Regional Regulatory Harmonization Working Parties for *in-vitro* Diagnostics

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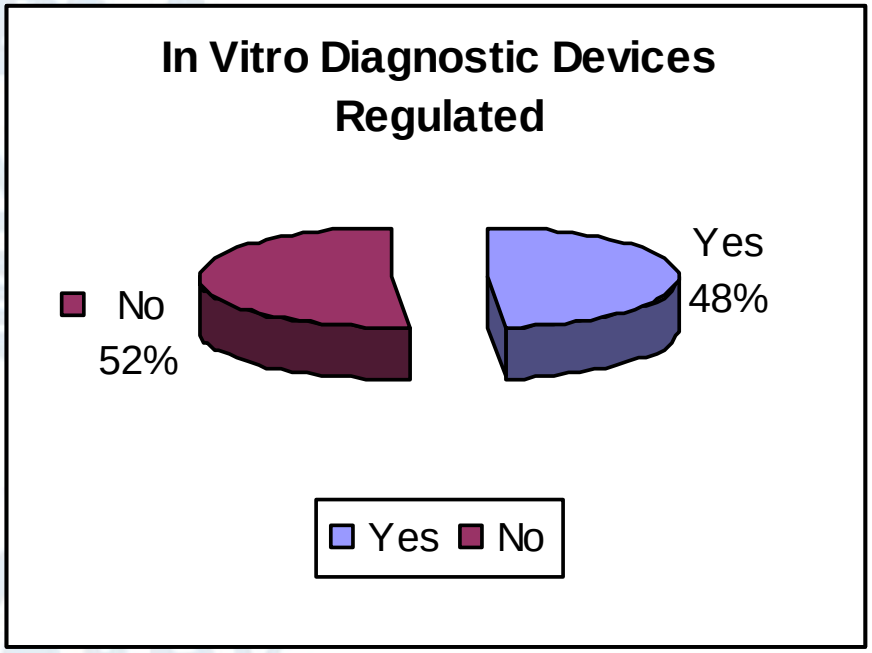
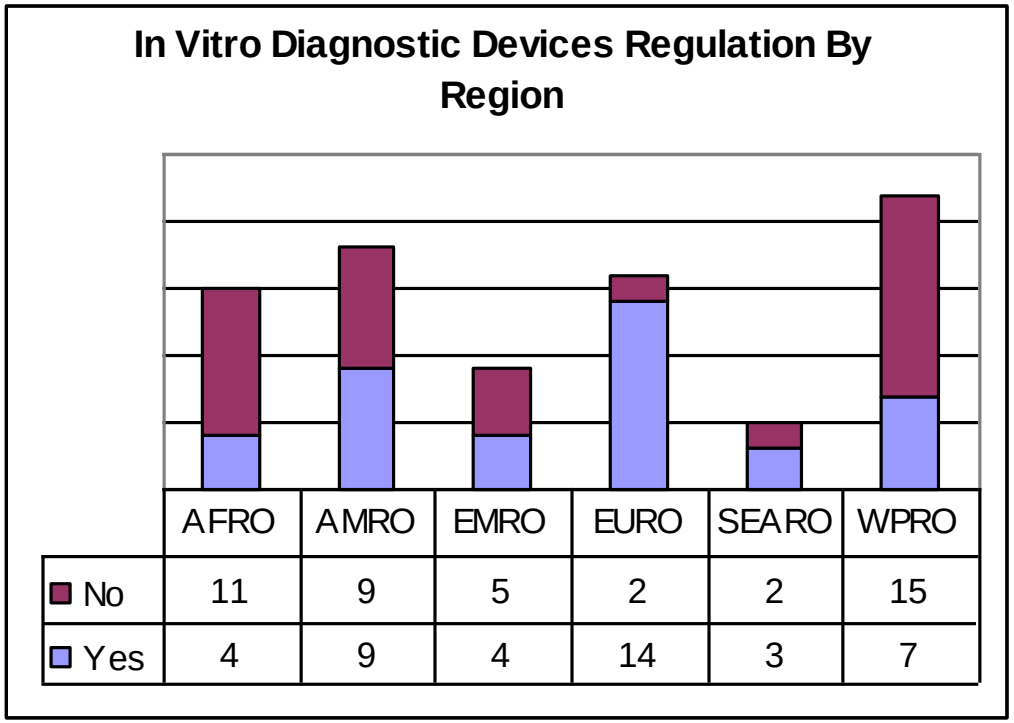
The International Diagnostics Centre
www.idx-dx.org

