

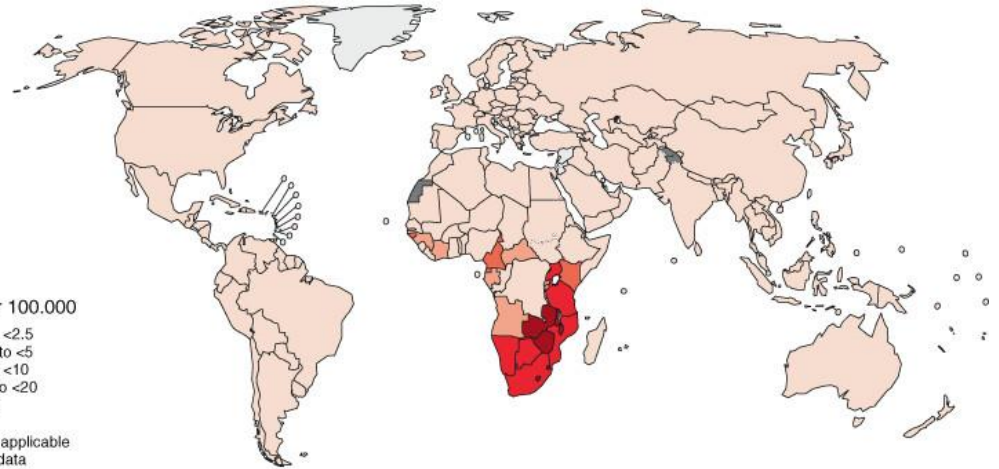
Phase 4: U.S. and Low- and Middle-Income Countries (LMICs) HIV Associated Malignancy Research Centers

