



Global Landscape of IVDs

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Diagnostics Landscape in the Developing World

- **Lack of access**

Although high-quality diagnostics are available for many infectious diseases, they are neither affordable nor accessible to patients in the developing world

- **Lack of regulatory oversight**

Tests are often sold and used without evidence of effectiveness, discouraging companies with quality products from competing

- **Lack of quality standards for test evaluations**

Claimed accuracy on product inserts often misleading

- **Lack of investment**

Little industry interest in developing quality diagnostics for diseases prevalent in the developing world, due to a perceived lack of return for investment. Fragmented landscape, no coordination.

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Affordable Access to Diagnostics

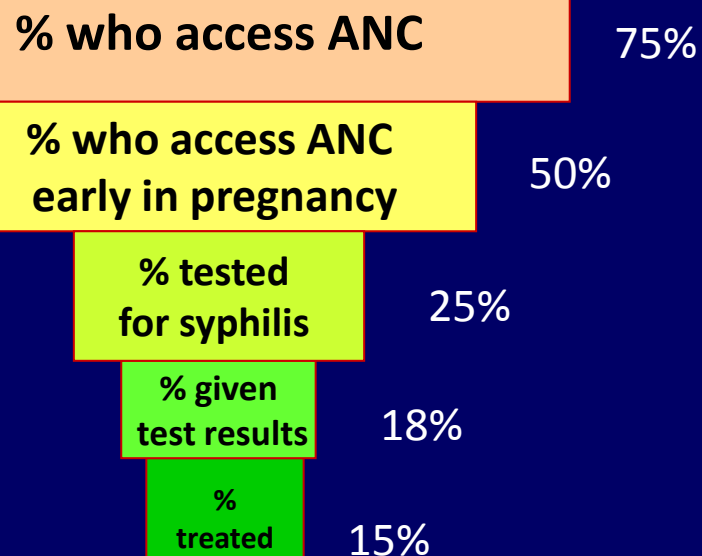
The 2004 Health Development Report cited the lack of access and unaffordability as two major reasons why services fail

Distance to Nearest Medical Facility for the Poorest 5th of the population:

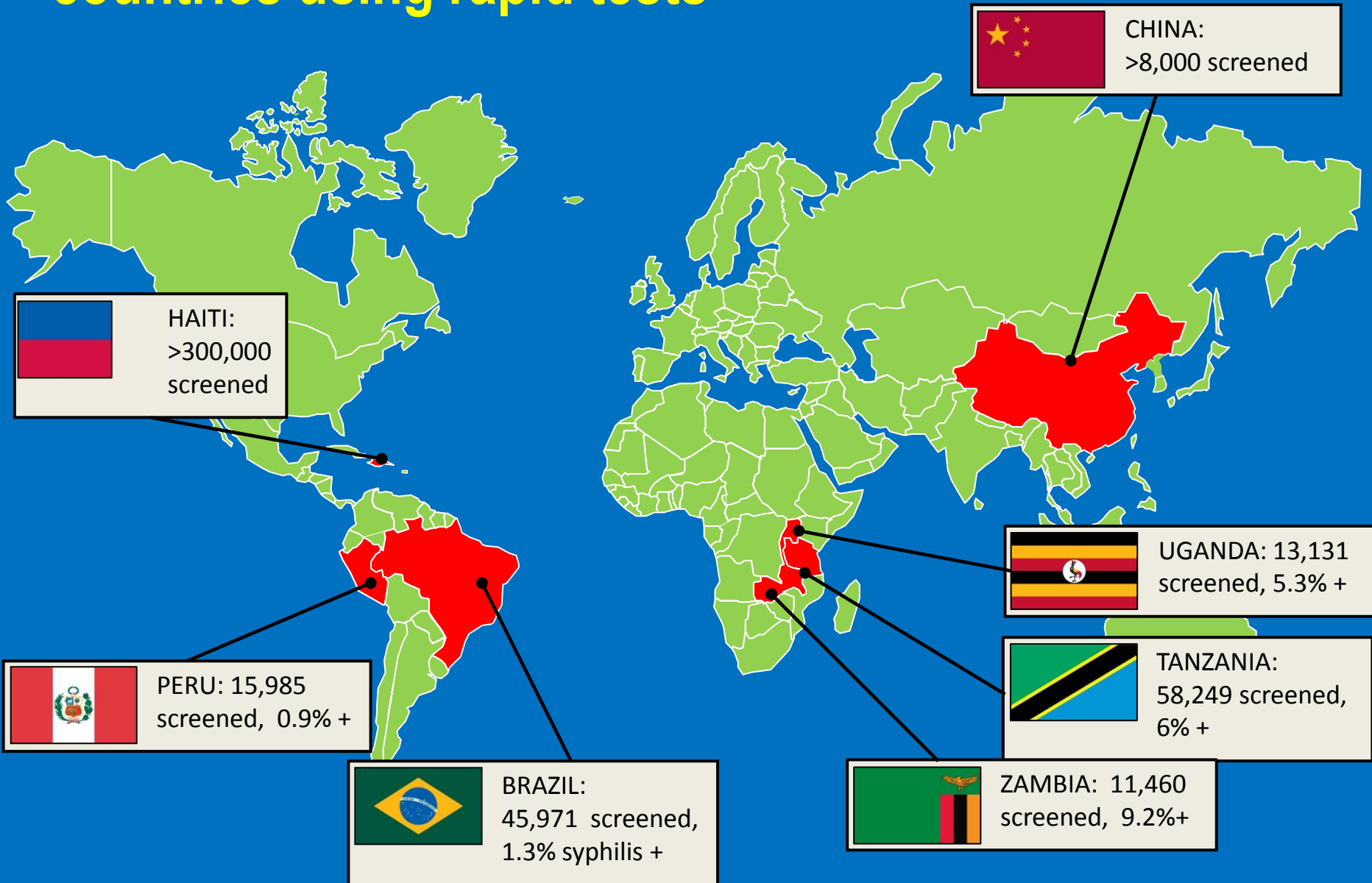
<u>Country</u>	<u>Distance (km)</u>
Benin	7.5
Bolivia	11.8
Chad	22.9
Haiti	8.0
Madagascar	15.5
Niger	26.9
Tanzania	4.7
Uganda	4.7
Zimbabwe	8.6

