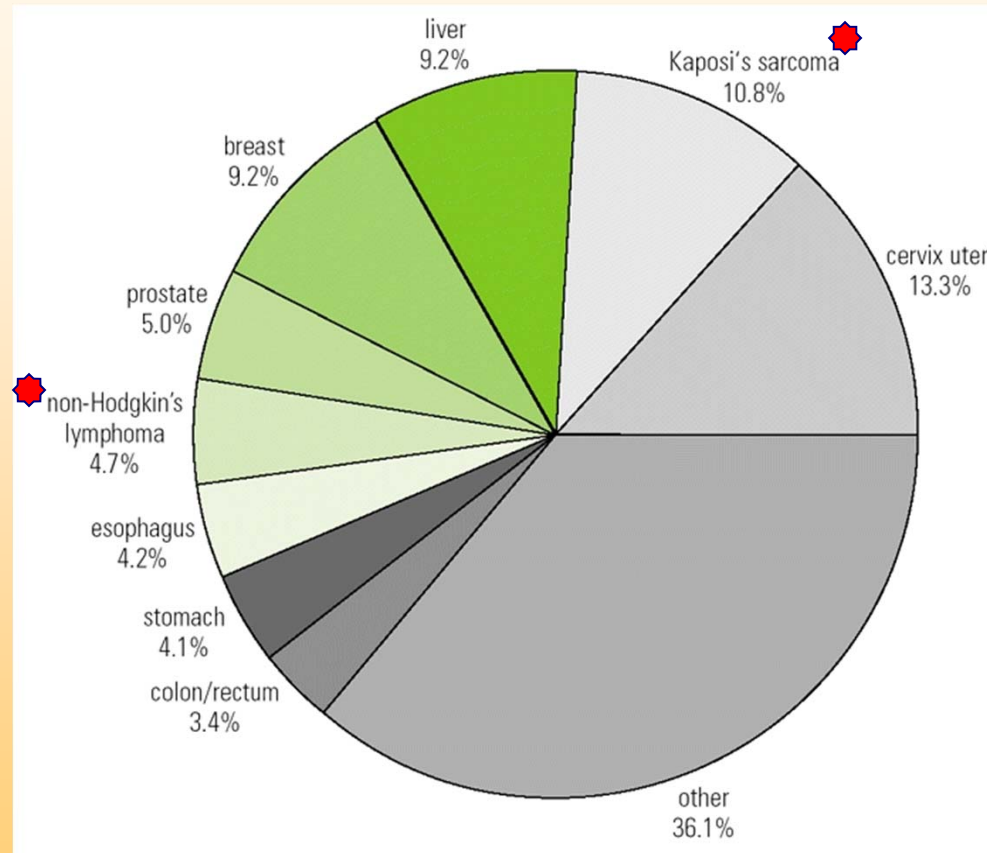
KS Incidence



KS



Major Cancer Types in Sub-Saharan Africa, Both Sexes, All Ages



★ Malignancies that are AIDS defining when they occur in an HIV-infected patient

Disease and Mortality in Sub-Saharan Africa (2nd edition)

Edited by Dean T. Jamison , Richard G. Feachem , Malegapuru W. Makgoba , Eduard R. Bos , Florence K. Baingana , Karen J. Hofman , Khama O. Rogo

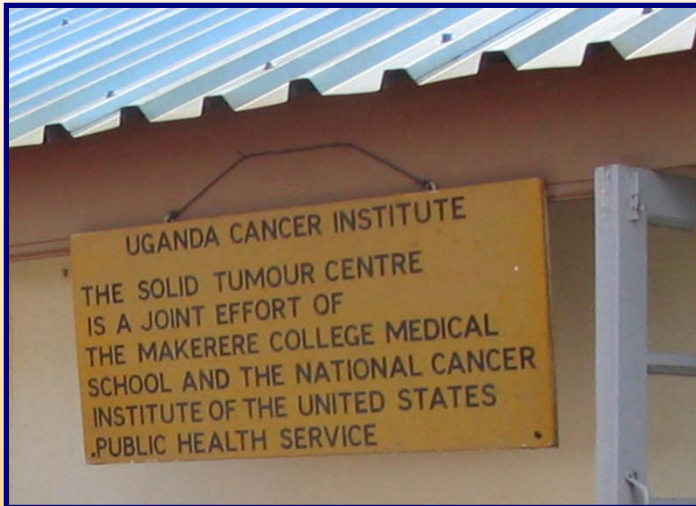
Lack of Research Training Is a Major Barrier to AIDS Malignancy Research in Africa