Regulatory Oversight of *in-vitro* Diagnostics





	AFRO	AMRO	EMRO	EURO	SEARO	WPRO
No	11	9	5	2	2	15
Yes	4	9	4	14	3	7

WHO/TDR survey 2002

Regulation of In-vitro Diagnostics in the Developing World

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1. The primary goal of regulation is to protect public health and safety
2. A regulatory system should ensure that valuable new technologies are made available to the clinical community and to patients and consumers expeditiously while preventing unsafe and ineffective devices from reaching the market
3. Regulatory decisions must be based on strong and clear science

Extracted from:
A model regulatory program for medical devices: an international guide. WHO & FDA, 2001

1. Regulatory landscape for IVDs highly variable
2. Many countries have a legal framework and policy for medical devices but lack capacity for implementation
3. The process of approval is often costly, lengthy and not transparent
4. Many IVDs are sold and used without evidence of effectiveness, leading to waste of precious resources and in some cases, wrong diagnosis

Pacific Health Summit 2012
Game Changers

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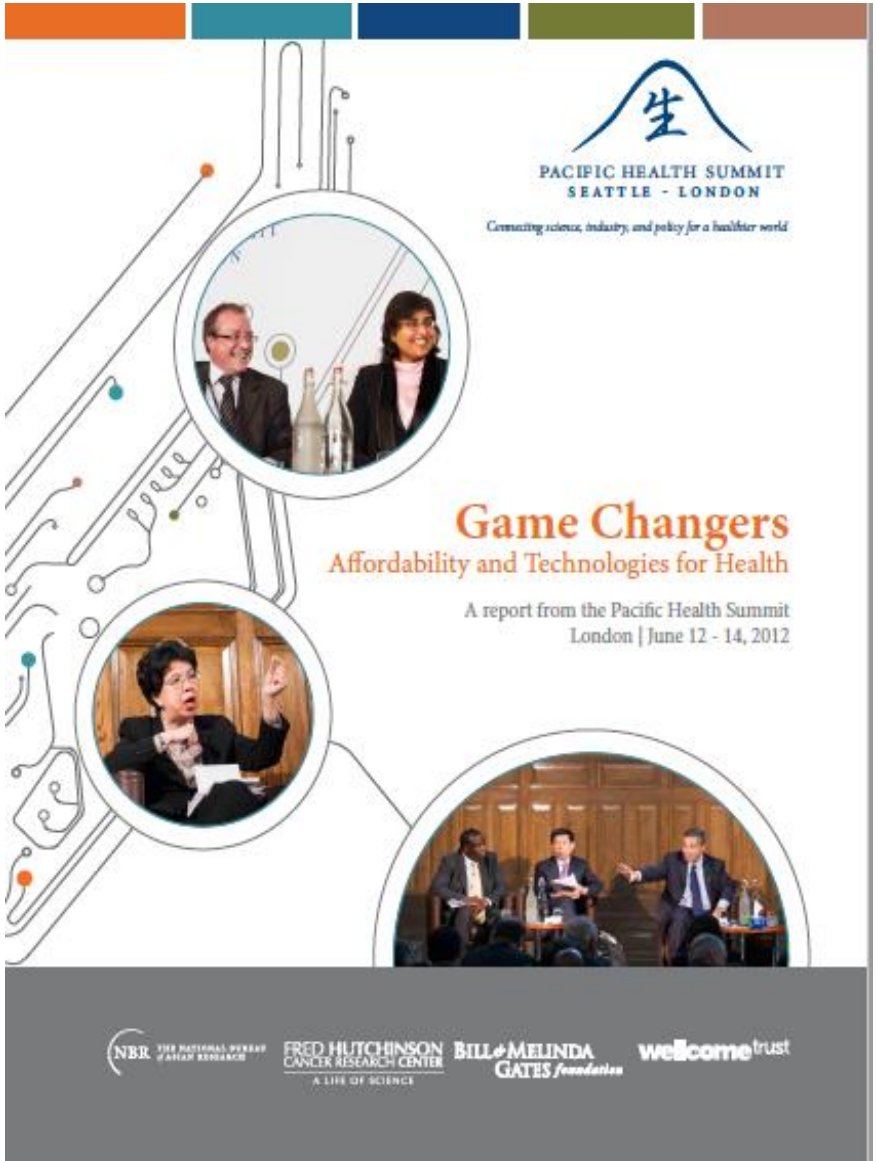

Regulation of Medical Devices: Better, Faster, Cheaper

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"HOW MANY OF YOU would travel on an airline that is not a member of the International Air Transport Association?" asked Rosanna Peeling, Professor and Chair, Diagnostics Research, London School of Hygiene and Tropical Medicine.

Regulators should add value and be a part of the quality system, not an audit system, which comes after the fact and tries to establish guilt.