Selected from the 2004 World Health Report, p.22

Pregnant women with syphilis



> 440,000 screened for syphilis in 7 countries using rapid tests



Screening for HIV and Syphilis in Amazonas, Brazil



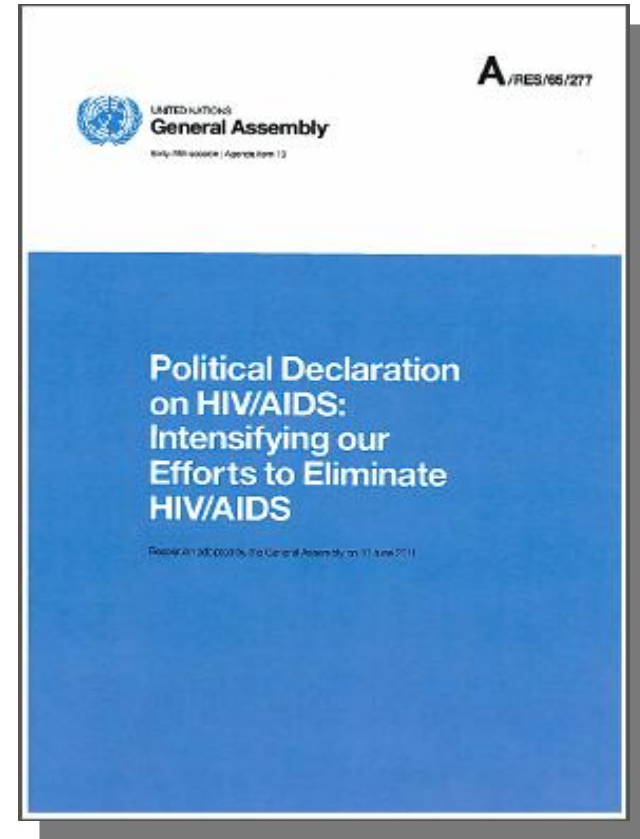
Rapid Test Project in Brazil





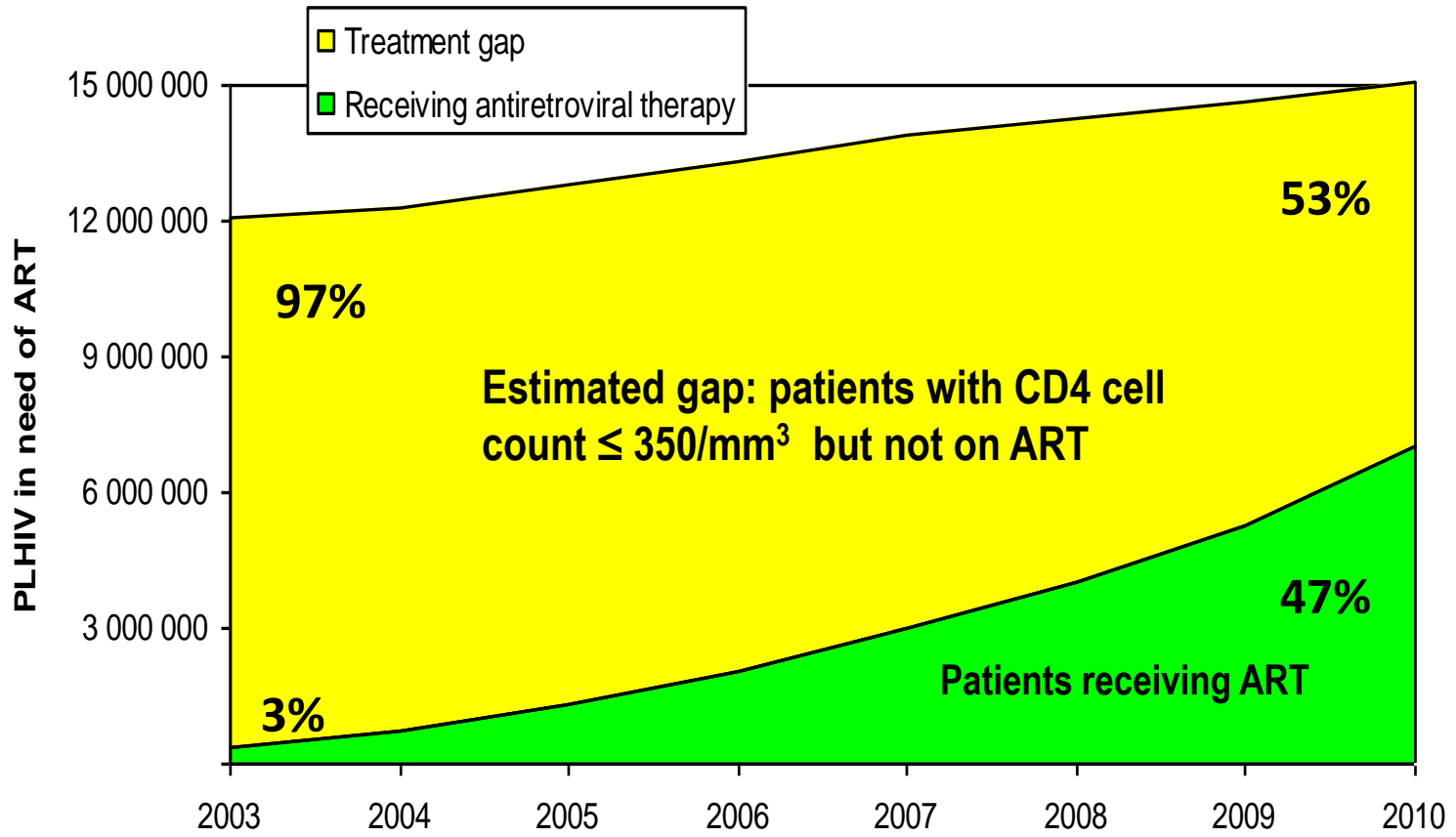
HIV/AIDS Global Targets

