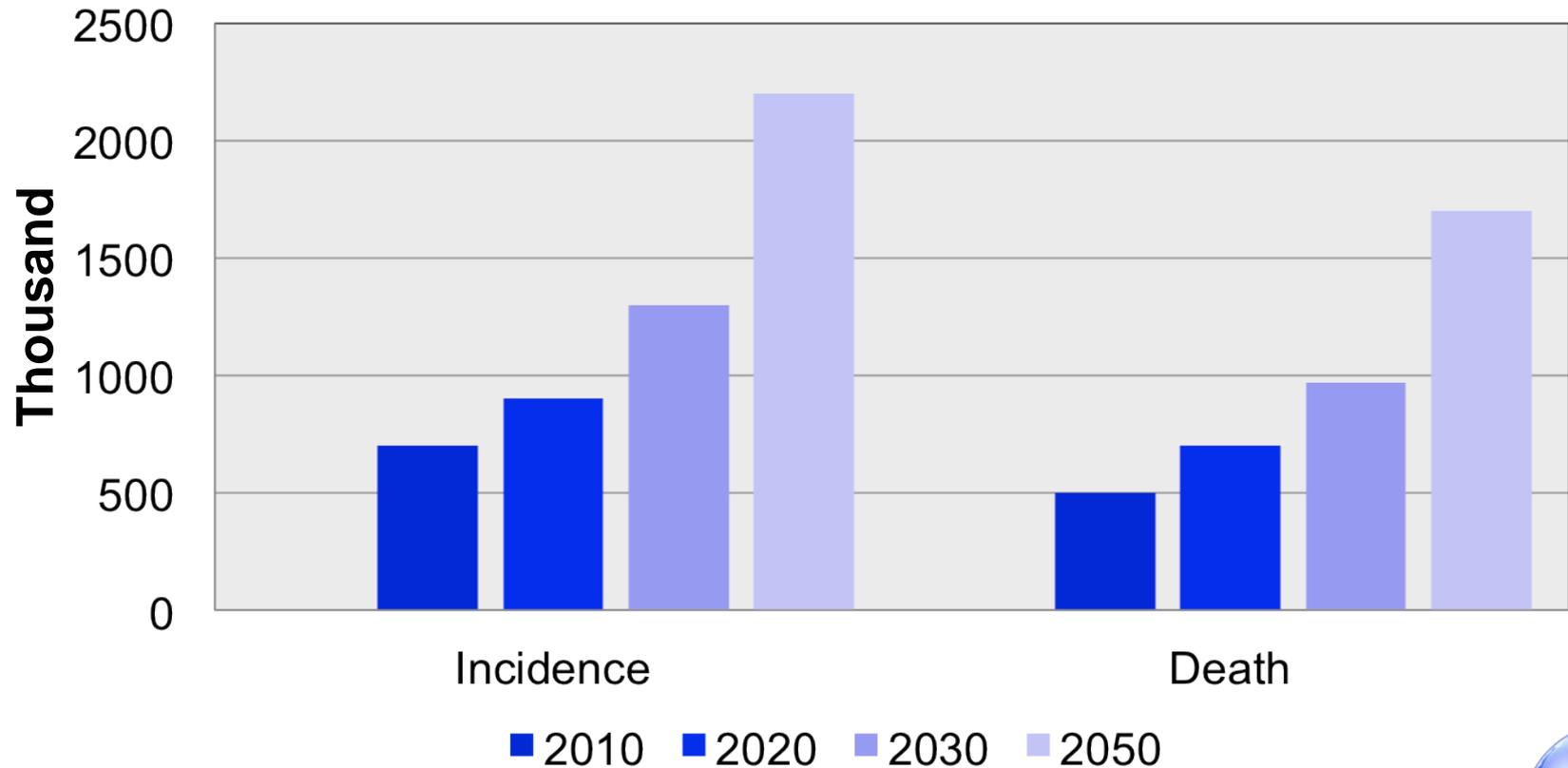


Phase 2: Sub-Saharan African Collaborative HIV and Cancer Research Consortia (U54)



Office of HIV and AIDS Malignancy
(OHAM)

Cancer in Africa: A Significant Problem



Adapted from Sylla and Wild, Int J Cancer. 2012 Jan 15;130(2):245-50.

