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Cancer Detection, Diagnostic and Treatment Technologies for Global Health

Main Goal

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

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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:

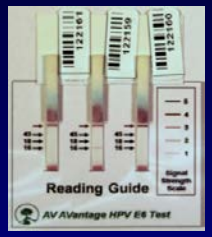
- Portability
- Low cost
- Training adapted to low-resource settings
- Ease of use by local providers
- Minimal invasiveness

Concept Aim: <u>Produce low-cost devices for cancer detection, diagnosis and treatment in low resource settings</u>

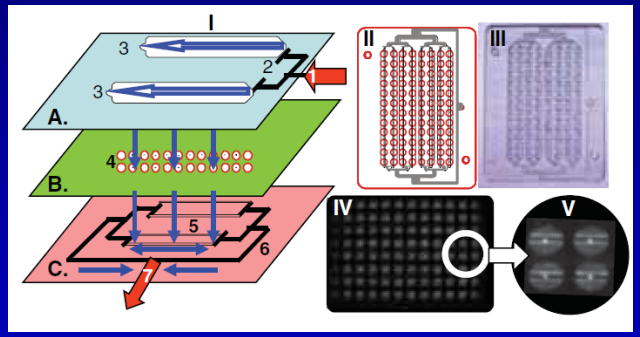
Technologies Adaptable to Low Resource Settings

Microfluidics—Lab-on-Chip:

Cervical cancer: From Vinegar To Lab-on-Chip: A Vantage, careHPV (China).



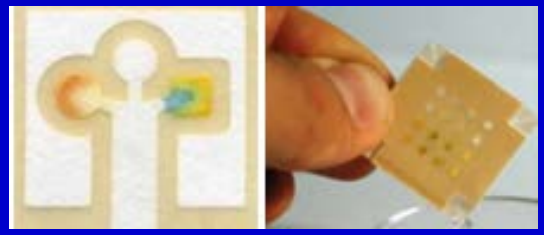
ELISA—Lab-on-Chip



Lab-on-Paper (George M. Whitesides, Harvard):

Paper printed with hydrophobic polymer using a solid wax printer.

Quantitative detection can be done using a cell phone.



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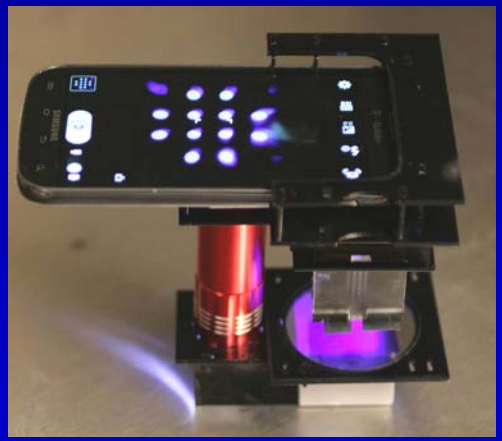
Technologies Adaptable to Low Resource Settings

DermLite (marketed world wide):
Low cost dermatological illuminator-microscope;
iPhone interface for distant diagnosis and records.

Smart Phone Technology /Smart Phone App:

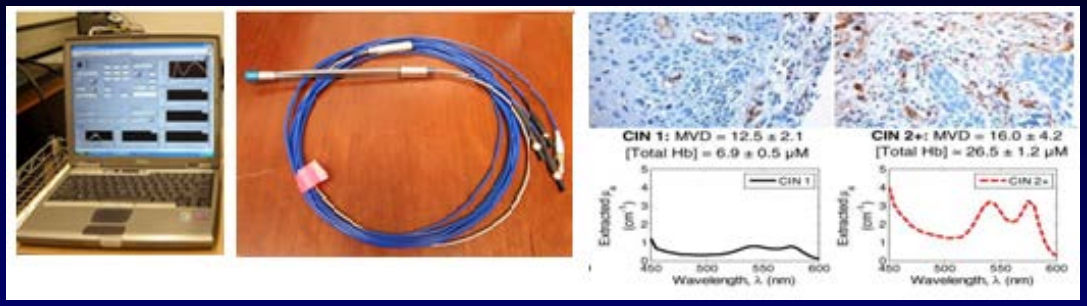
Remote retinoblastoma diagnosis by automated leukocoria detection