- **Place 15 million people on ART**
- Reduce TB deaths among PLHIV by 50%
- Eliminate new HIV infections in children
- Intensify HIV prevention

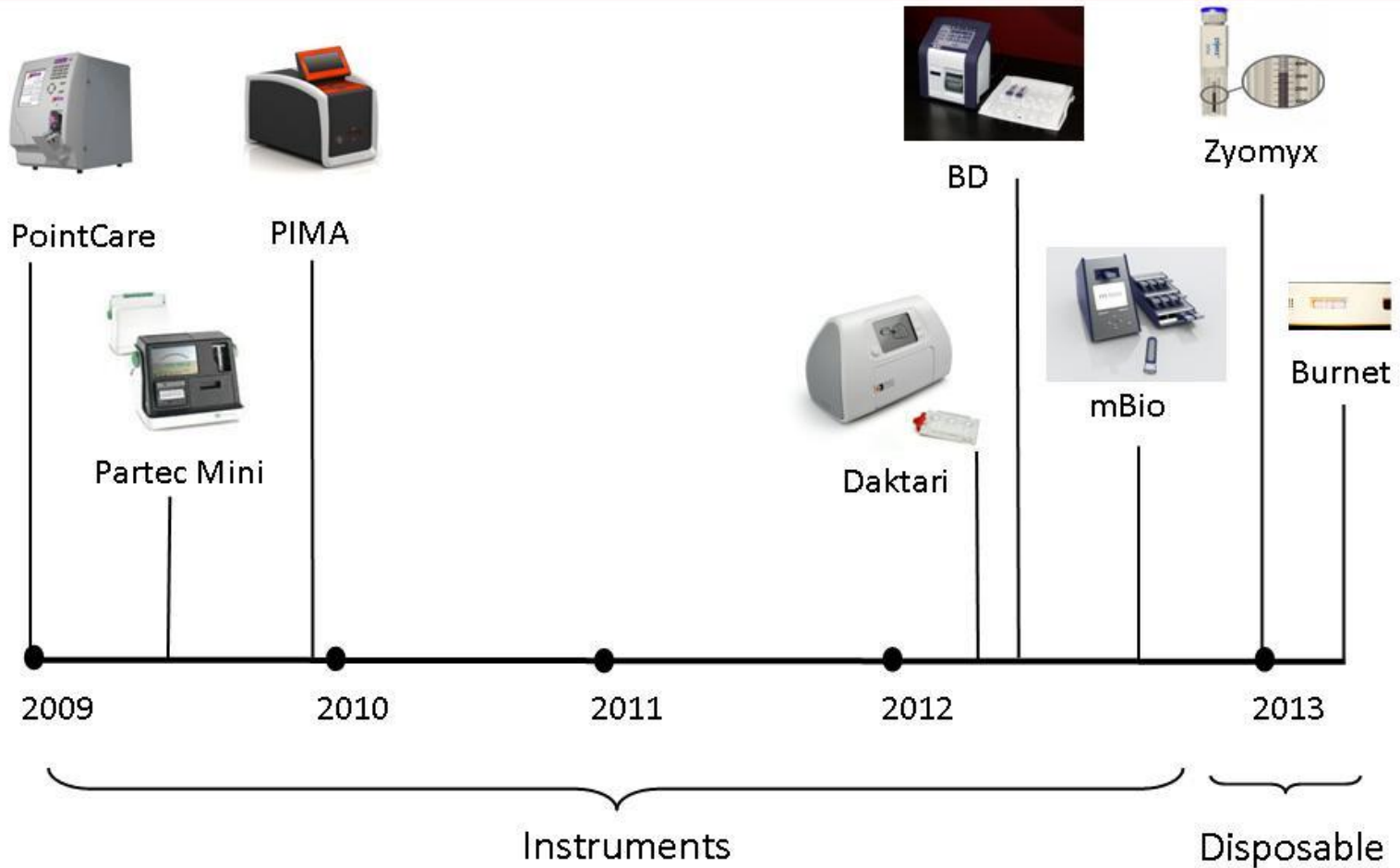


Investments of at least US\$ 22 billion are needed by 2015

Progress of estimated ART coverage in low- and middle-income countries (2003-2010)