Trevor Mundel, President, Global Health, Bill & Melinda Gates Foundation

East African Community (EAC)

- A regional intergovernmental organisation:





Kenya **Uganda** **Tanzania** **Rwanda** **Burundi**

- EAC was established in 1999
- **Vision:** a prosperous, competitive, secure, stable and politically united East Africa
- Launched **the EAC Medicines Registration Harmonization Project** on 30 March 2012, Arusha, Tanzania with support from New Partnerships for African Development (NEPAD), WHO, Wold Bank, BMGF, Clinton Health Access Initiative, DFID, GIZ and others.
- **EAC Secretariat initiated discussions on harmonization of diagnostics at its meeting in September 2012**

Regulation of IVDs in Africa

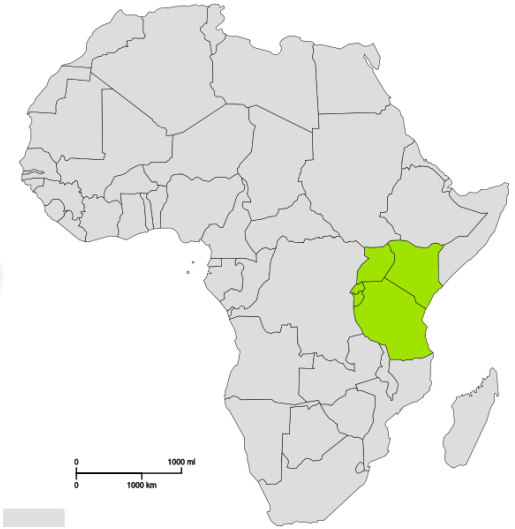
Regulations	Burundi	Kenya	Rwanda	Tanzania	Tanzania/ Zanzibar	Uganda	Ethiopia	Nigeria	South Africa
Legal framework	✓	✓	✓	✓	✓	–	✓	✓	✓
IVD regulated?	–	✓	–	✓	✓	–	✓	✓	✓
Premarket controls									
Adoption of GHTF classification	–	–	–	✓	✓	–	✓	In process	✓
Registration	–	+	–	✓	–	–	✓	✓	✓
Clinical performance Evaluation capacity	+	✓	–	✓ Limited	–	✓ HIV only	✓ Limited	–	✓
Manufacturing audit	–	–	–	–	–	–	–	–	–
Marketing controls									
Advertising control	✓	+	–	✓	–	✓	✓	✓	✓
Marketing controls	–	+	HIV, TB	✓	–	✓	✓	✓	✓
Postmarketing controls									
Surveillance	–	+	–	✓	–	–	–	–	✓
Accredited laboratories	–	✓	–	✓	–	✓	✓	–	✓
Device reporting	–	+	–	–	–	–	–	–	✓
Corrections/recall	–	+	–	–	–	–	–	–	✓

Abbreviations: GHTF, Global Harmonization Task Force; HIV, human immunodeficiency virus; IVD, in vitro diagnostics; TB, tuberculosis.

McNerney and Peeling Clin Infect Dis 2015;61(S3):S135–40

IVD Regulation in the East African Community

Country	Documents reviewed	Organisations interviewed (Number of persons)
Burundi	1	i. Ministry of Health ii. Directorate of Pharmacies, Medicines and Laboratories
Kenya	17	i. Pharmacy and Poisons Board (3) ii. National Quality Control and Medical Devices Laboratory iii. Kenya Medical Laboratory Technicians and Technologists Board (2)
Rwanda	4	
Tanzania (Mainland)	11	i. Tanzania Food and Drugs Authority (2) ii. Private Health Laboratories Board
Tanzania (Zanzibar)	6	i. Zanzibar Food and Drugs Board (2) ii. Central Medical Stores, Ministry of Health and Social Welfare iii. Chief Pharmacist, Ministry of Health and Social Welfare
Uganda	8	i. National Drug Authority (3) ii. Pharmacy Division, Ministry of Health iii. Uganda National Bureau of Standards (2) iv. Allied Health Professionals Council v. Medilab (Laboratory supplies company) vi. Central Public Health Laboratories
Total	47	16 (24)



Rugera et al. BMC Health Services Research 2014;14:524

Pan-African Harmonization Working Party

Founded in Dec 2012 to steer regulatory harmonization activities in the region in partnership with AHWP, the Latin American Diagnostic Alliance, AU, WHO and IMDRF

Founding members:

- **African Union – New Partnership for Africa's Development (AU-NEPAD)**
- **East African Community (EAC)**
- **African Society for Laboratory Medicine (ASLM)**
- **GIZ**
- **LSHTM**

PAHWP Executive:

Chair: EAC

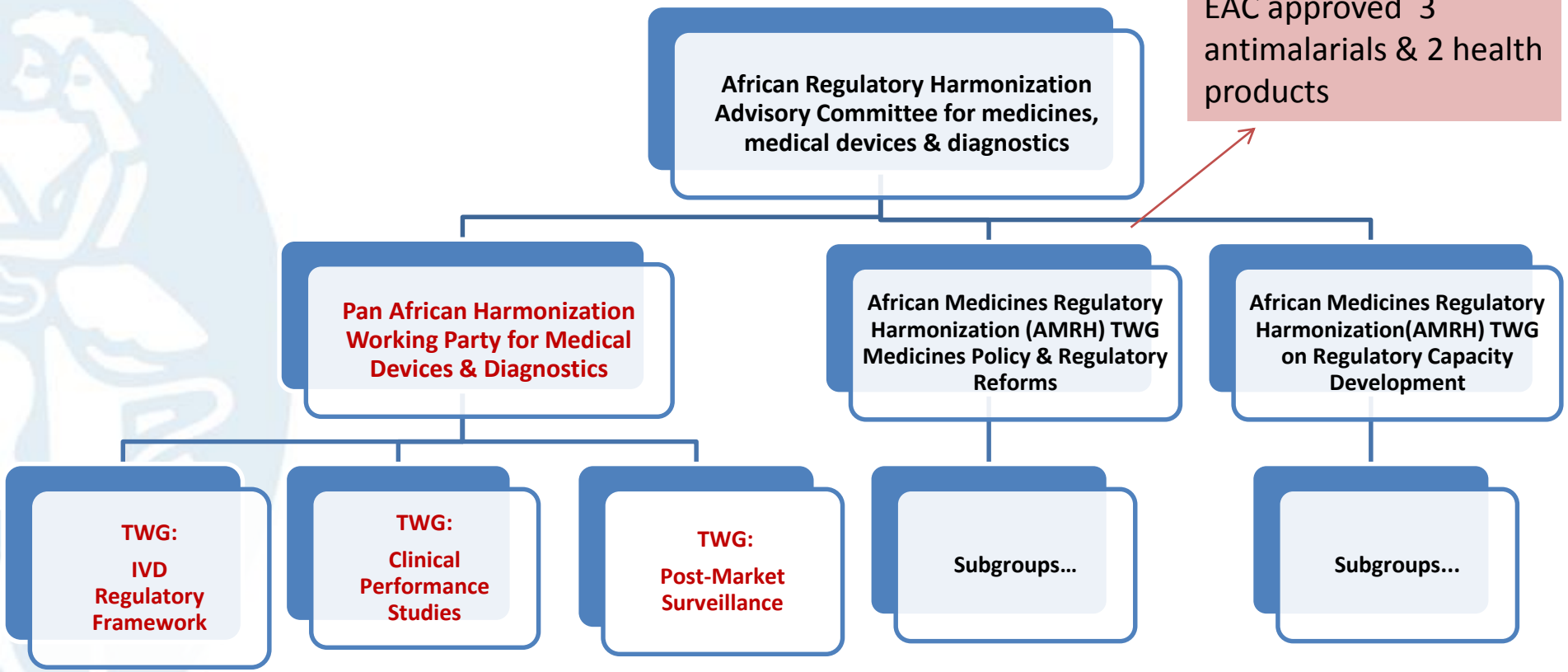
Vice-Chair: Nigeria

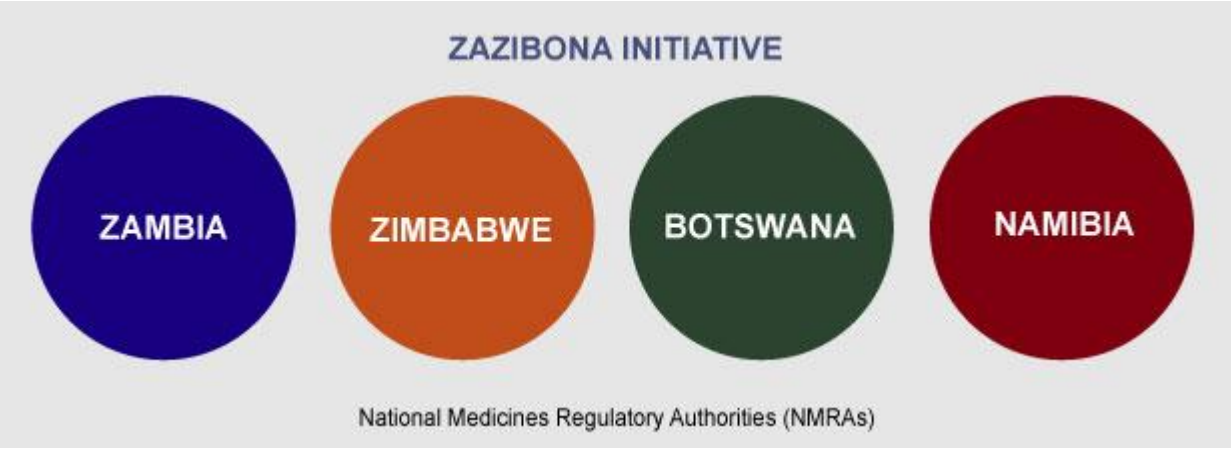
Secretariat: South Africa

3 African Regulatory Forum for Medical Diagnostics were held on July 2013, Feb and Nov 2014

2013: PAHWP is hosted within the African Union-NEPAD Agency

May 13 2014:
EAC approved 3 antimalarials & 2 health products





National Medicines Regulatory Authorities in Zambia, Zimbabwe, Botswana and Namibia, with support from WHO-PQT, have formed the ZAZIBONA initiative and undertaken ongoing pilot collaborative activities.

