

RFA-13-015

Cancer Detection, Diagnostic and Treatment Technologies for Global Health (UH2/UH3)

Main Goal:

To stimulate technology development and adaptation for low-cost use to detect, evaluate, diagnose and treat cancer in low resource settings.

Ted Trimble, MD, MPH
*Director, Center for Global Health
National Cancer Institute, NIH*

Background

Two thirds of cancer deaths occur in low- and middle-income countries (LMICs) due to:

- Limited access to health care
- Need for early detection and diagnosis
- Lack of treatment options
- Poor prognosis and outcomes

Technologies for detection, diagnosis and treatment can help address challenges in LMICs through:

- Portability
- Low cost
- Training adapted to low-resource settings
- Ease of use by local providers
- Minimal invasiveness

Aim: Produce low-cost devices for cancer detection, diagnosis and treatment in low resource settings .

Examples of Technologies Adaptable to Low Resource Settings

- Microfluidics—Lab-on-Chip:
- Lab-on-Paper
 - Paper printed with hydrophobic polymer using a solid wax printer. Quantitative detection can be done using a cell phone.
- DermLite (marketed world wide):
 - Low cost dermatological illuminator-microscope; iPhone interface for distant diagnosis and records.
- Smart Phone Technology /Smart Phone Apps:
 - Lense-free microscopy, cytometry
 - Digital imaging/Computer-aided diagnosis and detection
- Spectrometry
- Endoscopy
 - Potentially with molecular imaging agents.
- Cryotherapy for Cervical Cancer Treatments
- Hand-held Ultrasound



Examples of Projects Approved for Funding

Cancer	Country	Technology
Oral leukoplakia	India	Battery-powered PDT
Cervical cancer	Brazil	Optical endoscopy
Cervical neoplasia	Peru and Columbia	Cryotherapy (CryoPen)
HPV detection	South Africa	PCR (Cepheid GeneXpert)
Hepatitis C virus	Nigeria	RNA viral load test
Cervical dysplasia	Philippines	Cryotherapy (using liquid CO2)
Breast cancer	Mexico	Ultrasound/CADD

Point-of-Care Technologies for Global Health

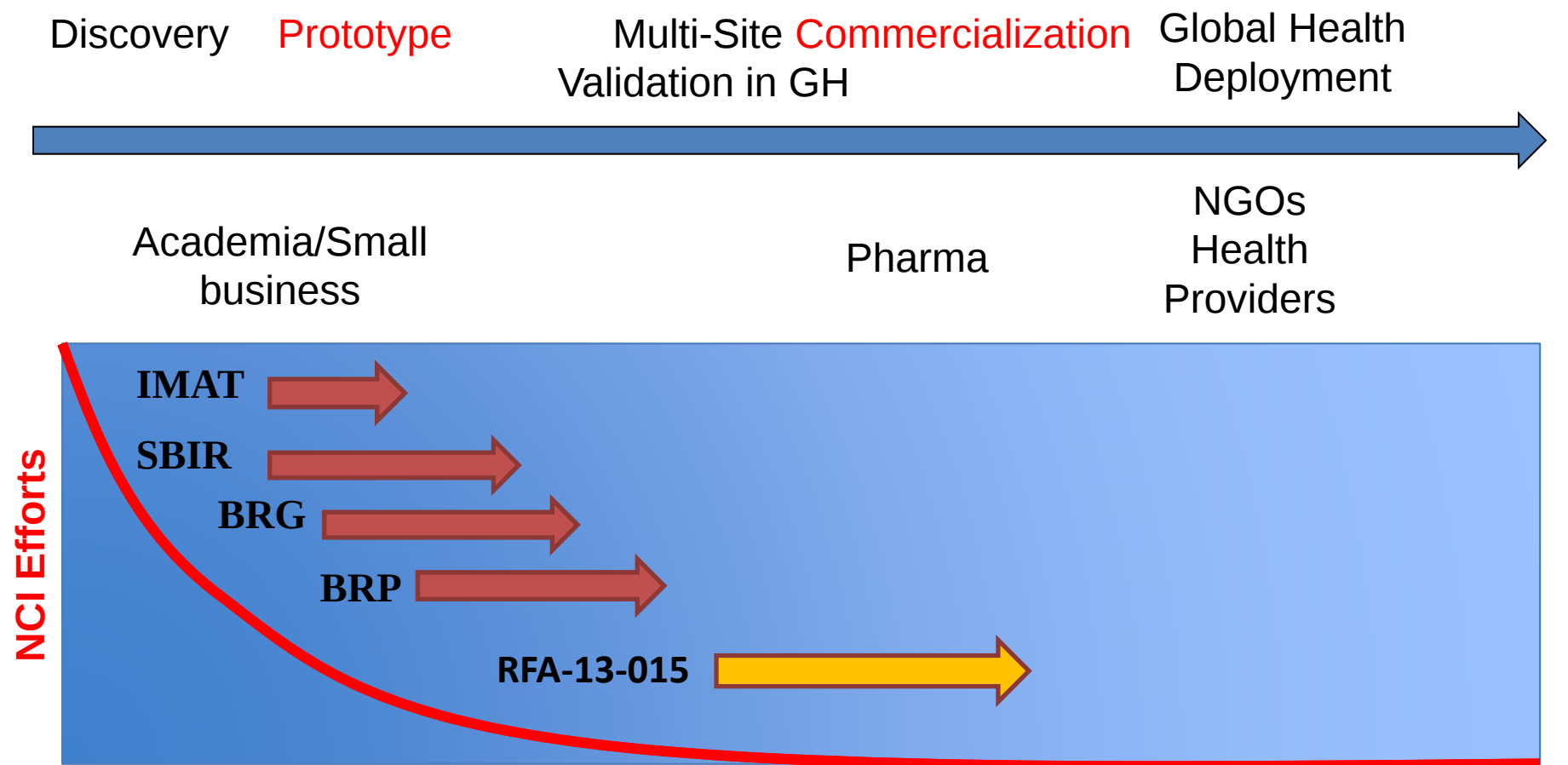
The project must focus on a specific cancer type that is preventable or treatable in the proposed LMIC setting and must show promise to deliver medical utility for improved health outcomes.