Smartphone based fluorescent detector

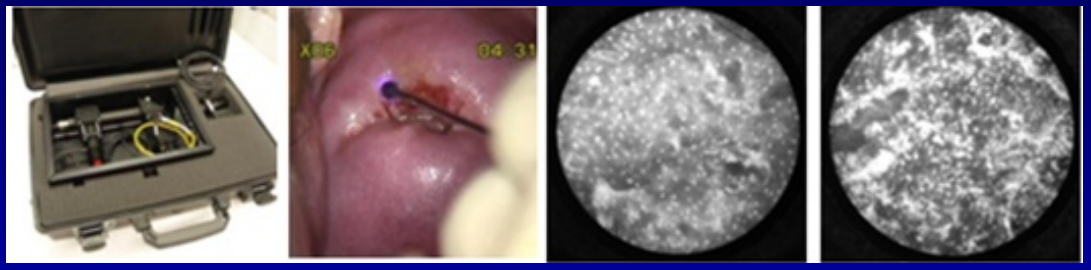


Technologies for Low Resource Settings

Spectrometer (Haiti): Cervical Intraepithelial Neoplasia



Endoscope-Microscope + molecular imaging agents (China).



Cryotherapy for Cervical Cancer Treatment (WHO specs)

Hand Held Ultrasound (marketed world wide): Triage for cysts, effusions, palpable masses.

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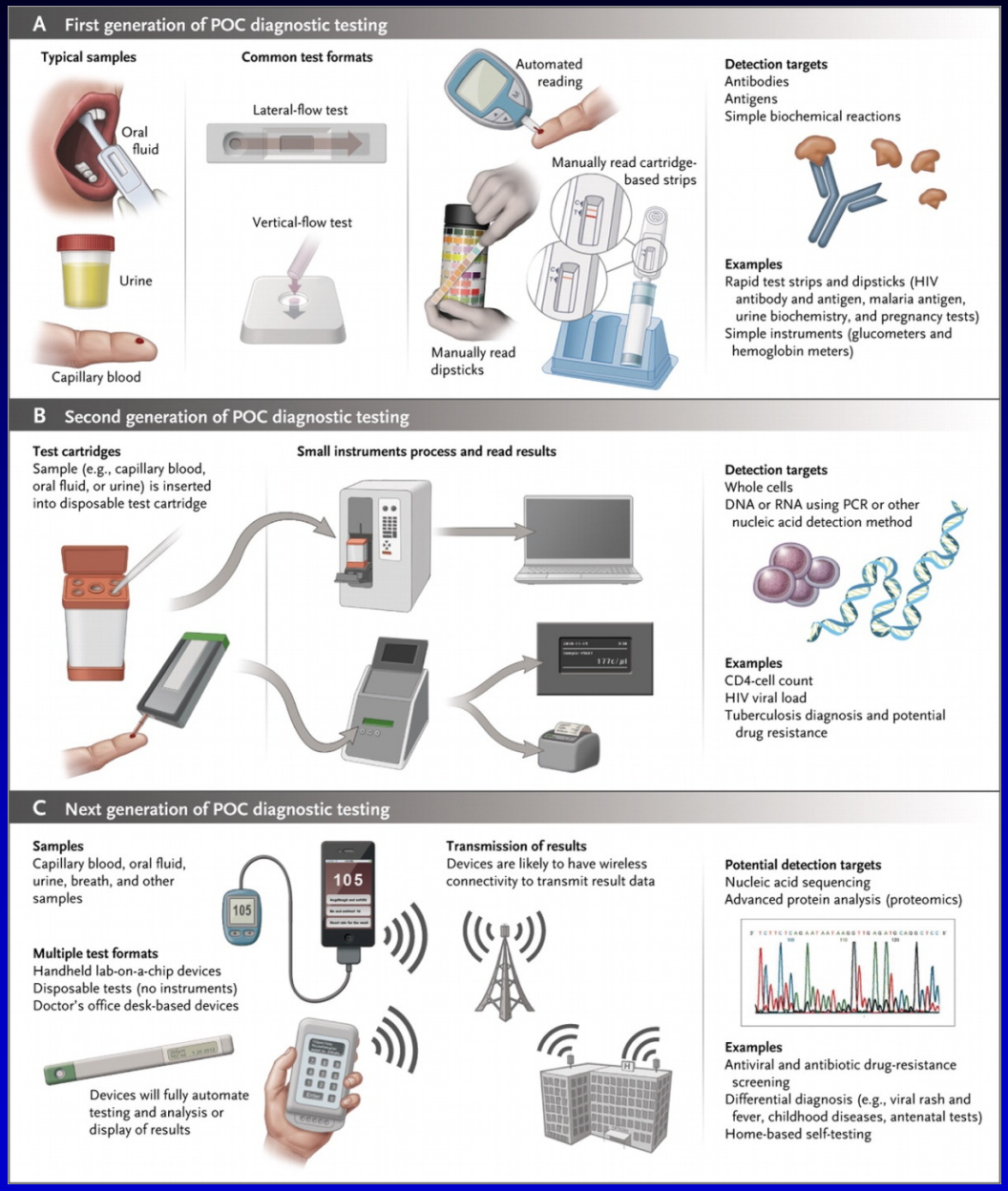
Point-of-Care and Global Health