The 4 countries share several commonalities and face similar challenges regarding medicine regulations which created an opportunity for a mutually beneficial collaboration.

The benefits of harmonization include:

- reduction of regulatory workload
- accelerated registrations of required products
- mutual trust and confidence in regulatory collaboration
- improved information sharing and networking

Advanced Course on Diagnostics, Annecy, France, September 2012

Rosanna Peeling , Carlos Gouvea , Adele Benzaken, Graciela Russomando
Alain Mérieux, Patricia Velez Moller and Segundo Leon

Progress towards IVD Regulatory Harmonization 2012-4

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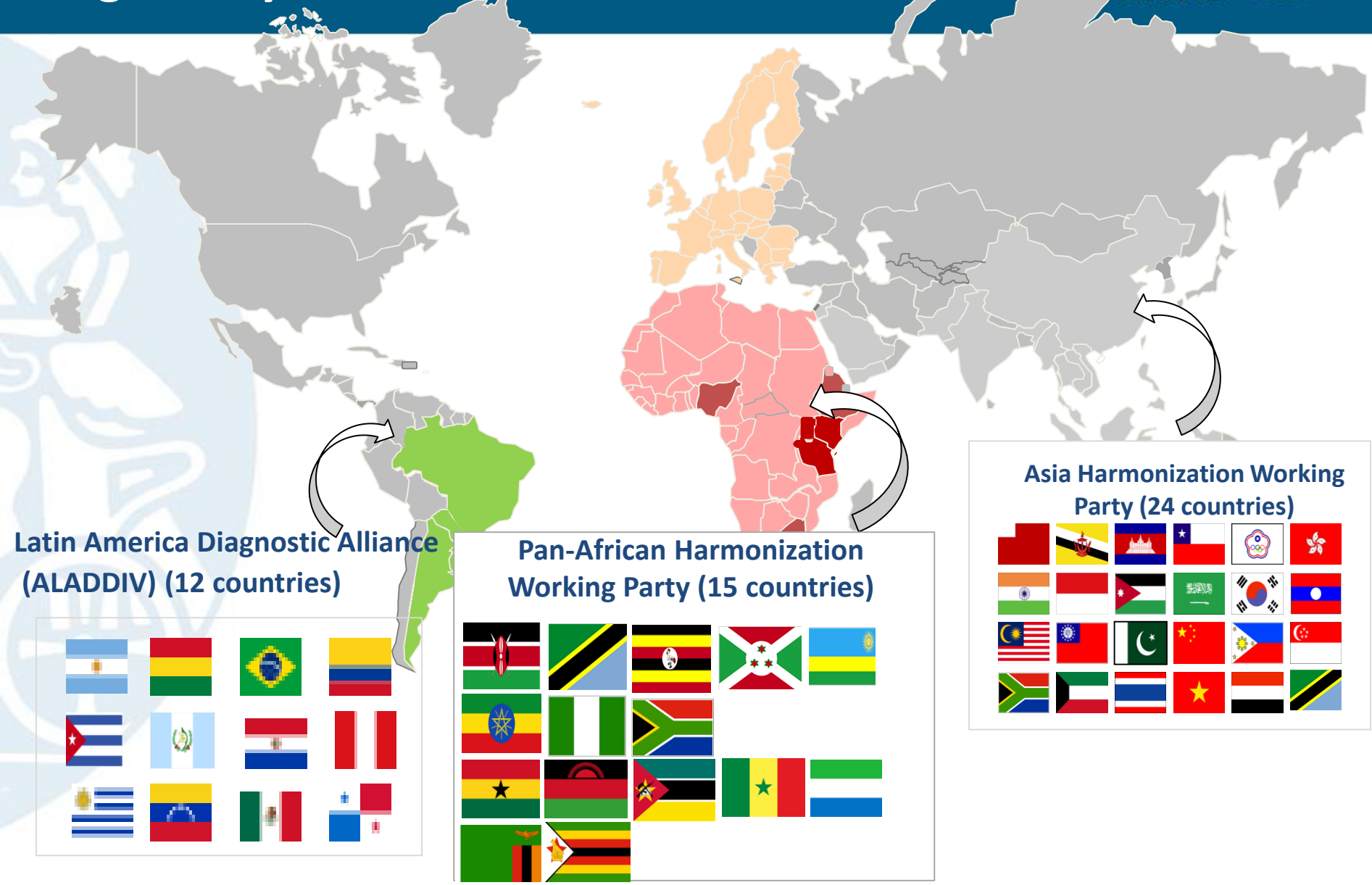

