

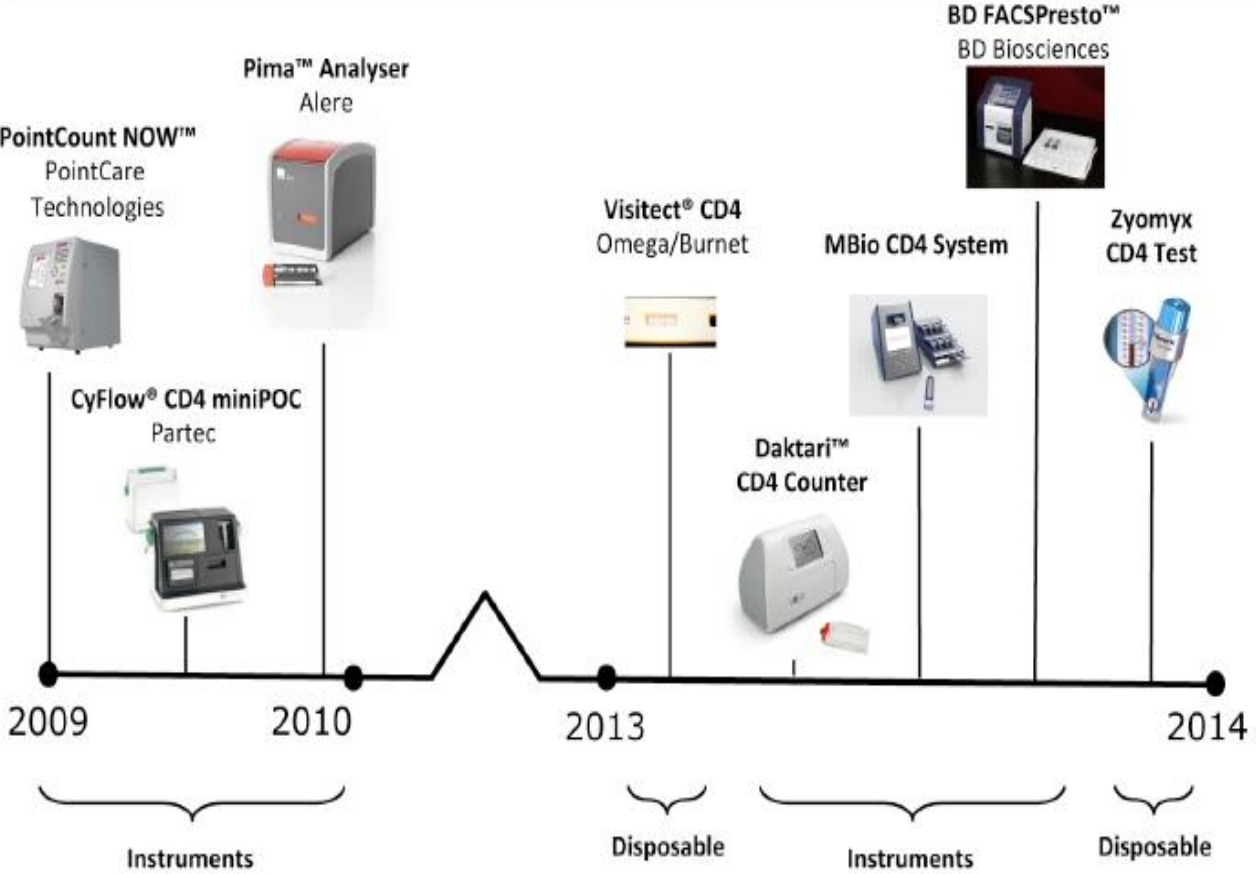


POC Diagnostics for CD4, Viral Load and Early Infant Diagnosis

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United Kingdom

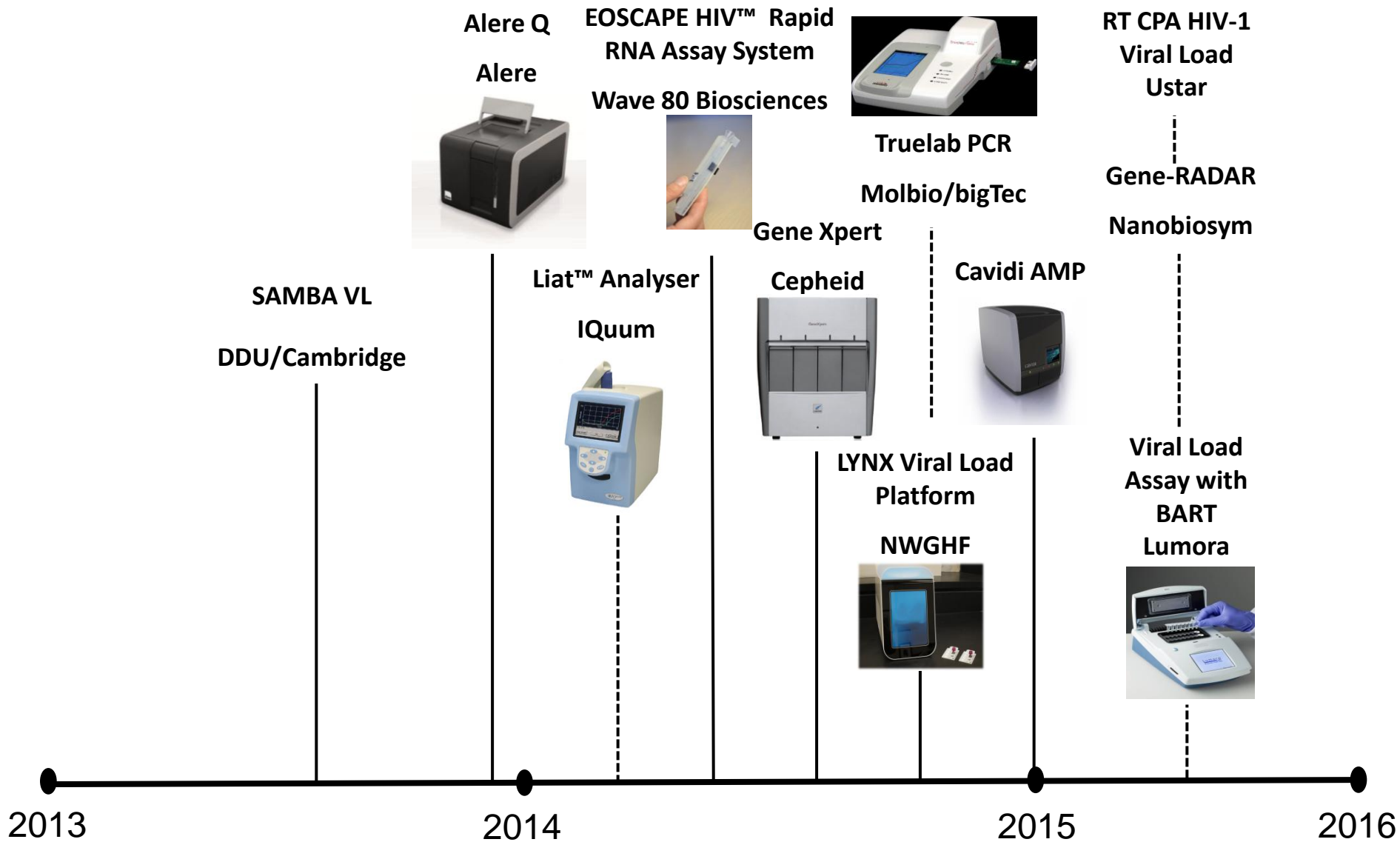
Pipeline for POC Diagnostics

CD4 Product Pipeline*

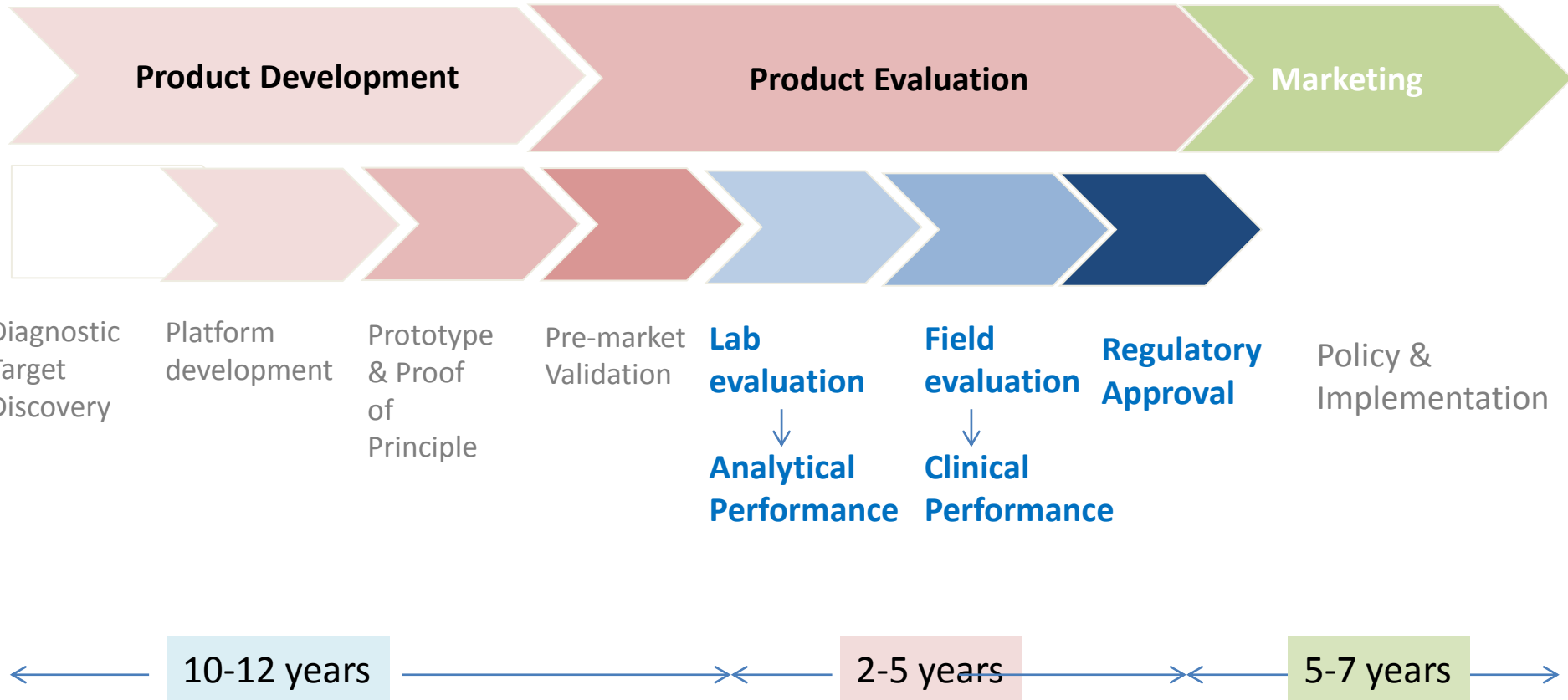


*Estimated as of March 2013 - timeline and sequence may change.

Viral Load Product Pipeline*



Diagnostics Bench to Bedside Pathway



UNITAID Project

- **Lower barriers to market entry**
 - Define target product profiles, performance expectations, and methods of validation (standardised evaluation protocol)
 - Prepare network of competent trial sites
 - Joint review of trial data by national regulatory authorities
- **Accelerate policy development and adoption**
 - Investing in POCTs vs laboratory systems
 - Introduction and scale up
 - Data transmission
 - sustainability
- **Implement quality assurance systems, including post-marketing surveillance**

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. Risk Classification
2. Common Registration File
3. Convergence on inspections of manufacturing sites
4. Reduction in number of clinical trials
5. Post-marketing surveillance