Jani V. Ilesh, June 13, 2013 N. Engl J Med

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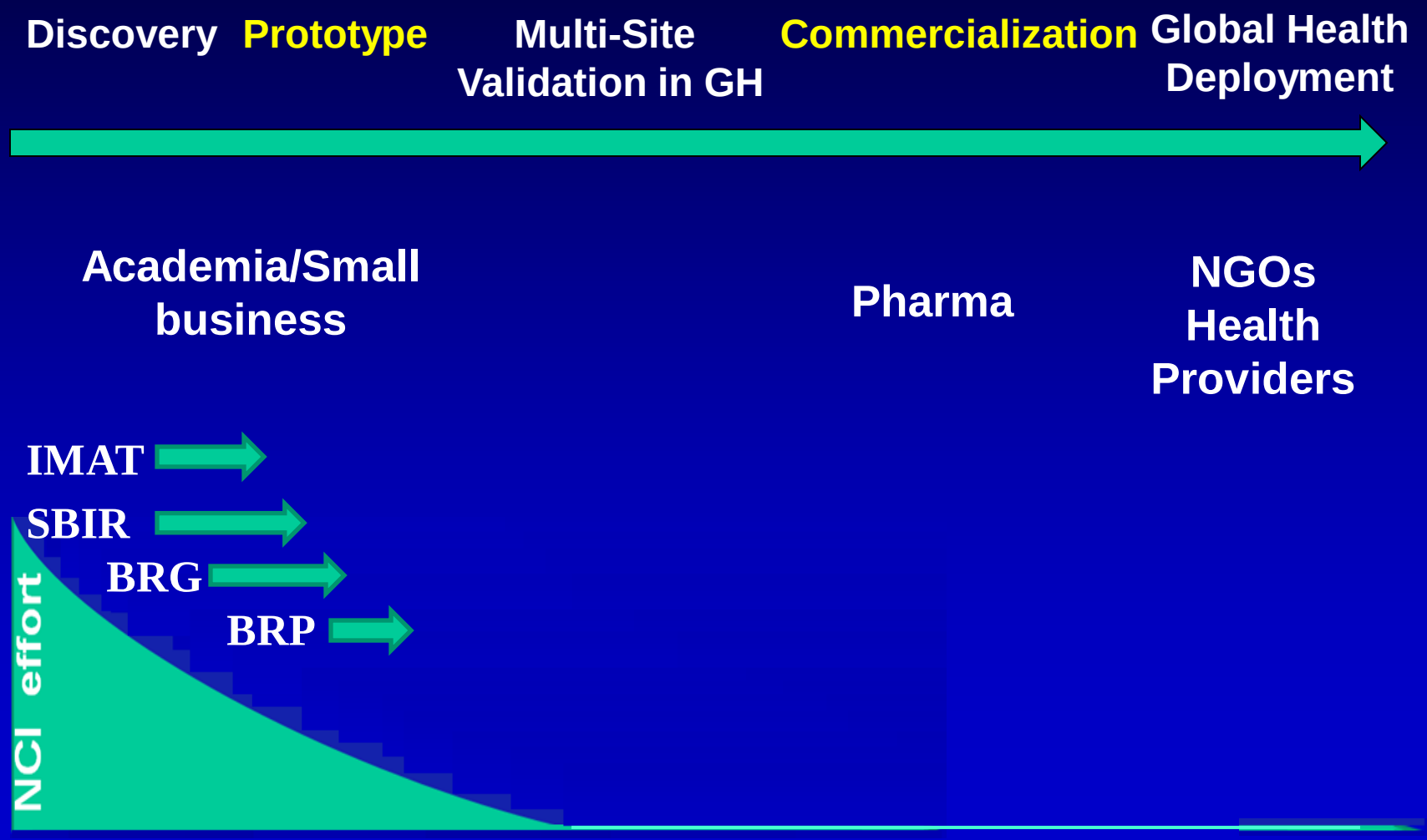
Technology Development Pipeline