All proposed devices must adapt, apply, engineer, and validate existing or emerging technologies or assays into a new generation of technologies and assays for detection, imaging, screening, in vitro diagnosis, or treatment of cancers preventable.

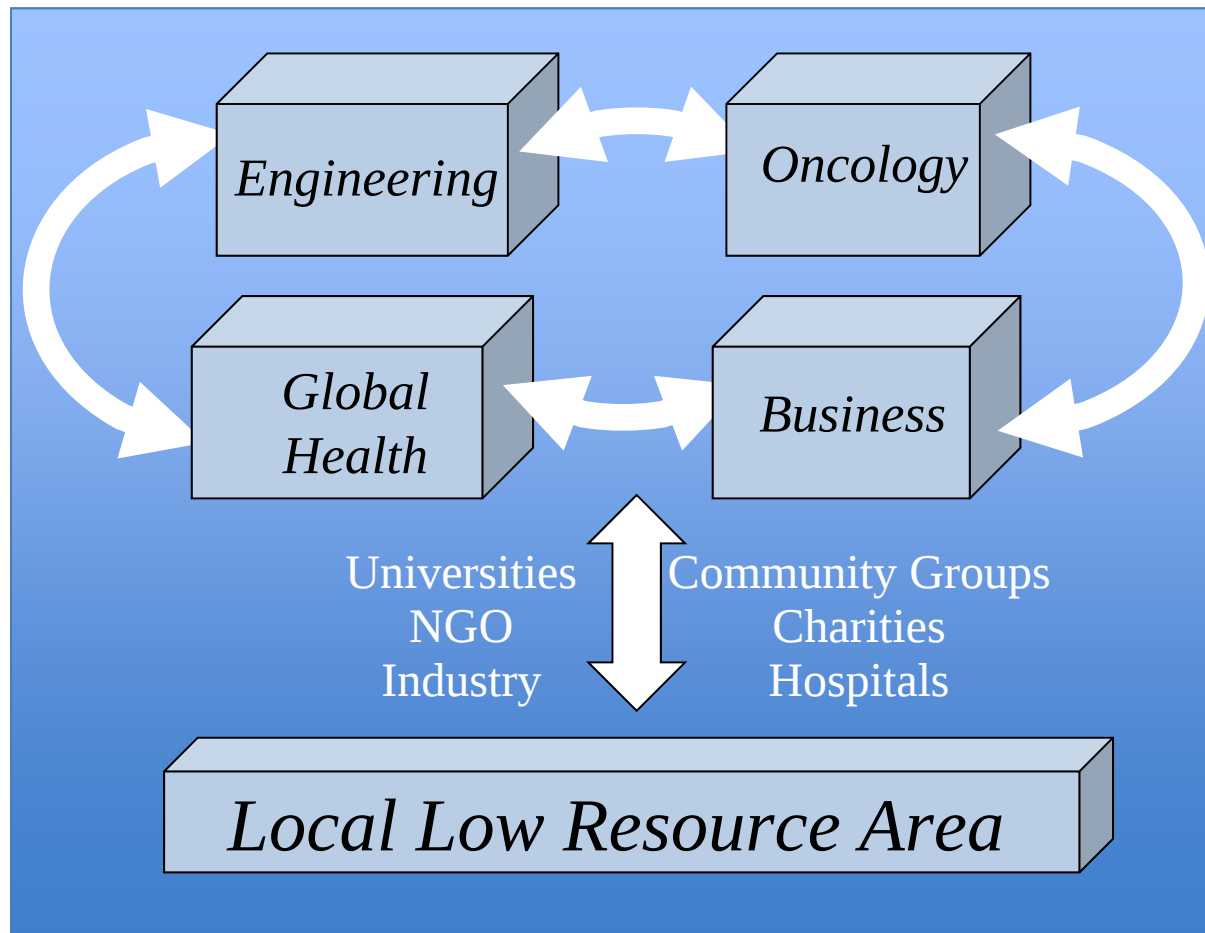
Specific Required Attributes for proposed technologies