Latin America Diagnostic Alliance (ALADDIV) (12 countries)

Pan-African Harmonization Working Party (15 countries)

Asia Harmonization Working Party (24 countries)

PAHWP Updates 2015

- Membership: 15 Countries

  Kenya, Tanzania, Uganda, Rwanda, Burundi

  Ethiopia, Nigeria, South Africa

  Ghana, Malawi, Mozambique, Senegal, Sierra Leone, Zambia, Zimbabwe

- Tanzania became a member of the AHWP in Nov 2014

- Ghana, Kenya, and Zimbabwe are members of the IVD Working Group of AHWP

- PAHWP as a liaison member of ISO working group on POC devices under discussion

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Capacity Building Workshops

Training on Assessment of Clinical Performance data from HIV POC Test Evaluations in 2014

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- Basic course on qualitative assays
- Advanced course on quantitative assays

Faculty:
LSHTM
WHO PQ
Regulatory consultant

ADVANCED TRAINING WORKSHOP 20-23rd OCTOBER 2014 DAR ES SALAAM

Grand Challenges Canada™
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BOLD IDEAS FOR HUMANITY.™

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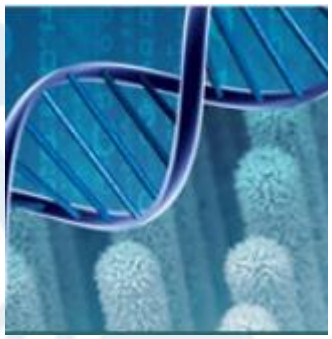
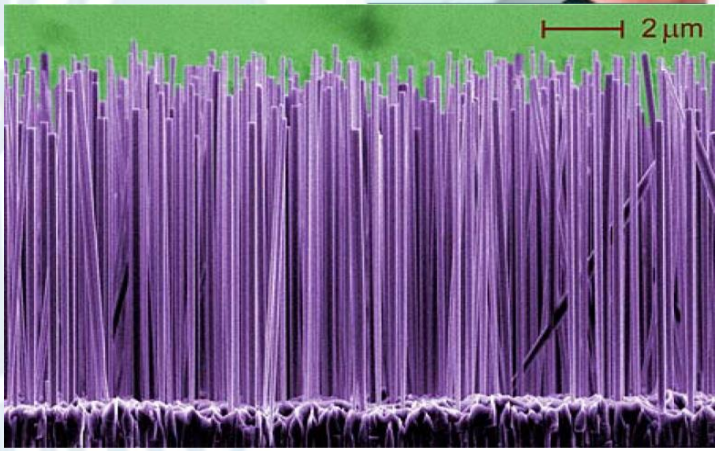
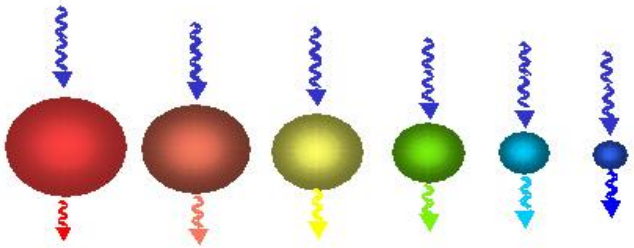
Rapid Advances in Technologies





Nanowire technology:
From a finger-pricked sample of blood,
It is possible to detect in 20 min:
- malaria parasites
- distinguish malaria species
- malaria drug resistance



Nanocrystals absorb light then re-emit the light in a different color – the size of the nanocrystal (at the Angstrom scale) determines the color

Six different quantum dot solutions are shown excited with a long wave UV lamp

Nanodot technology: can create molecular barcodes with nanodots. These barcodes can represent molecular signatures and allow the system to detect pathogens and their resistance genes or host responses such as cytokines.