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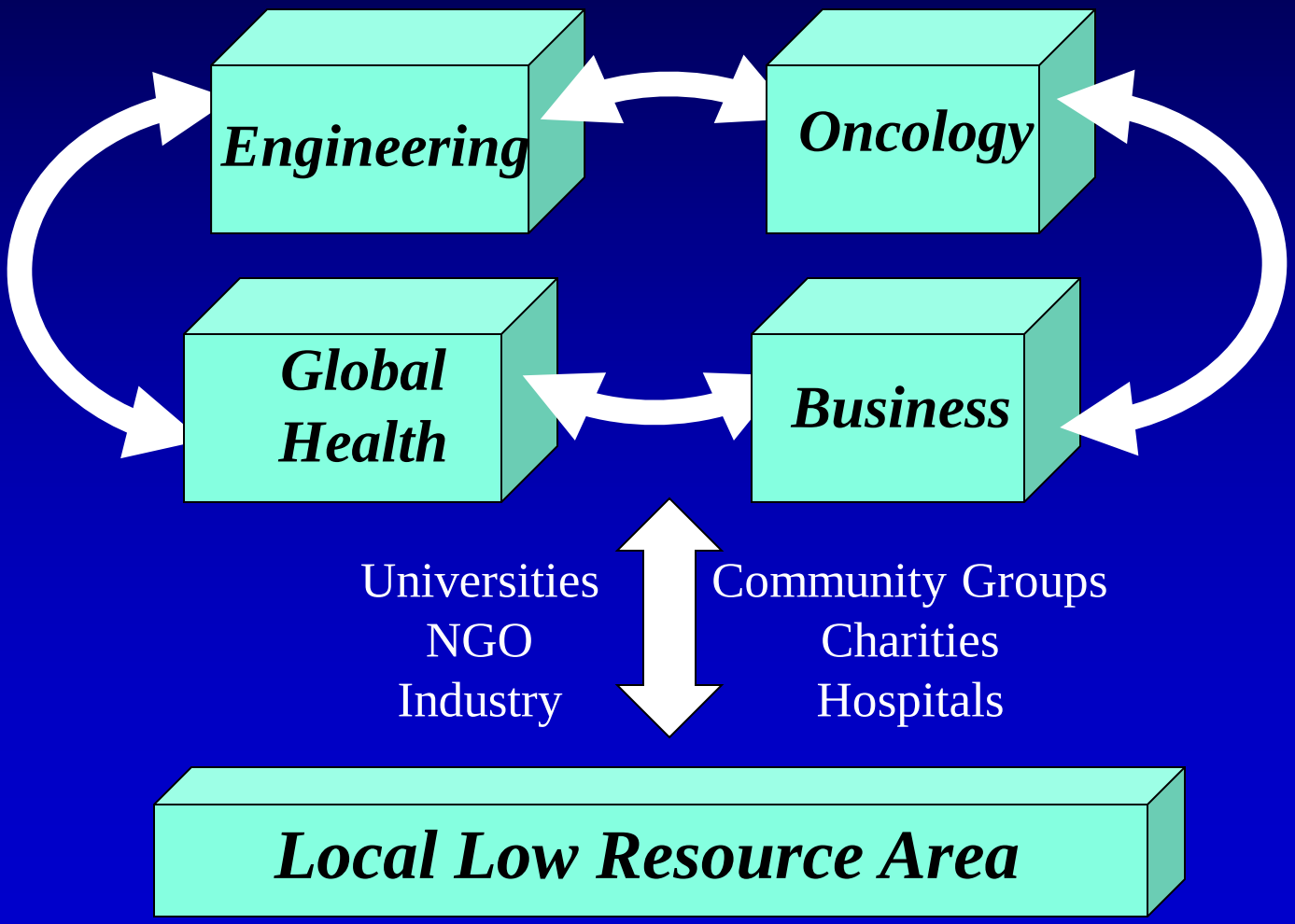
Approach

