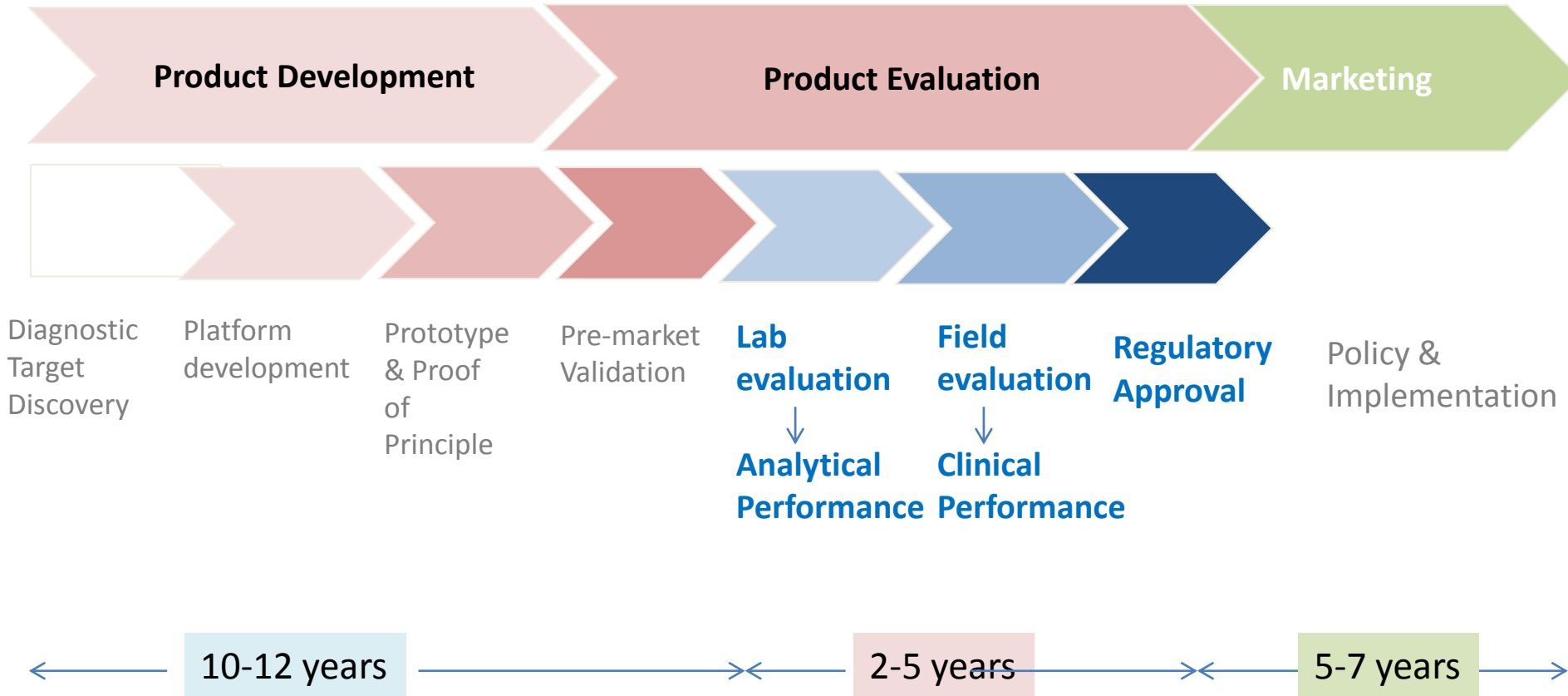




# **Accelerating the health impact of Diagnostics: progress towards Regulatory Harmonization**

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**London School of Hygiene & Tropical Medicine**  
**United Kingdom**

# Diagnostics Bench to Bedside Pathway



# Regulation of *In-vitro* Diagnostics:

## Goal:

To protect public health and safety by **ensuring safety, quality, and effectiveness**