Office of HIV and AIDS Malignancy (OHAM)
Geraldina Dominguez, PhD

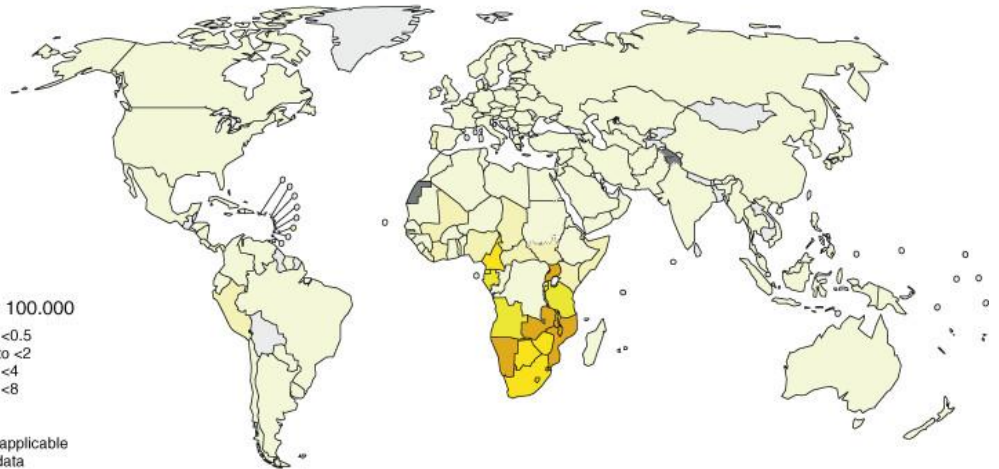


Background

(A) HIV-attributable Cervical Cancer



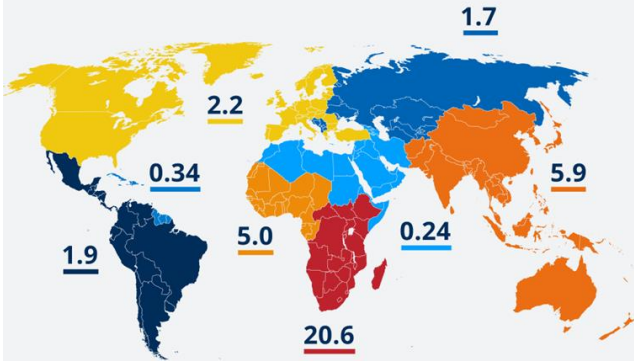
(B) HIV-attributable Kaposi Sarcoma



People estimated to be living with HIV

In millions

Total: **37.9 million**



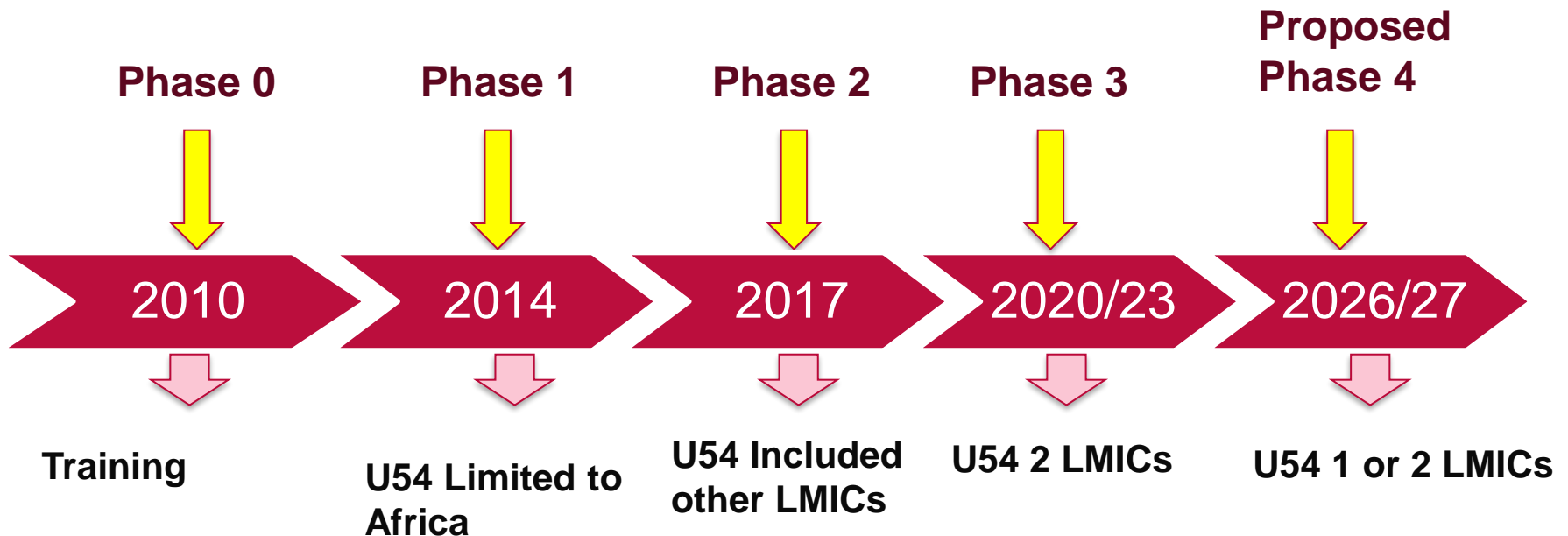
Source: UNAIDS | 2018

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~39.0 million people globally were living with HIV in 2022.

Engels E. et. al. Intl Journal of Cancer, Volume: 154, Issue: 4, Pages: 596-606, First published: 15 September 2023, DOI: (10.1002/ijc.34727)