This approach establishes a strategic alliance between engineers/developers, cancer care professionals, experts in global health delivery, and business. They must assemble a critical mass of expertise to accomplish what they cannot readily do separately.



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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
- 18 grants funded over three years

Phase II (UH3), three years:

- Validate device in global health setting
- $1M per grant per year
- 50% of Phase I grants advance to Phase II (9 grants)

Progression from UH2 to UH3:

- Grantee must meet specified milestones
- Milestones reviewed by NCI program staff.

Deliverables for Phase I (UH2)

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

Deliverables for Phase II (UH3)

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

Budget anticipating 50% of Phase I awards advancing to Phase II

The RFA is issued over three years, with six Phase I awards anticipated each year; $500K total cost per award per year. The budget profiles are as follows:

Year	Cost 1st set of awards in millions (6 awards, $500K each)	Cost 2nd set of awards in millions (6 awards, $500K each)	Cost 3rd set of awards in millions (6 awards, $500K each)	Total Dollar Amount per year in millions
1	(UH2) $3M			3
2	(UH2) $3M	(UH2) $3M		6
3	(UH3) $3M (3 awards phase II, $1M each)	(UH2) $3M	(UH2) $3M	9
4	(UH3) $3M	(UH3) $3M (3 awards phase II, $1M each)	(UH2) $3M	9
5	(UH3) $3M	(UH3) $3M	(UH3) $3M (3 awards phase II, $1M each)	9
6		(UH3) $3M	(UH3) $3M	6
7			(UH3) $3M	3

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Funding Opportunity Summary

Mechanism	UH2/UH3 Cooperative Agreement
Number of awards	18 awards
Length of the awards	5 years
Set Aside for first year	$3 million total cost
Total cost	$45 million

Project Organization and Management

- RFA with central coordination by Center for Global Health.
- UH2/UH3: Program oversight for effective project coordination.
- Steering Committee of Principal Investigators and NCI personnel.
- DOC program directors manage individual awards.