## Challenges:

1. Regulatory landscape **highly variable**
2. Path to approval is often **not transparent**
3. Excessive **duplication** in clinical trials and inspection of manufacturing sites
4. Approval process often **costly** and **lengthy**, especially for imported tests
5. **Regulatory frameworks have not kept up with technological advances and have become a disincentive to innovation**

## Possible solutions:

1. **Convergence/Harmonization of standards and oversight**
2. **Streamlining processes**
3. **Increase in transparency**

# Global Harmonization Task Force (GHTF)



- **Conceived in 1992 in response to the growing need for international harmonization in the regulation of medical devices to ensure their safety, quality, and effectiveness**
- **GHTF publishes and disseminates harmonized documents on basic regulatory practices and serves as an information exchange between national regulatory authorities and industry. GHTF documents are developed by 5 Study Groups (SG):**
  - [SG1 - Premarket Evaluation](#)
  - [SG 2 - Post-Market Surveillance/Vigilance](#)
  - [SG 3 - Quality Systems](#)
  - [SG 4 - Auditing](#)
  - [SG 5 - Clinical Safety/Performance](#)
- **In 2013, GHTF will transition to a purely regulatory body called the International Medical Devices Regulatory Federation (IMDRF) which will continue to promote the principles of harmonization.**

# Asia Harmonization Working Party (AHWP)

- **A non-profit organization of regulatory authorities and the medical device industry**
- **Goal: to study and recommend ways to harmonize medical device regulations in the region in coordination with the Global Harmonization Task Force (now IMDRF), Asia Pacific Economic Community, and other related international organizations**

## **Member Economies: (N=23)**

- Brunei, Cambodia, China, Hong Kong, India, Indonesia, Korea, Laos, Malaysia, Myanmar, Pakistan, Philippines, Singapore, Taiwan, Thailand, Vietnam
- Abu Dhabi, Chile, Jordan, Kuwait, Saudi Arabia, South Africa, Yemen

# Pan-African Harmonization Working Party

Founded in 2012 to steer regulatory harmonization activities in the region in partnership with AHWP, the Latin American Diagnostic Association and WHO

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 Advisory Group** (under the African Advisory Group for Regulatory Harmonization of Medicines, Medical Devices and Diagnostics, AU):