Timeline of Programs to Increase Research Capacity in LMICs

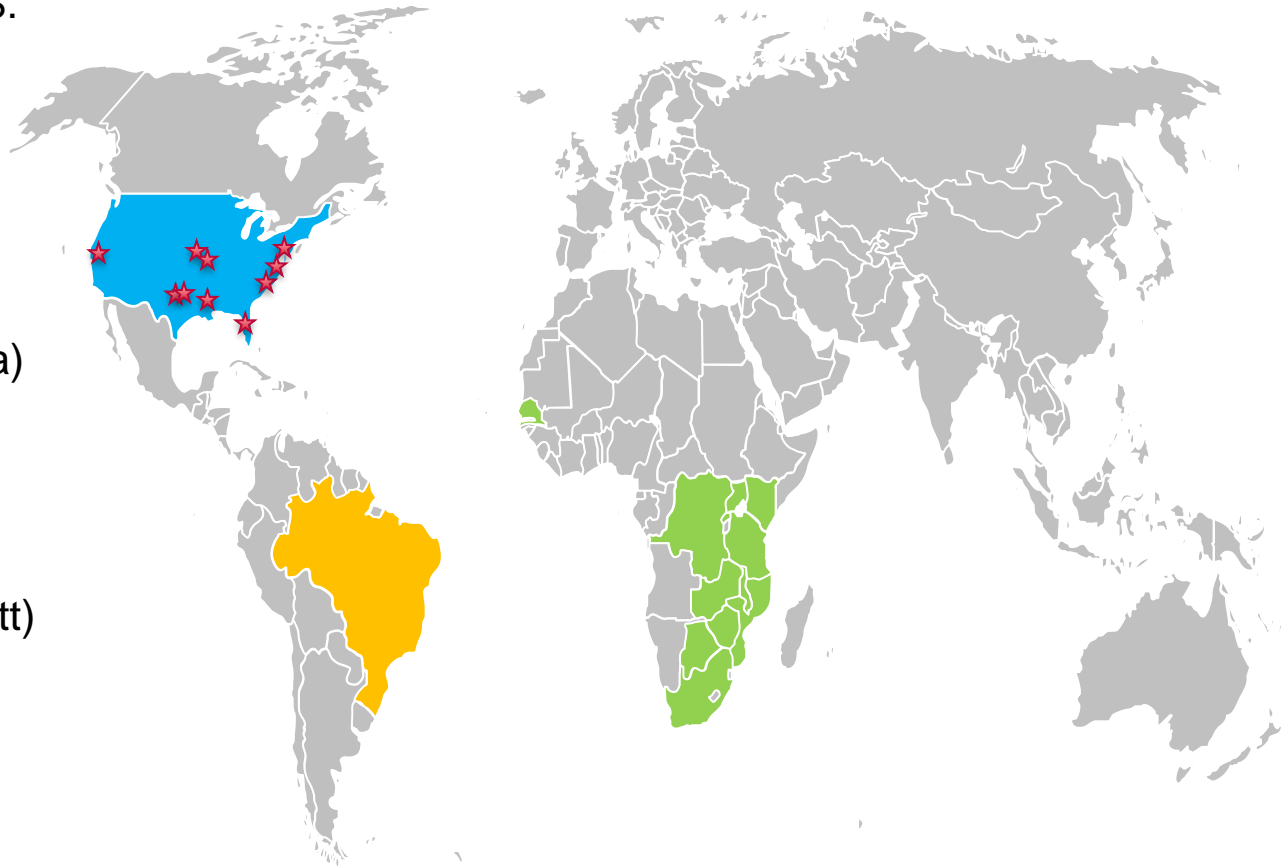


The Fogarty International Center (FIC) has been a partner in all Phases.

Funded centers are called HIV Associated Malignancy Research Centers (HAMRCs)

Phase 3 HAMRCs

- 10 HAMRCs
 - Partnerships between U.S. & LMIC institutions
- African Partners
 - Uganda (UCSF, Baylor, U. Indiana, Case Western, JHU)
 - Rwanda (Einstein)
 - Kenya (UCSF, U. Indiana)
 - DRC (Einstein)
 - Zambia (LSU)
 - Tanzania (UCSF, Case Western, LSU)
 - South Africa (UNC, Moffitt)
 - Botswana (Baylor,)
 - Zimbabwe (Moffitt)
 - Mozambique (MD Anderson)
 - Malawi (UNC, Baylor)
 - Senegal (JHU)
- South America Partner
 - Brazil (MD Anderson)



