POC Diagnostics for CD4, Viral Load and Early Infant Diagnosis

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Pipeline for POC Diagnostics

CD4 Product Pipeline*

PointCount NOW™
PointCare Technologies

Pima™ Analyser
Alere

CyFlow® CD4 miniPOC
Partec

Visitec® CD4
Omega/Burnet

MBio CD4 System

Daktari™
CD4 Counter

BD FACSPresto™
BD Biosciences

Zyomyx
CD4 Test

2009  2010  2013  2014

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

Diagnostics Bench to Bedside Pathway

Product Development
- Diagnostic Target Discovery
- Platform development
- Prototype & Proof of Principle
- Pre-market Validation

Product Evaluation
- Lab evaluation
  - Analytical Performance
- Field evaluation
  - Clinical Performance

Marketing
- Regulatory Approval
- Policy & Implementation

10-12 years
2-5 years
5-7 years
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

Product Development

Product Evaluation

Policy & Uptake

Latin America (ALADDIV)

Pan-African Harmonization Working Party

Asian Harmonization Working Party