Lives lost/year attributable to Antimicrobial Resistance by 2050

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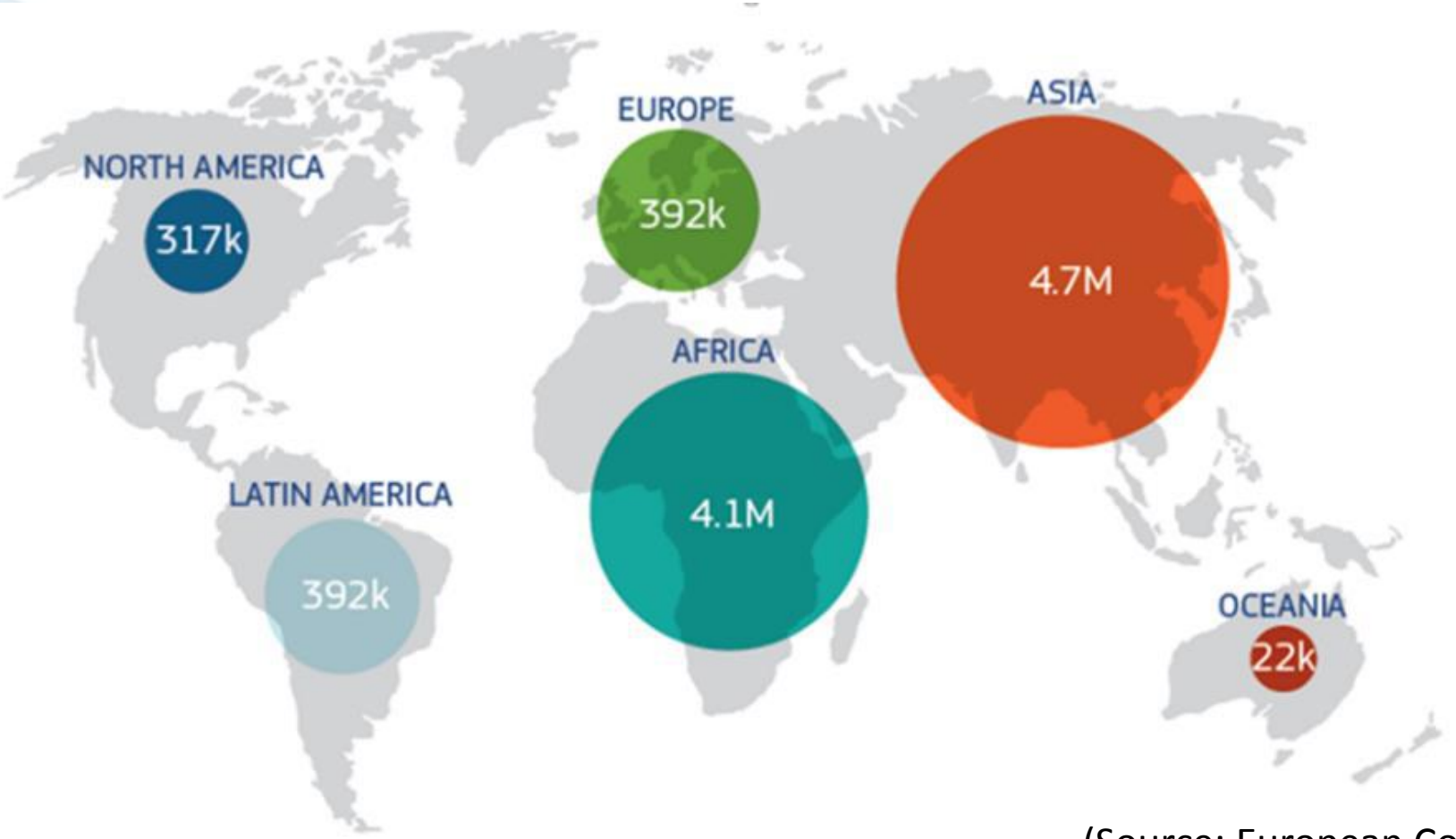
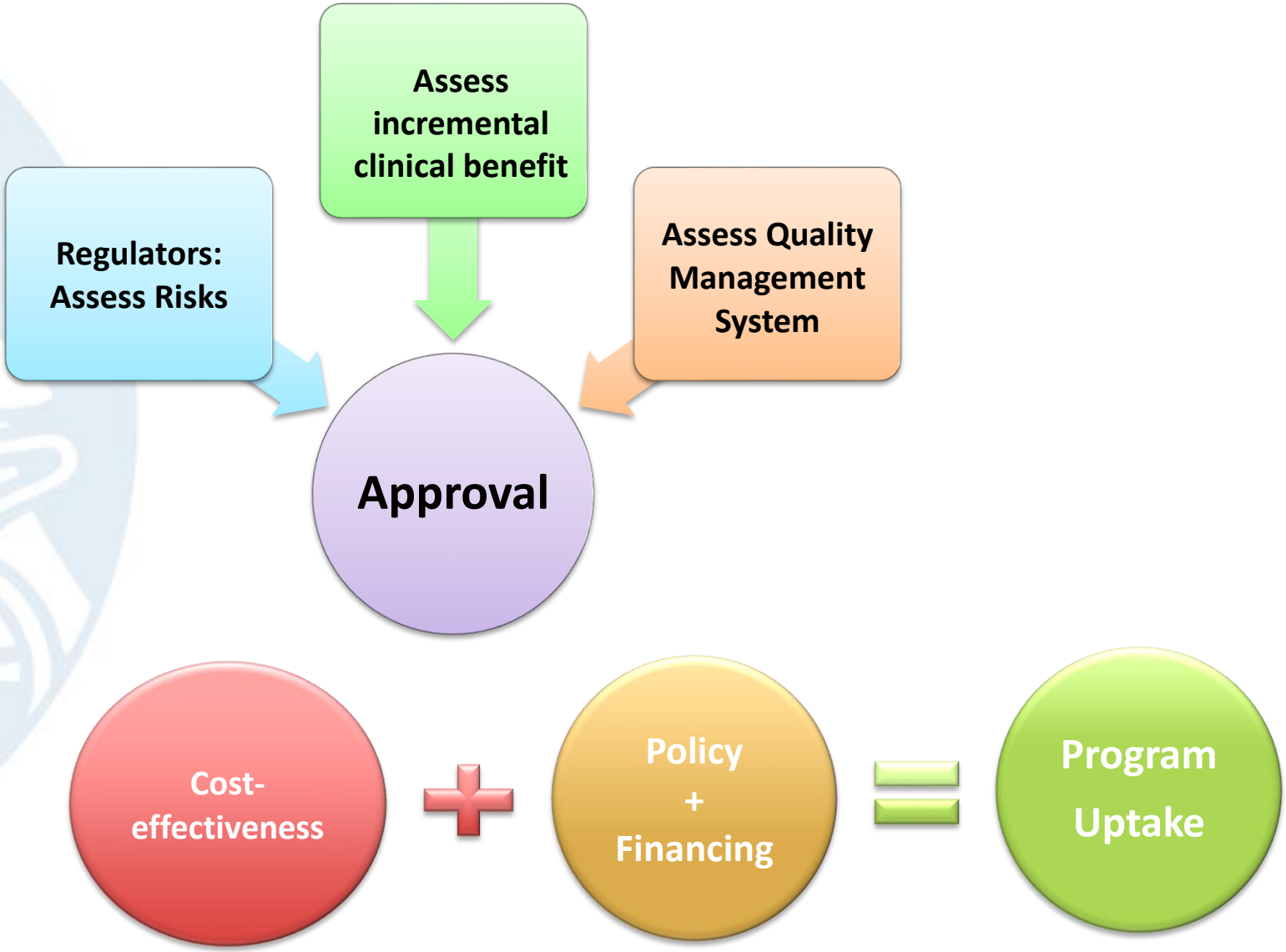