FY 2023 funding was 10.3 Million

Examples of Phase 3 Research Topics

Kaposi sarcoma
diagnosis &
progression

KSHV pathobiology

Screening and
diagnosis HPV-
associated cancers

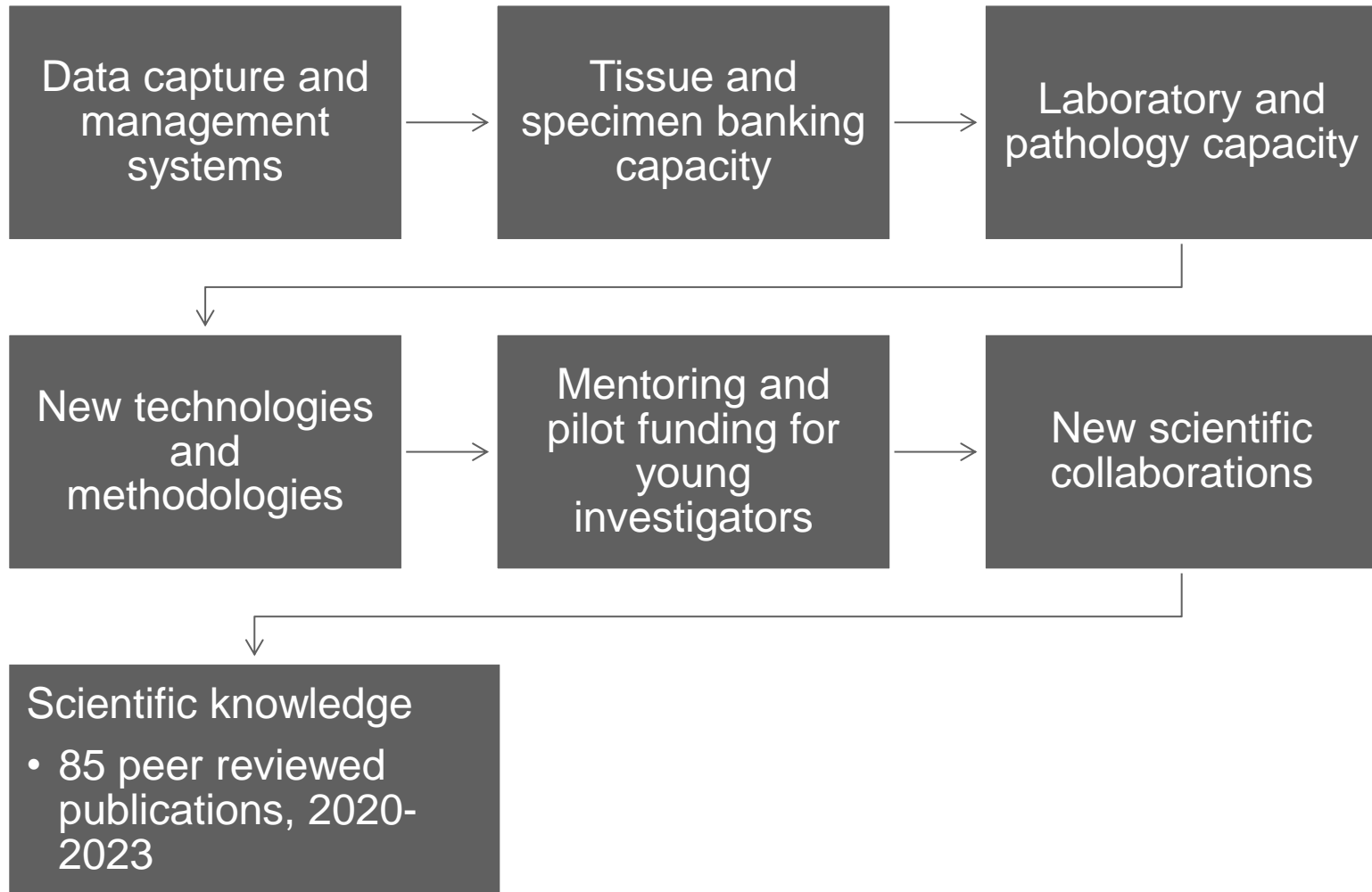
Lung cancer risk
factors and genetic
mutations

Developing evidence
guided treatments
for pediatric cancers

Interactions of HBV
and schistosomiasis
in liver disease and
hepatocellular
carcinoma