**Chair:** [EAC](#)

**Vice-Chair:** [Nigeria](#)

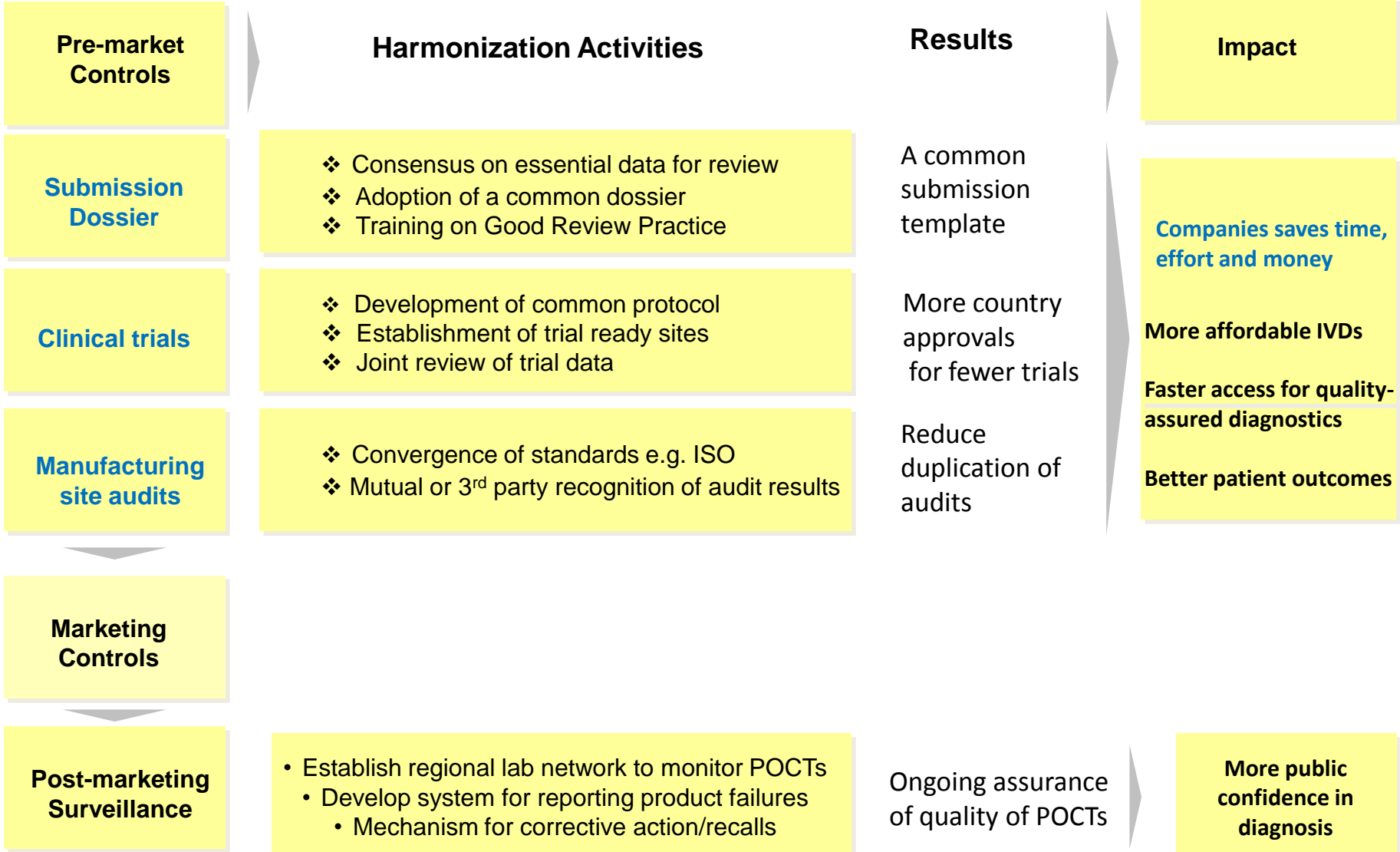
**Secretary:** [South Africa](#)

**Technical Working Groups:**

1. Common dossier
2. Convergence on inspections of manufacturing sites
3. Reduction in number of clinical trials
4. Post-marketing surveillance