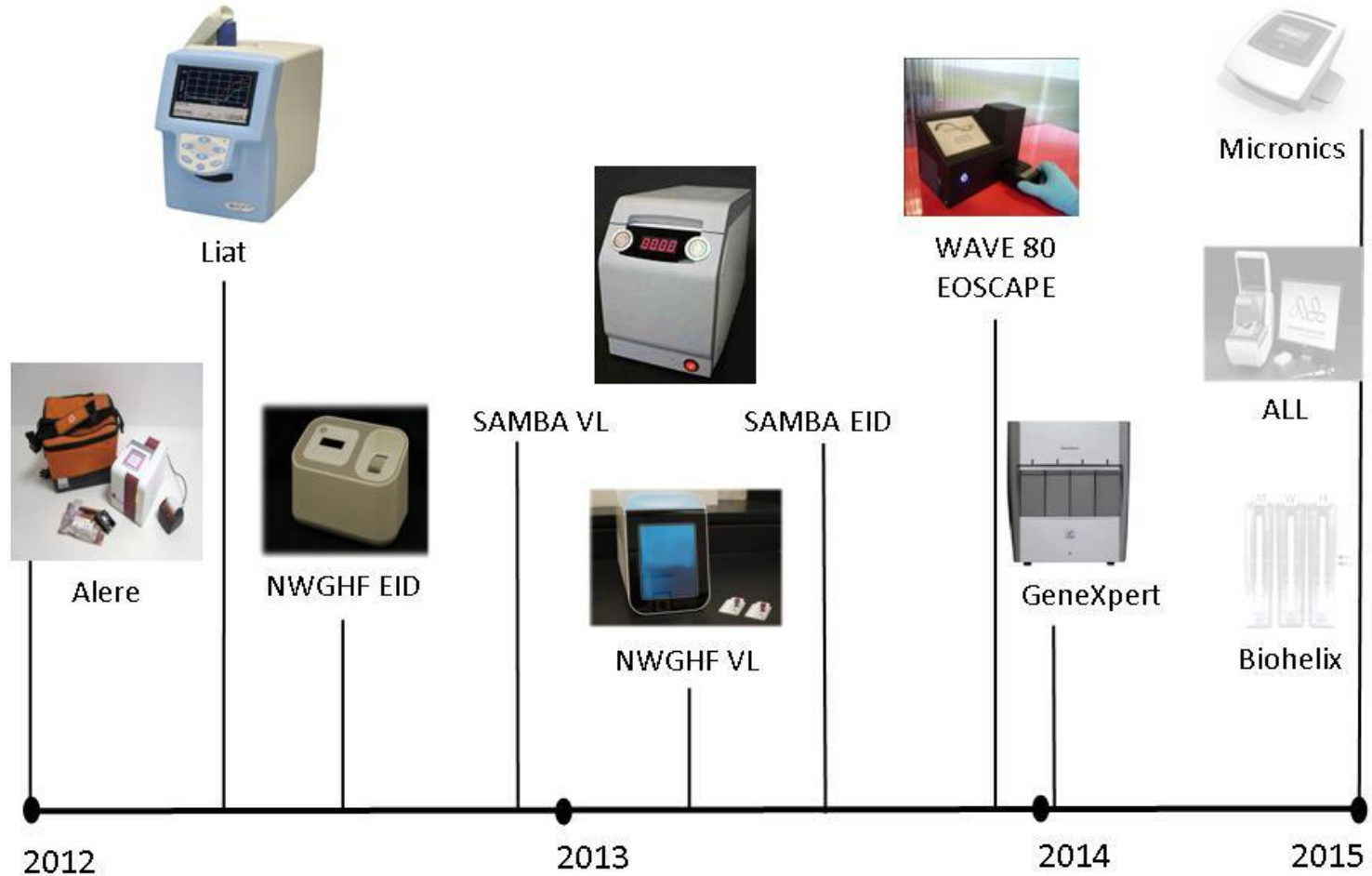


Point-of-Care CD4 Technologies in the Pipeline*



*Estimated; timeline and sequence may change.

Point-of-Care Viral Load and EID Technologies in the Pipeline*



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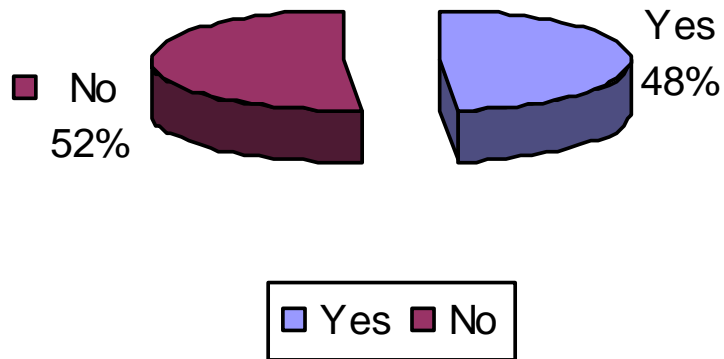
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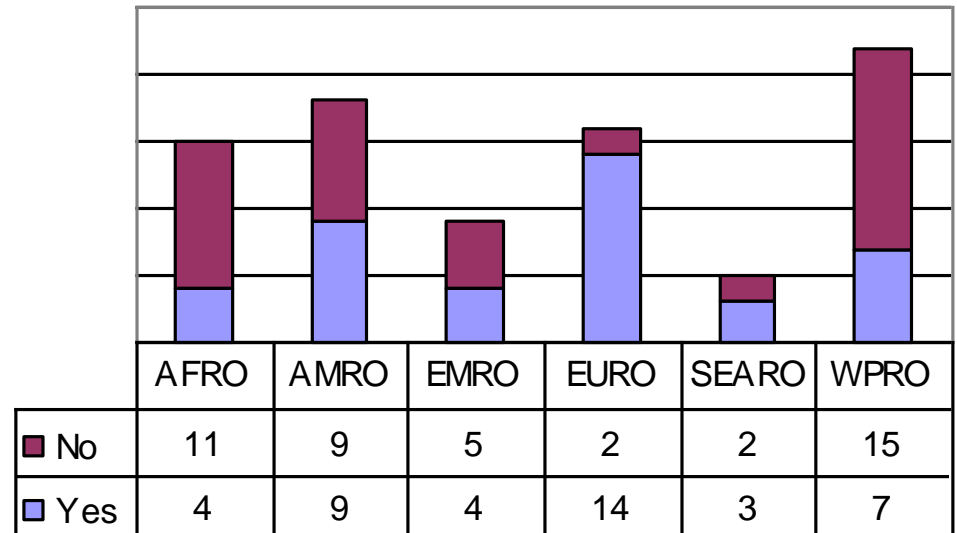
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Lack of Regulatory Oversight for Diagnostics