- Lack of trained partners in Africa was identified as a key barrier towards developing sustainable collaborations at 2 NIH-supported meetings.
 - October 1, 2007- “HIV/AIDS and Viral Attributable Malignancies in Africa”
 - November 5-6, 2008- “Opportunities for Strengthening the Research Enterprise in sub-Saharan Africa”
- Research training in underdeveloped regions was identified as an area of emphasis in the OAR Trans-NIH Plan for HIV-Related Research.

Building the Foundation for this Initiative

- Over the past 3 years, NCI has partnered with other ICs to begin to develop an international HIV/AIDS-related malignancy portfolio:
 - CFAR (Centers for AIDS Research)
 - IeDEA (International epidemiologic Databases to Evaluate AIDS)
 - ACTG (AIDS Clinical Trials Group)
 - AITRP (AIDS International Training and Research Program)
- The NCI has provided supplemental funding to CFARs and AITRPs to test the feasibility of cancer research in Africa.
- We can now leverage existing HIV infrastructure in Africa developed by NIH supported programs and other US programs such as PEPFAR.

Example: University of Washington AITRP- and CFAR-Supported Activities



- CFAR Supplement
 - Viral Oncology Translational Research Initiative
 - Build capacity for tumor specimen acquisition, processing, preservation, and distribution at UCI
 - Support UCI-based leadership in designing and conducting studies of high translational significance for cancers uniquely prevalent in Uganda
- AITRP Supplement
 - Train Uganda physician-scientists from UCI in research and clinical care with HIV-associated malignancies

Phase I - Strengthening Capacity for Research for HIV-Associated Malignancies in Africa

- Participating components: NCI (primary), Fogarty International Center (FIC)
- D43 grant mechanism will be used
- \$4.0 million per year
- Total of three years
- 6-7 awards
- Maximum of \$500,000 Direct Costs per Year
- Each application must have a US PI and an African co-PI
 - Any US investigator working in the field of HIV/AIDS-related malignancies-preference to investigators who have an established collaboration with an investigator at an African institution
- Anticipated Funding
 - Funds will come from dollars the NCI receives from the NIH Office of AIDS Research (OAR) that must be targeted to AIDS research.
 - Funding for this RFA will be supplemented by the Fogarty International Center.
 - The OAR has already endorsed this project as “high priority” AIDS research.

Why the D43 Mechanism?

- Goal of RFA is to train African investigators
 - D43 is specifically designed for non-NRSA research training
- Goal of RFA is to build project directed multidisciplinary research teams
 - D43 allows for flexibility in the development of a customized training program that meets the needs and resources of the targeted institute
- D43 mechanism has a positive track record in building research capacity
 - For example, AITRP, ICOHRTA (International Clinical, Operational and Health Services Research Training Award) and other Fogarty programs in the non-cancer setting
 - D43 trainees have graduated to become highly successful independent PIs who have been reliable partners with US investigators and go on to conduct joint studies

Possible Options for Training

- Short-term training in the US (3-6 months) for individuals with professional degrees , e.g. to learn specific procedures
- Long-term training in the US (up to 2 years) may include post-doctoral and degree training to develop in-depth capacity for a specific expertise.
- In-country Training
 - Short-term training (1-2 months) in a variety of topics
 - Workshops
 - On-line training