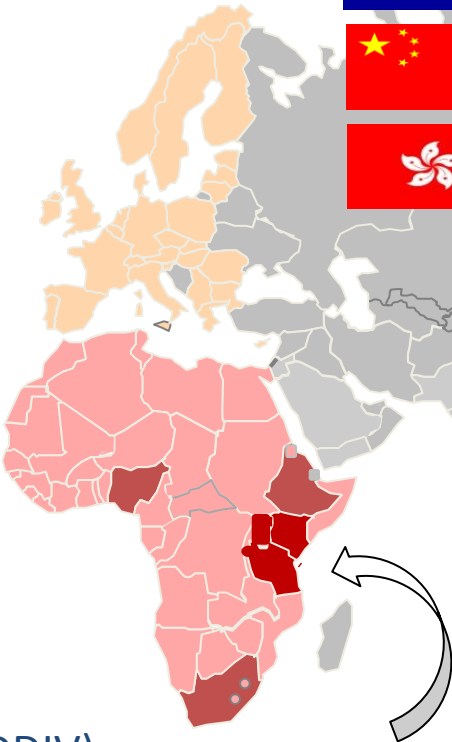
First African Regulatory Forum for Medical Diagnostics held on July 24-26 2013 in Nairobi, Kenya

Progress Towards IVD Regulatory Harmonization

Asia Harmonization Working Party
(23 countries). IVD sub group:



Latin America Diagnostic Association (ALADDIV)

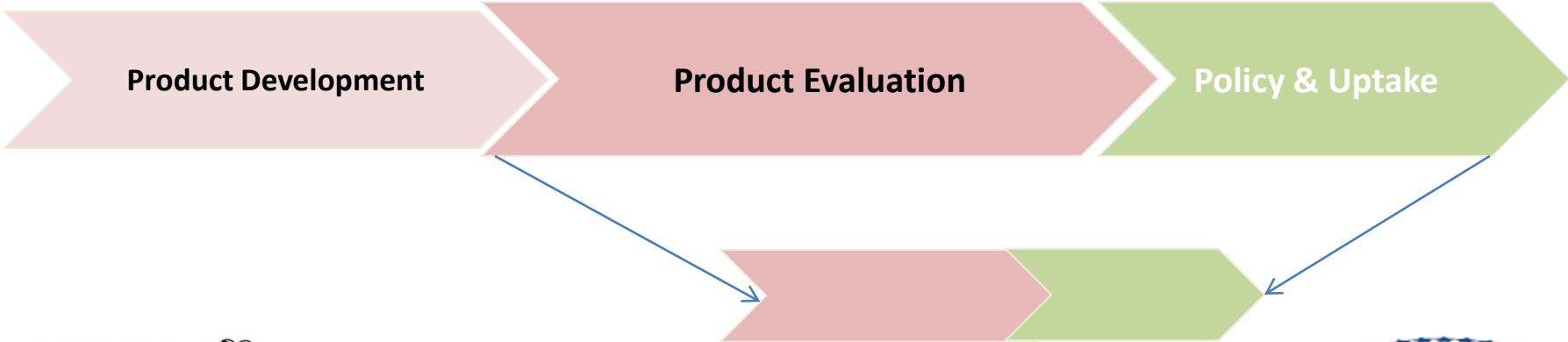


Pan-African Harmonization
Working Party



15 member states
in SADC: [Angola](#),
[Botswana](#), [DRC](#), [Lesotho](#),
[Malawi](#), [Mauritius](#), [Mozambique](#)
+ [Namibia](#), [Seychelles](#), [South Africa](#)
[Swaziland](#), [Tanzania](#), [Zambia](#)
[Zimbabwe](#) (Madagascar)

Faster Access to Quality-assured POC Diagnostics for CD4, Viral Load and Early Infant Diagnosis



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BOLD IDEAS FOR HUMANITY.™



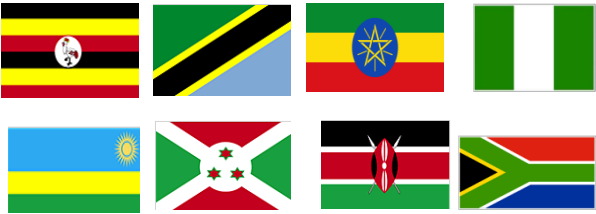
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Asian Harmonization
Working Party