In Vitro Diagnostic Devices Regulated



In Vitro Diagnostic Devices Regulation By Region



WHO/TDR survey 2002

Regulation of In-vitro Diagnostics: Top 10 Challenges

- 1. Regulatory landscape highly variable**
- 2. Approval process lengthy, especially for imported tests**
- 3. Path to approval is not transparent**
- 4. Most approval process lack quality standards**
- 5. Clinical trials often not required or lack rigour**
- 6. Limited success with standardisation and harmonization in spite of global efforts**
- 7. Tests are sold and used in the developing world without evidence of effectiveness**
- 8. Companies with quality tests unable or unwilling to compete in market flooded with low quality tests**
- 9. Cost of regulatory approval pass onto end-users**
- 10. Companies often do not bother registering in small countries or countries with small markets because of lack of return for investment**

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Performance of Dengue IgM Rapid Tests

Manufacturers' claims

Test	Accuracy (%)	
	Sens	Spec
Core	100	100
Diazyme	NS	NS
Globalemed	80	>99
Minerva	NS	NS
PanBio	70	100
Standard	93	100
Tulip	100	100

WHO evaluation

Accuracy (%)	
Sens	Spec
23	99
18	98
63	69
9	100
65	98
22	99
6	99

NS = not stated

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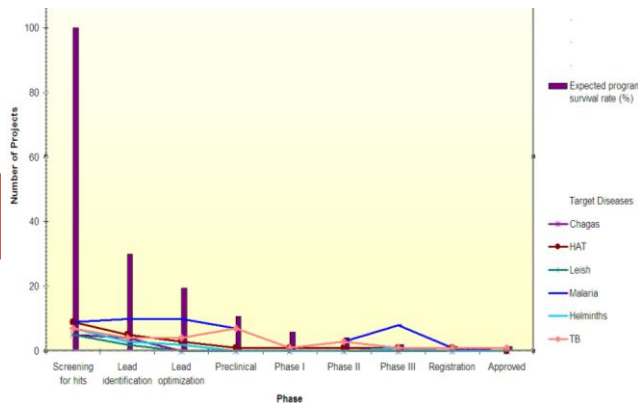
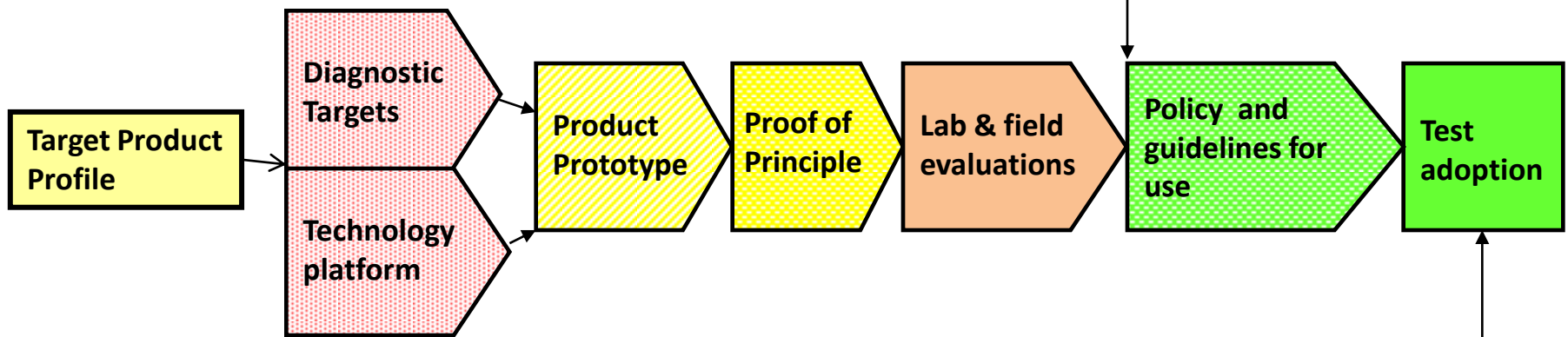
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Bench-to-Bedside Pathway for Diagnostics R&D: Fragmented Landscape, Lack of Coordination & Synergy

R & D: 2-10 years; \$ 10-100 million

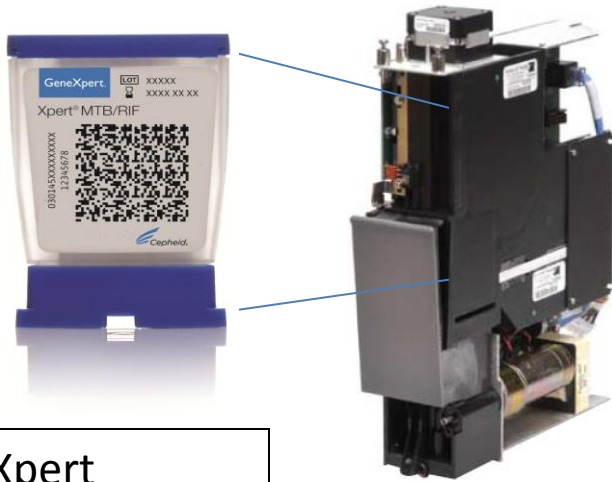
Regulatory Approval: 2-5 years



Valley of Death:

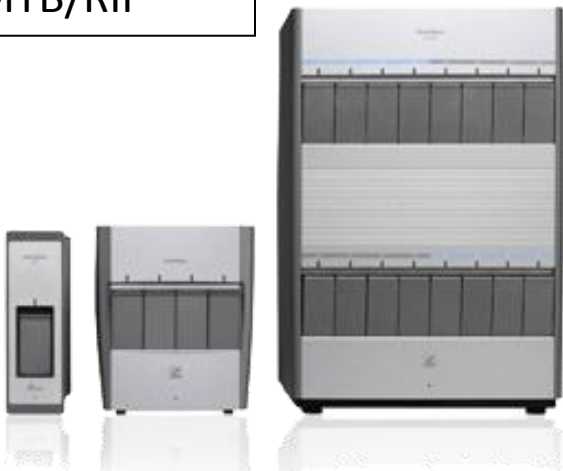
Policy & Uptake 5-7 years

GeneXpert: A multi-disease, Random Access Platform based on Real-time PCR



Xpert
MTB/RIF

MTB/RIF
CT/Ng
HIV Viral Load



5 20 80 Samples per shift 500-1000

How many TB patients will die waiting for an affordable and effective diagnostic test?

WHO estimates:

- 9.27 million new cases in 2007
- **1.8 million deaths a year**
- Up to 50 million are infected with drug-resistant forms of *M. tuberculosis* (MDR-TB)

What is on the Horizon?



Competition Details

Media

Blog

About



Science ~~fiction~~ *reality* in the palm of your hand

Just announced: A \$10 million competition to empower your own healthcare.



- capture key health metrics and diagnose 15 diseases
- Maximum weight 2.2 kg

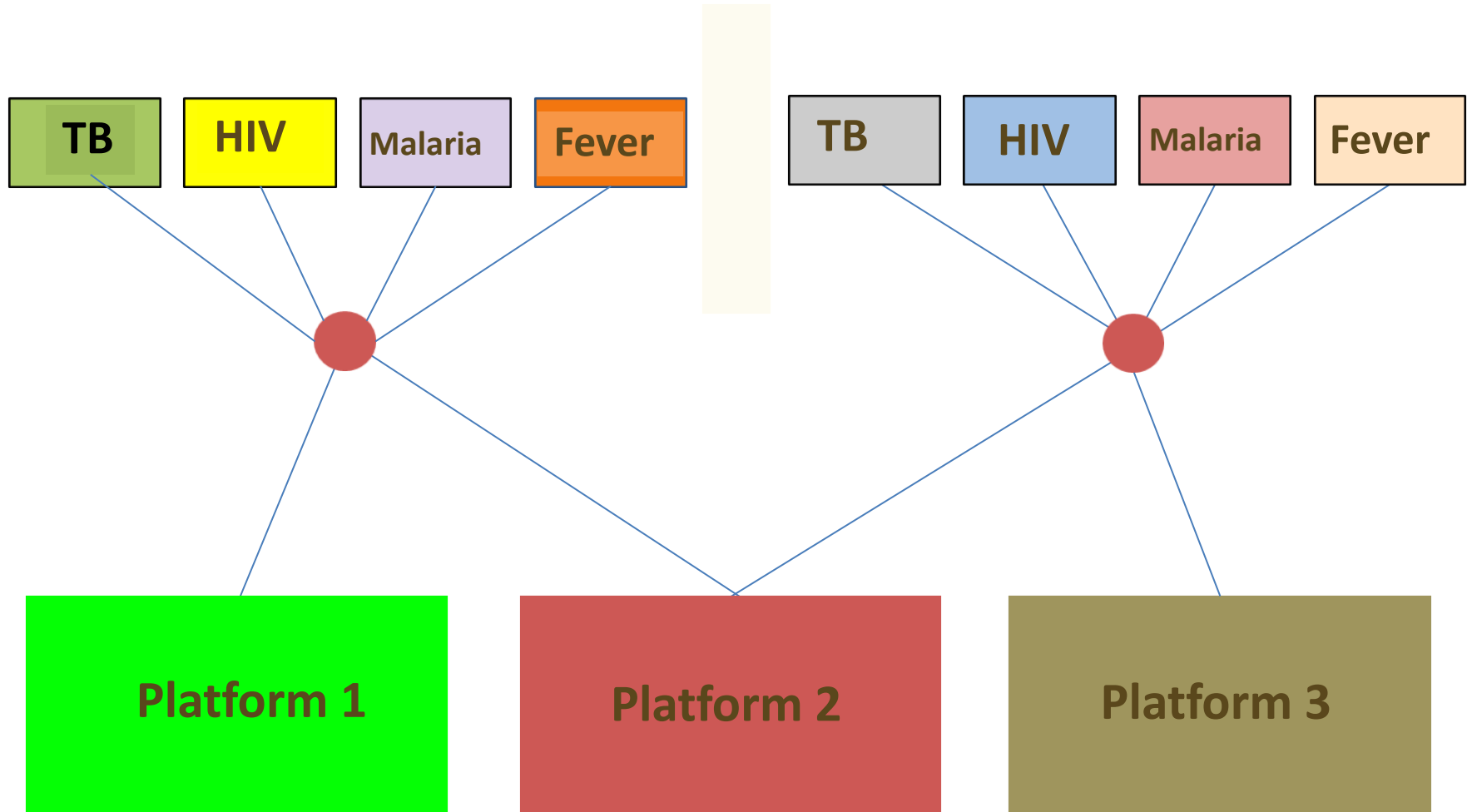


POC Dx Initiative Goals

- **Develop an open point of care instrument platform capable of delivering optimum performance**
- **Establish interoperability standards to encourage menu expansion by competing companies/sources**
- **Reduce barriers to entry into global health markets by eliminating the need for expensive instrument development**
- **Achieve a harmonized regulatory environment**