(Source: European Commission)

Urgent need for a simple rapid test to reduce inappropriate antibiotic usage

Accelerating Regulatory Approval and Program Uptake of Diagnostics



Accelerating Regulatory Approval and Programme Uptake, Brazil, Sept 15-16 2016

How many patients suffer
expecting an AFFORDABLE
AND EFFECTIVE DIAGNOSTIC TEST?

ALAD DiV

III Workshop Internacional

Pan-African Harmonization Working Party
Regulatory Forum and Workshop

Saturday December 3, 2016, 1-5 pm

International Conference Centre, Room 1.61-1.62
Cape Town, South Africa

Regulatory Forum:

Collaborative mechanisms to accelerate regulatory review and assure quality

Workshop for regulators:

Review of data from HIV self-testing kits (STAR Project, funded by UNITAID)

Thank you

- LSHTM: Ruth McNerney, Kim Sollis, Liz Corbet
- AU: Paul Tanui
- EAC: Stanley Sonoiya, Jane Masingia, Louisa Kosimbei
- WHO: Jean-Bosco Ndihokubwayo, Willie Urassa, Robyn Meurant
- ASLM: Trevor Peter, Tsehaynesh Messele
- GIZ: Wesley Ronoh, Thomas Walter
- PAHWP: Issac Kadowa, Agnes Kijo,, Ilonze Chinyere, Patience Dabula, Sagie Pillay
- AHWP: Liling Liu, Albert Poon, Jeffrey Chern, Jack Wong, Benny Ons
- ALADDIV: Carlos Gouvea, Adele Benzaken, and many others
- National regulatory authority representatives
- Consultants: Maurine Murtagh, Ben Cheng, Elliott Cowan, Albert Poon, Simon Rugera, Skating Panda Ltd
- Many companies who have contributed to the regulatory fora
- Funding:
  - Grand Challenges Canada
  - Bill & Melinda Gates Foundation
  - UNITAID