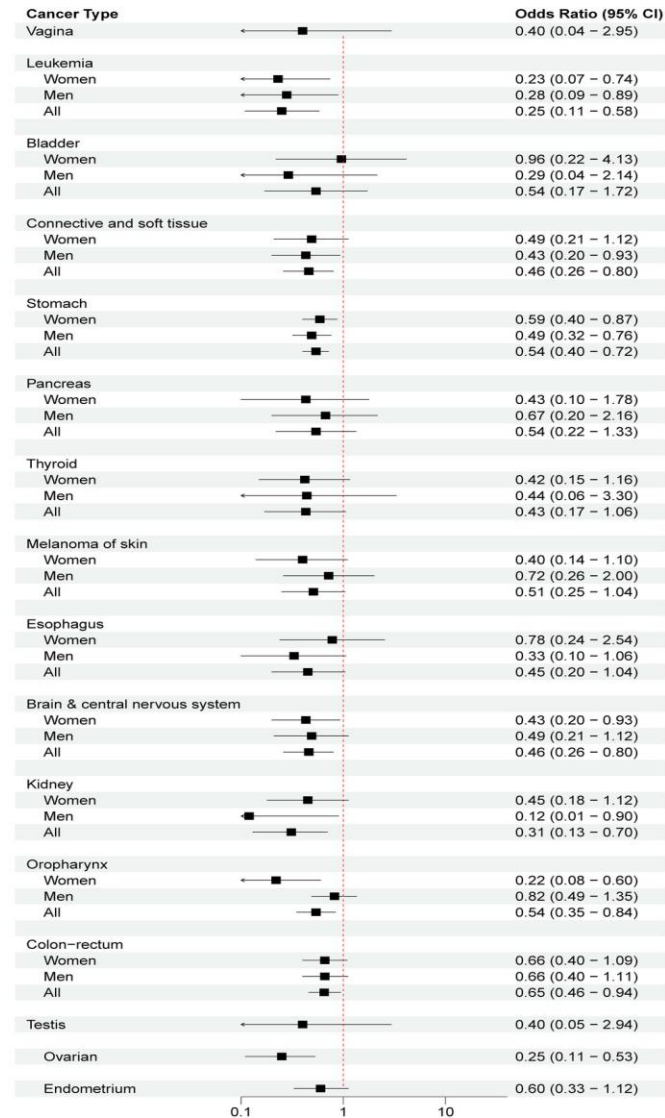
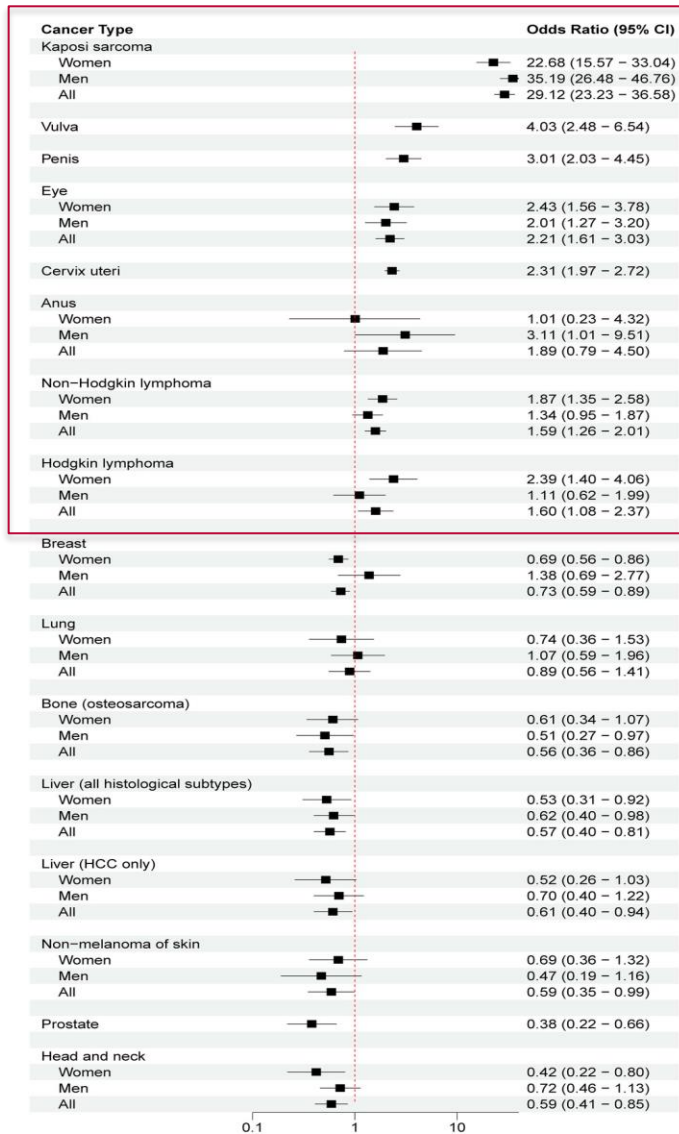
Tumor-associated
biomarkers for HIV-
associated Diffuse
Large B-cell
Lymphoma