Bill & Melinda Gates Foundation- Grand Challenges Canada

POC DX Platform Options



African Network for Drug and Diagnostic Innovation: Fostering DEC-led Product Development

● WIDELY AVAILABLE

- Basic exploratory research
- Natural products/traditional medicine
- Hit identification
- Clinical studies
- Marketing

▲ AVAILABLE

- Lead identification and optimization
- Management of intellectual property
- Regulatory expertise
- Manufacturing
- Phase IV/Pharmacovigilance

■ LIMITED AVAILABILITY:

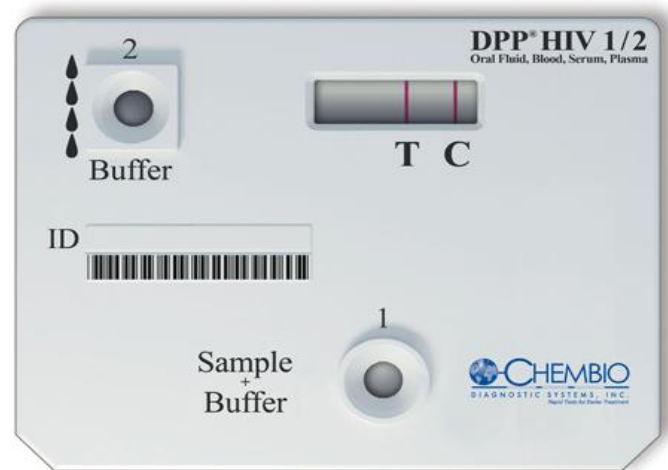
ANDI promotes:

- capacity/infrastructure building
- coordinated & result-driven effort
- leveraging existing activities
- generation & management of IP
- public-private partnership



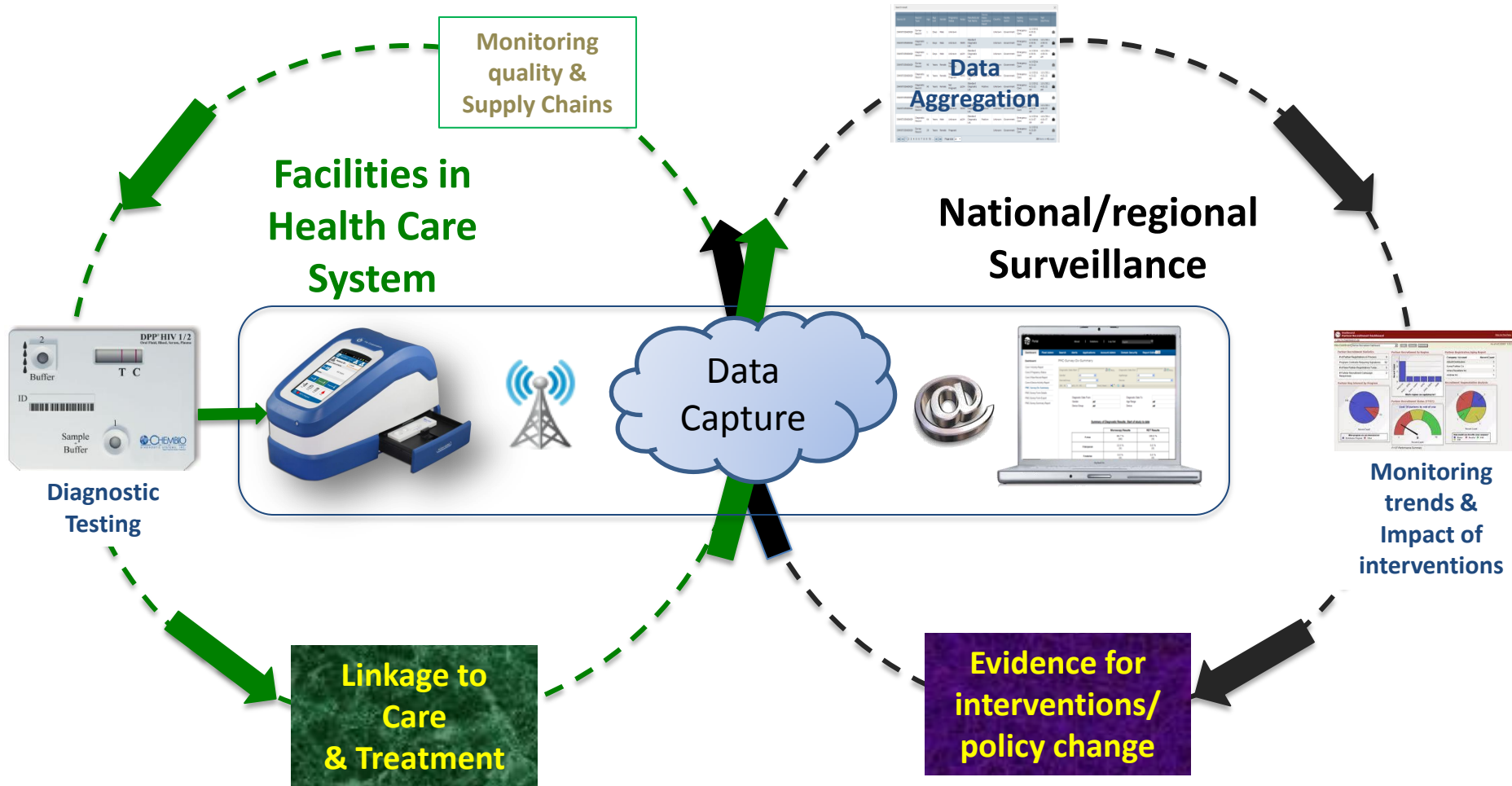
Technology Transfer and Local Production: Dual Path