- Portable;
- Operable in locations with limited or no medical infrastructure (e.g., limited access to electricity, landline communication, refrigeration, or central water supply);
- Manufacturable at low cost and with low-cost disposables;
- Simple to operate by locally trained healthcare staff;
- Rapid results (for diagnostic technologies);
- Sustainable and affordable by local providers (either low enough in cost to easily replace, easily replaceable parts/ease of repair, or durability)

Technology Development Pipeline



RFA-13-015 Elements



- Establish strategic alliance between engineers/developers, cancer care professionals, experts in global health delivery, and business.
- Assemble a critical mass of expertise to accomplish what individual investigators cannot readily do separately.

RFA-13-015 Funding Opportunity Overview

- Two-phase cooperative agreement (UH2/UH3). RFA reissued yearly over three years.
- **Phase I (UH2) - two years:**
 - Demonstrate clinical potential in a global health setting
 - \$500K per grant per year
- **Phase II (UH3) - three years:**
 - Validate device in global health setting
 - \$1M per grant per year
- **Progression from UH2 to UH3:**
 - Grantee must meet specified milestones
 - Milestones reviewed by NCI program staff.

Deliverables for Phase I (UH2)

1. Prototype adapted to specifications appropriate to low-resource settings
2. Must demonstrate working relationship with local site(s)
3. Update business plan based on phase I experience
4. Update validation study design and leverage with ongoing clinical research/care at chosen site(s)
5. Identify clinical research network to validate trial; priority use of existing US government networks (NIH, CDC, PEPFAR etc.)
6. Provide evidence of progress toward regulatory approval for Phase II validation study

Deliverables for Phase II (UH3)

1. Regulatory approval for deployment and use of device
2. Adequate accrual for validation study, with real-time review of QC and endpoint data; modifications of protocol as needed
3. Updating of business plan for commercialization if validation is confirmed
4. Confirm commercial partners for production and marketing
5. Develop education plan for use in health care delivery; assure progression toward clinical utility and benefit from validated technology

CGH Contact Information

Website:

www.cancer.gov/globalhealth

<http://www.cancer.gov/aboutnci/globalhealth/lowcosttech>

Telephone number:

+1-240-276-5810

New office street address:

9609 Medical Center Drive, Rockville, MD
(near Shady Grove Adventist Hospital)

Email:

NCIGlobalHealth@mail.nih.gov

Twitter Handle:

@NCIGlobalHealth