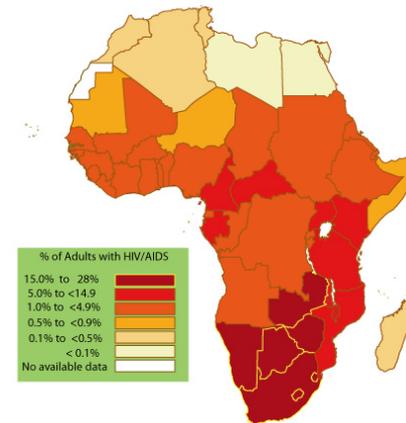


HIV and Cancer in Africa

- As of 2011 69% of all people infected with HIV live in sub-Saharan Africa
- Africa was the epicenter of viral related cancers even prior to the HIV epidemic (e.g., Kaposi's sarcoma (KS), Burkitt's lymphoma, cervical cancer, and hepatocellular carcinoma)
- Lymphoma, cervical, and KS are a major causes of morbidity and mortality in sub-Saharan Africa
 - Since the HIV epidemic, the relative risk of KS has increased 30 – 50 fold

HIV

Estimated HIV Infection in Africa in 2007
based on statistics from the Joint UN Programme on HIV/AIDS



KS



■ <0.6 ■ <3.7 ■ <10.1 ■ <22.0 ■ <74.9
GLOBOCAN 2002 Incidence per 100,000

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Why Africa?

- Africa has a double burden of disease – a high prevalence of HIV and of oncogenic viruses such as HHV-8/KSHV.
- The NCI leadership has identified global cancer research, particularly in resource-constrained areas, as one of its priorities.
- There is a rich history of partnership between Africa and the NCI (e.g. Burkitt's lymphoma studies at the Uganda Cancer Institute).
- We can now leverage existing HIV infrastructure in Africa developed by NIH-supported programs and other US programs such as PEPFAR (President's Emergency Plan for AIDS Relief).
- As combination anti-retroviral therapy becomes more available, it will shift the cancer burden in ways that cannot be easily predicted without further research.
- Studies conducted in Africa will inform our understanding of the biology of cancers in the United States (e.g. Burkitt's lymphoma).



OHAM's Efforts in Supporting HIV-Associated Malignancy Research in Africa

- AIDS Malignancy Consortium
- AIDS Cancer Specimen Resource
- NCI partners with other ICs
 - CFARs (Centers for AIDS Research)
 - IeDEA (International epidemiologic Databases to Evaluate AIDS)
 - ACTG (AIDS Clinical Trials Group)
 - AITRP (AIDS International Training and Research Program) and now the new HIV Training Program
- Phase 1: D43 Research Training Program (ending)