Technology: HCV/HIV/Syphilis Assays

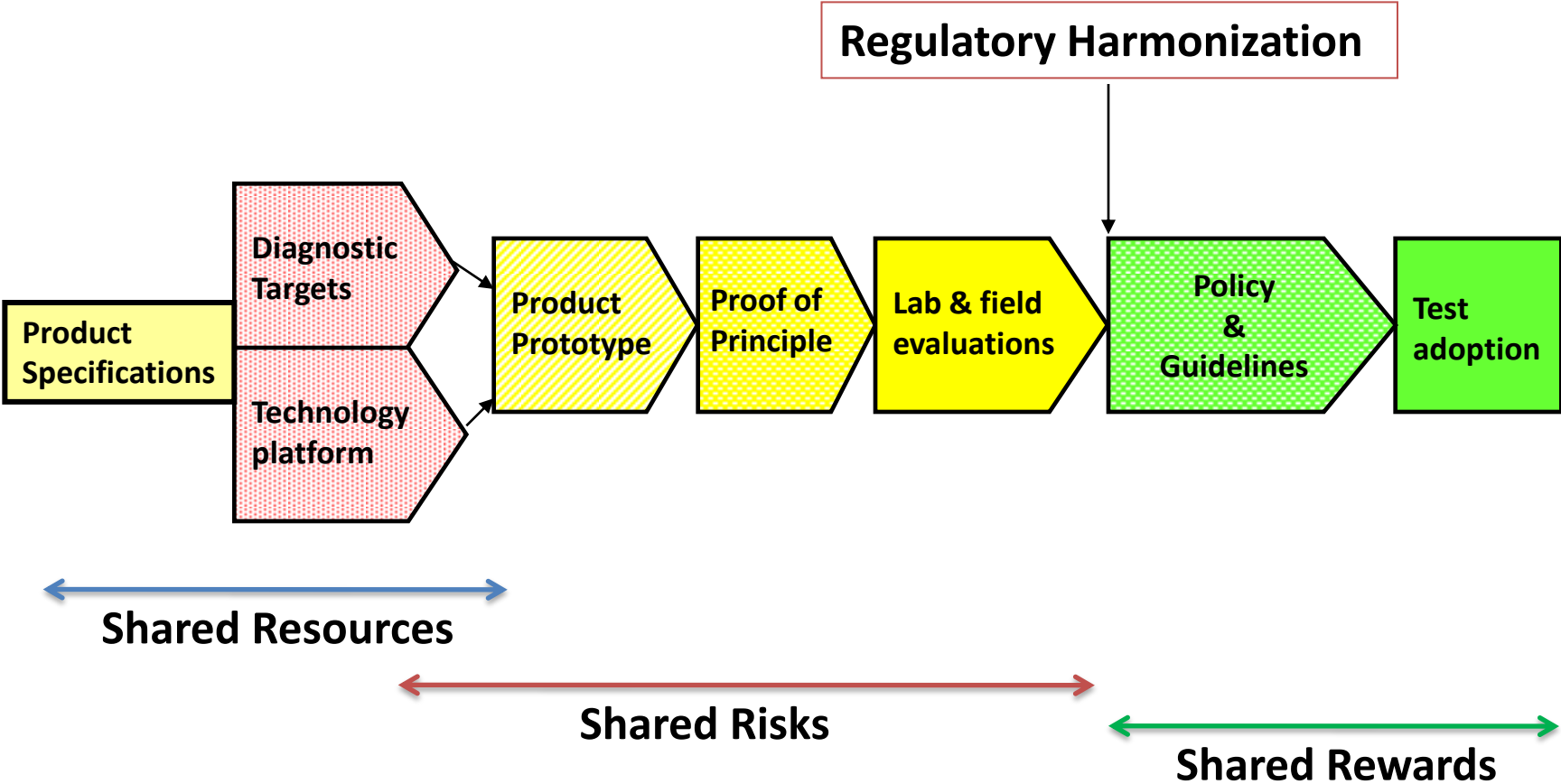


HCV, HIV and Syphilis Test

Readers: Linking POC Testing Results to Surveillance



The 3Rs of Partnerships for Affordable Access



Advanced Course in Diagnostics Annecy France, Sept 2011



Summary

- **Access to affordable IVDs are urgently needed to improve global health and save lives**
- **Need to maximize the potential of the next generation of diagnostic technologies to develop innovative models of service delivery to achieve global health targets**
- **Connectivity from diagnostic equipment/readers can link test results to central databases for surveillance and monitoring quality and supply chains**
- **Need to have a platform for communications and synergies between public private efforts at test development, to shorten time to market by streamlining and harmonizing regulatory approval processes, and to maintain quality standards of health products**

Global Health Diagnostics

Open Access Forum for:

- **Sharing information**
- **Enhancing collaboration**
- **Promoting best practice**
- **e-learning**

E-communities:

- **Discussion rooms**
- **Workspaces**

www.globalhealthdiagnostics.org

A photograph of a garden bed filled with numerous white daisies with yellow centers. The daisies are growing in a bed of dark mulch, interspersed with several large, smooth, grey rocks. In the background, there are green plants and trees. A semi-transparent white rectangular box is centered over the middle of the image, containing the text "Thank you!" in a bold, dark blue font.

Thank you!