**First African Regulatory Forum for Medical Diagnostics July 24-26 2013 in Nairobi, Kenya**

# Regulatory Oversight: Better, Safer, Faster & Cheaper

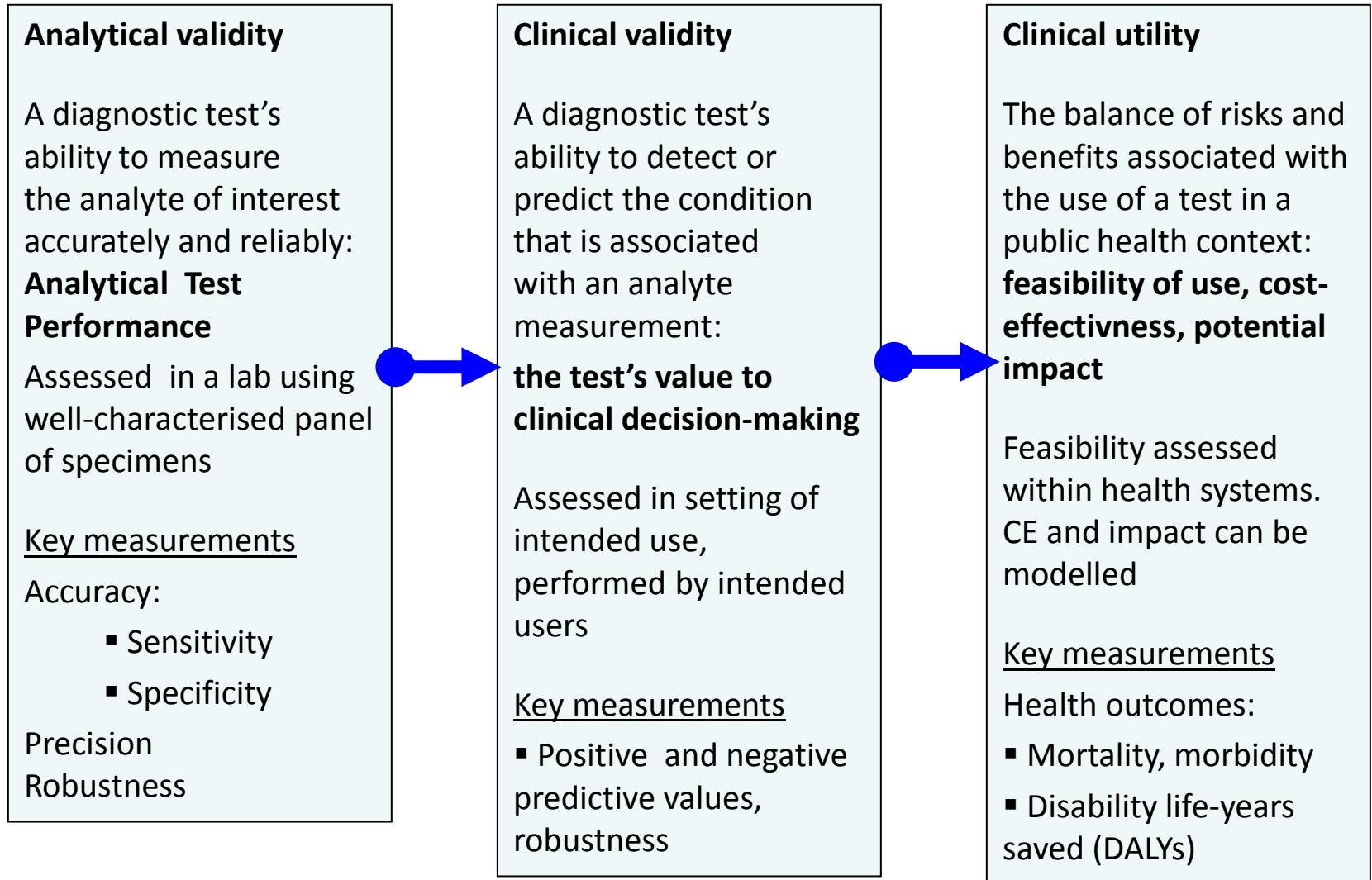


# Moving Forward: Better, Safer, Faster Cheaper

- Why use these POC tests for CD4, viral load and early infant diagnosis as pilots?
- World Health Organization and UNAIDS has committed to putting 15 million people living with HIV on treatment by 2015
- **CD4:** it is estimated that millions of HIV infected patients have no access to a CD4 test to determine whether they are eligible for life-saving treatments, e.g. in Malawi, <10% of HV service facilities offer CD4 tests
- **Viral Load:** <30% of HIV patients on treatment have access to a viral load assay to know if their treatment is still effective
- **Early infant diagnosis:** Most countries do not have access to tests that can diagnose HIV in babies born to HIV + mothers as babies carry their maternal antibodies up to 18 months of age. 53% of HIV+ babies are dead by 2 years of age, compared to a mortality rate of 7.6% for HIV- babies



# Validation of IVD Effectiveness



# Accelerating the Health Impact of Diagnostics

Product Development

Product Evaluation

Policy & Uptake



Grand Challenges Canada™  
Grands Défis Canada™

BOLD IDEAS FOR HUMANITY.™

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MEDICINE



**giz**



Asian Harmonization  
Working Party

Latin America  
(ALADDIV)



Pan-African Harmonization  
Working Party