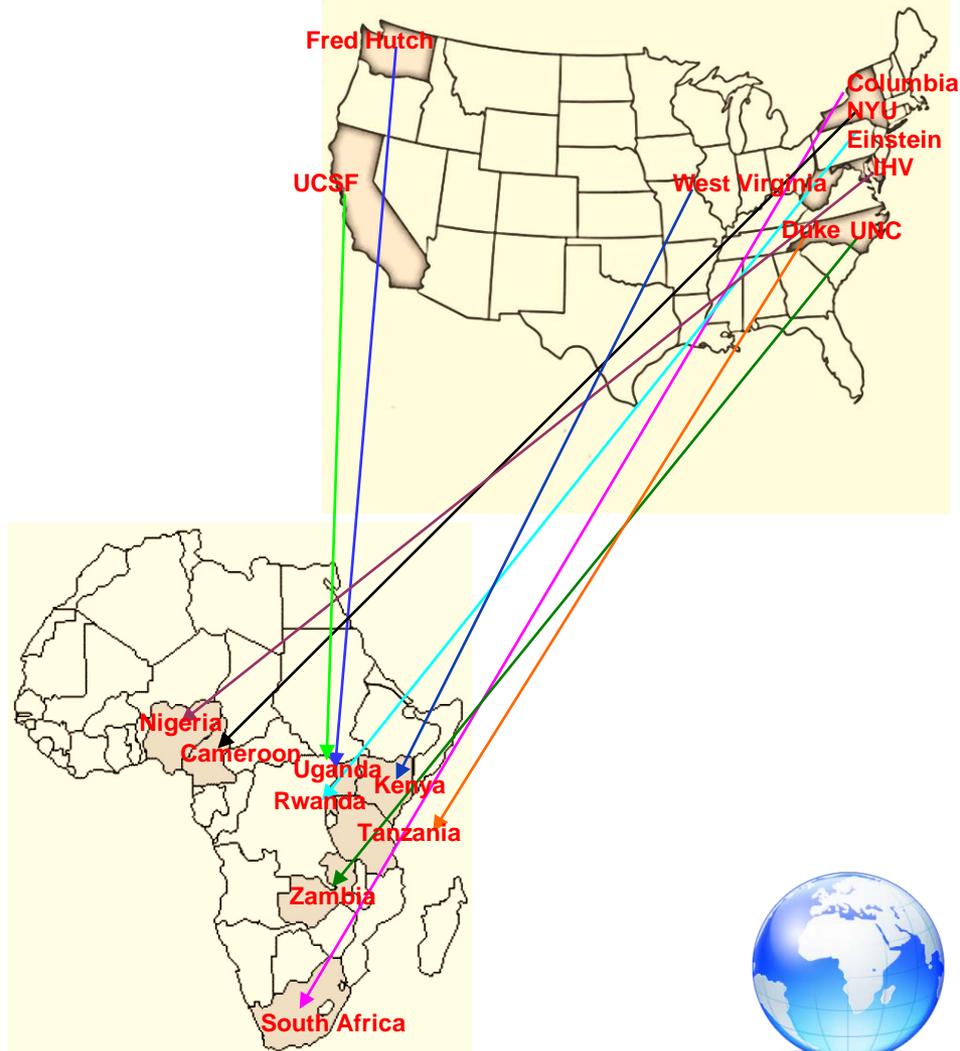
Phase 1: Strengthening Capacity for Research for HIV-Associated Malignancies in Africa

- Background
 - Lack of trained personnel in sub-Saharan Africa was identified as a major barrier for developing and maintaining sustainable collaborations in HIV-associated malignancies.
 - 2000-Present: Supported cancer-focused AITRP grants
 - 2007-2008: Targeted supplements to AITRP grants
 - 2009-Present: (RFA-CA-09-016), “Developing Research Capacity in Africa for Studies on HIV-Associated Malignancies (D43)”
 - 9 awards (FY 2010-2012) for a total cost of \$4.6 million per year for 3 years (FIC is a co-funder)
 - FY 2013 additional funds will be available to support pilot research projects
- At the time of the D43 RFA, plans were communicated to the NCI leadership and the Board of Scientific Advisors of the intent to propose a Phase 2 RFA as a future step.



D43 Research Training Programs in HIV-Associated Cancers

- **Nigeria/IHV:** Clinical trials, cancer epidemiology and cancer registration
- **Rwanda/Einstein:** Clinical research of HPV and AIDS-associated malignancies
- **Tanzania/Duke:** Clinical and laboratory research methodology, pathology and radiology in HIV-associated malignancies
- **Uganda (UCI)/UW:** Clinical trials and cancer epidemiology of HIV-associated malignancies
- **Uganda (IDI)/UCSF:** Kaposi's sarcoma epidemiology, early detection and clinical intervention
- **South Africa/Columbia:** Clinical studies of Kaposi sarcoma, non-Hodgkin lymphoma and cervical cancer
- **Cameroon/NYU:** Basic laboratory research in HIV/AIDS cancers
- **Zambia/UNC:** Prevention and treatment of cervical cancer
- **Kenya/West Virginia:** Clinical studies of HIV-related malignancies



Highlights of the Outcomes of the D43 Research Training Program

- **Long-term: Non-degree training**
 - Physician-scientists and Post-doctoral fellows (31)
- **Long-term: Degree training**
 - PhD (7)
 - Master in Public Health (5)
 - Master in Clinical Research (1)
 - Master of Medicine (4)
 - Master of Science (2)
- **All long-term trainees will conduct mentored research projects**
- **Medium-term training**
 - Pathology (immunohistochemistry)
 - Laboratory science (HPV typing, RT PCR, HIV RNA)
 - Data management
 - Cancer registration
- **Short-term training**
 - KS-recognition training for traditional healers
 - Cervical cancer screening and cervicography