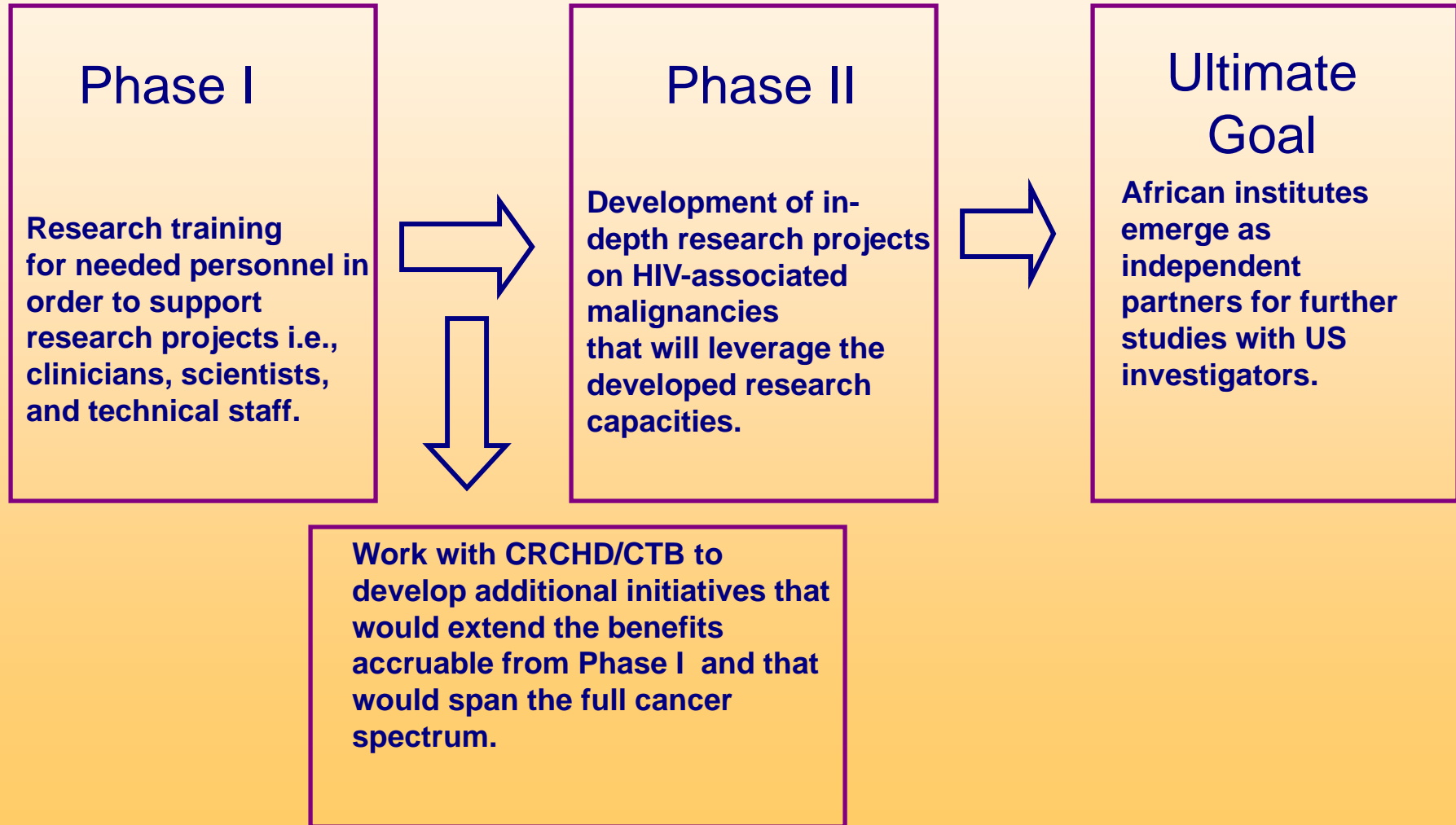
Evaluation Criteria for Assessing Phase I

- Number and score of grants received compared to the 2008 AITRP competitive supplement request “Revision Awards to Support AIDS-related Malignancies Research Training to Currently Funded AIDS International Training and Research Program Awards (D43)”.
- The number of grants that leveraged existing infrastructure and programs.
- The number and diversity of disciplines targeted for training.
- The gap in research that was targeted.
- The ability of the collaborating PIs in obtaining the required country approvals.
- Data provided in the annual progress report and report from the “evaluative committee” will be used to monitor and assess the type and quality of training received.

Oversight of the Training Program

- Establishment of a joint AMP, CRCHD, CTB and FIC committee to monitor progress.
- Grantees must provide documentation of the impact of the training program:
 - How it increases research capacity at the African institution
 - What impact it has on the careers of the trainees
- Grantees will provide tables with specific documentation:
 - Trainees and level of education prior to training
 - Training received
 - Diversity of thematic areas being offered
 - Expertise of faculty or trainer
 - Topics that were taught by each faculty or trainer
 - Resulting abstracts or publications

Planned Next Steps in Order to Sustain Research Capacity



Scientific Contacts

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