Impact of HAMRCs on Research Capacity and Research in LMICs



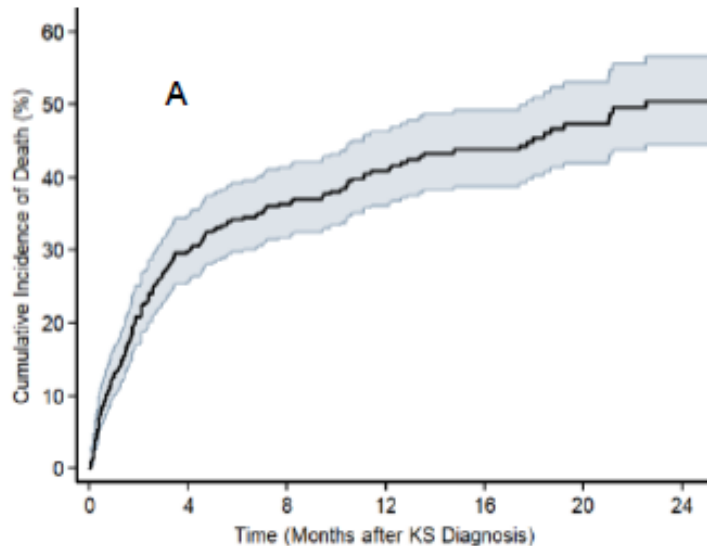
Determining Cancer Risk in People with HIV in Rwanda

Virally Associated Cancers



Dusingize J.C. et. al. Intl Journal of Cancer, Volume: 155, Issue: 12, Pages: 2149-2158, First published: 11 August 2024, DOI: (10.1002/ijc.35091)

Survival Following a KS Diagnosis in Patients Seen at HIV Clinics in Uganda and Kenya



- Characterized newly diagnosed KS patients in Uganda and Kenya
- KS was confirmed on histopathology
- 95% were on ART
- 40% had undetectable HIV RNA
- Median CD4 was 233 cells/ μ l
- Incidence of death was 34%, 41% and 45% at 6, 12, 18 month, respectively

Byakwaga H. et. al. Preprint. 2024 Aug 28:2024.08.26.24312536. doi: 10.1101/2024.08.26.24312536.

Goals of the Phase 4 RFA



- Support collaborations between U.S. and LMIC investigators to conduct research projects that address high-priority research questions on malignancies in people with HIV (PWH) in LMICs
- Foster the development of early- and mid-career investigators from the U.S. and LMICs interested in conducting research on malignancies in PWH

Main Features of the Proposed Phase 4 RFA

- Open to all investigators (Phase 3 investigators are eligible with new projects and/or LMIC partners)
- U54 mechanism
 - Supports a full range of research (basic, translational, clinical and implementation)
 - Allows multiple projects in a single application and needed cores
 - Allows for scientific and programmatic input
- Research projects that address questions related to the HARMC's theme
 - 1 or a maximum of 2 projects
- Cores
 - Administrative Core (mandatory)
 - Developmental Core (mandatory)
 - Shared Resource Cores (e.g., laboratory, data management, biospecimen)

Examples of Research Topics



Pathogenesis and molecular mechanisms in cancer development



Cancer risk, spectrum, role of co-infections across the lifespan



Quality of life issues in people in PWH and cancer



Social determinants of health that impact cancer screening, treatment, and outcomes



Optimal approaches that will guide strategies to improve the integration of cancer care with HIV care



Identification of barriers and facilitators associated with implementing interventions aimed at PWH

Proposed Budget



- Can request up to \$800,000 direct costs if partnering with 2 LMICs and \$700,000 if partnering with 1 LMIC per year for 5 years
- Two receipt dates
- Requested set-aside (total \$51 million over the 6 years of the project)
 - 1st Receipt: (FY 2026) **\$7.1** million per year for 5 years (35.5 million)
 - Expect to support 6-7 awards
 - 2nd Receipt: (FY 2027) **\$3.1** million per year for 5 years (15.5 million)
 - Expect to support 2-3 awards
- Funds will come from NCI's HIV/AIDS allocation from the Office of AIDS Research (OAR) that must be used to support HIV/AIDS research
- Funding will come from ending Phase 3 HAMRCs
- Fogarty International Center is interested in co-funding
- The concept is approved by the OAR as a FY2026 NCI initiative

Responses to BSA Reviewers Feedback

- Thanks to:
 - Dr. Are Chandrakanth
 - Dr. Karen Basen-Engquist
 - Dr. Gloria Coronado
- Implementation science expertise
 - Will seek implementation science expertise when crafting the RFA
- Role of investigators
 - The RFA will encourage that individual research projects and cores be led by a U.S. and LMIC early- or mid-career investigator
 - PIs must demonstrate previous research collaborations and clearly articulate the role for each PI

Past In Person U54 Meetings



2016
Kampala,
Uganda



2019 Dar es
Salaam,
Tanzania



2017
Eldoret,
Kenya



2018
Lilongwe,
Malawi



2023 Gaborone,
Botswana



THANK YOU FOR YOUR ATTENTION!

Questions?



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