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Goals of the Phase 2 RFA

- Solicit research projects that address high-priority research questions in HIV-associated cancer in the sub-Saharan African partnering country
- Accelerate basic, translational, population, and implementation research in HIV-associated malignancies in sub-Saharan Africa
- Enhance the ability of African institutions to serve as a national/regional resource for training and career development of scientific leaders in cancer research



Phase 2: Sub-Saharan African Collaborative HIV and Cancer Research Consortia (U54)

- U54 grant mechanism will be used
 - Supports a full range of research (basic, translational and clinical)
 - Allows multiple projects in a single application
 - Allows for scientific and programmatic input
- Phase 2 was developed in consultation with the NCI Center for Global Health, Office of Cancer Centers, the Center for Cancer Training, and the Fogarty International Center
 - FIC has indicated they will provide co-funding
- Requested set aside of \$5 million per year for 5 years
 - Anticipate ~20 applications and funding of 6-7 applications
 - Funds will come from part of the NCI budget set by the NIH Office of AIDS Research (OAR) that must be targeted to HIV/AIDS research.



Features of the Phase 2 U54 RFA

- RFA will be open to all qualified applicants, not just D43 Research Training recipients
- Applications can either be submitted by an institution in sub-Saharan Africa or by a U.S. institution
 - Research will involve one sub-Saharan African country
 - Multiple institutions in the same African country can form a consortium with one U.S. institution
- Demonstrate equal and shared partnership between the African & U.S. partners
 - Leadership plan must be provided
- African institutions should provide evidence of institutional commitment
- Budget should support research and career development in Africa
- Applicants can request up to \$750,000 total cost per year for 5 years



Features of the Phase 2 RFA (continued)

- Each applicant must propose 3 research projects and at least 2 cores
 - Topics can include epidemiological, population, social behavioral, basic, translational and clinical studies
 - Administrative and Coordinating Core (mandatory)
 - Mentoring and Career Development Core (mandatory)
 - Technical Cores as needed for the proposed studies
 - Clinical/Translational (patient recruitment, sample acquisition, study design, IRB approval)
 - Epidemiology/Biostatistics (statistical support)
 - Laboratory (pathology, virology, immunological assays)
 - CLINICAL TRIALS are not permitted, but CLINICAL RESEARCH using human specimens is permitted
- Projects should either address a variety of topics for a single category of cancer or one topic for a related group of cancers



Examples of Possible Research Areas

- **Studies in HIV-associated cancers and pre-cancers**
 - Determine the role of mutations of co-infecting viruses (i.e. HBV, HCV, HPV and KSVH) on the development of pre-cancer and cancer
 - Evaluating tumor immunity in the context of HIV
- **Studies in the prevention, diagnosis, and treatment of cancer in HIV+ people**
 - Identification of pathological and immunohistochemical tools that aid in classifying disease entities
 - Evaluating treatment associated toxicities, optimal supportive care and overall survival
- **Studies to identify strategies to improve the integration of HIV and cancer care**
 - Evaluating the prevalence and disease course of cervical dysplasia in HIV-positive women attending HIV clinics
 - Evaluating strategies for early detection and rapid referral for KS, cervical, and NHL within primary HIV clinics and the acceptability by the HIV providers and clinic directors
- **Studies that assess regional strategies that reduce the burden of cancer and significantly impact health outcomes**
 - Determinants of late stage diagnosis, including HIV status, behavioral risk factors (tobacco, alcohol, & diet), other cancer prognostic factors, and barriers to care (e.g., socioeconomic, lack of trained oncologists, geography)
 - Role of “Patient Navigation” approaches for HIV-positive cancer patients in Africa



Evaluation Criteria for the RFA

- Number of grants received
- Quality of grants (score range) and number funded
- Diversity of thematic areas (epidemiology, pathology, basic, clinical studies behavioral sciences, and implementation science)
- Institutional commitment provided
- Geographic areas represented
- Number of grants received that leverage other existing resources (NIH or non-NIH supported)



Thank You!



Questions?



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