

# A Collaborative Approach to Market Entry and Procurement of Diagnostic Products

## *Partnerships for Introducing New Diagnostics*

Wednesday 03 December  
ASLM, 2014, Cape Town

# OUTLINE

- 1 Key partners and partnerships: introducing new Dx
- 2 Priority areas of partner engagement and harmonization
- 3 New Diagnostics Pipeline

# THE TASK AHEAD



tested



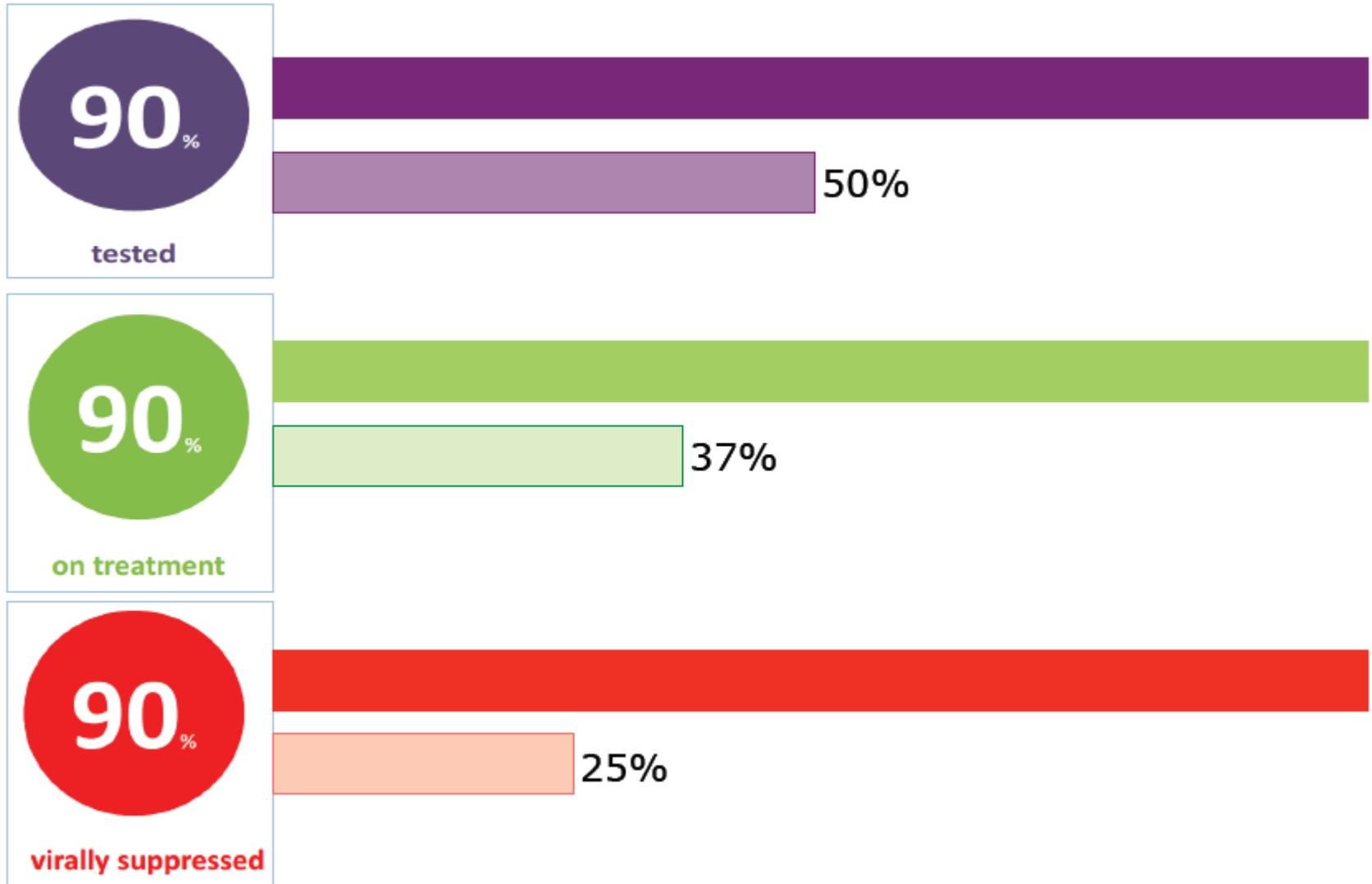
on treatment



virally suppressed



# THE TASK AHEAD



Source: R Peeling

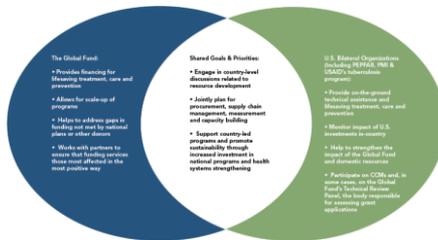
# KEY PARTNERSHIPS

## DIAGNOSTICS ACCESS INITIATIVE

to achieve final HIV treatment targets



## Global Diagnostics Working Group



# KEY PARTNERS



World Health Organization



LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE



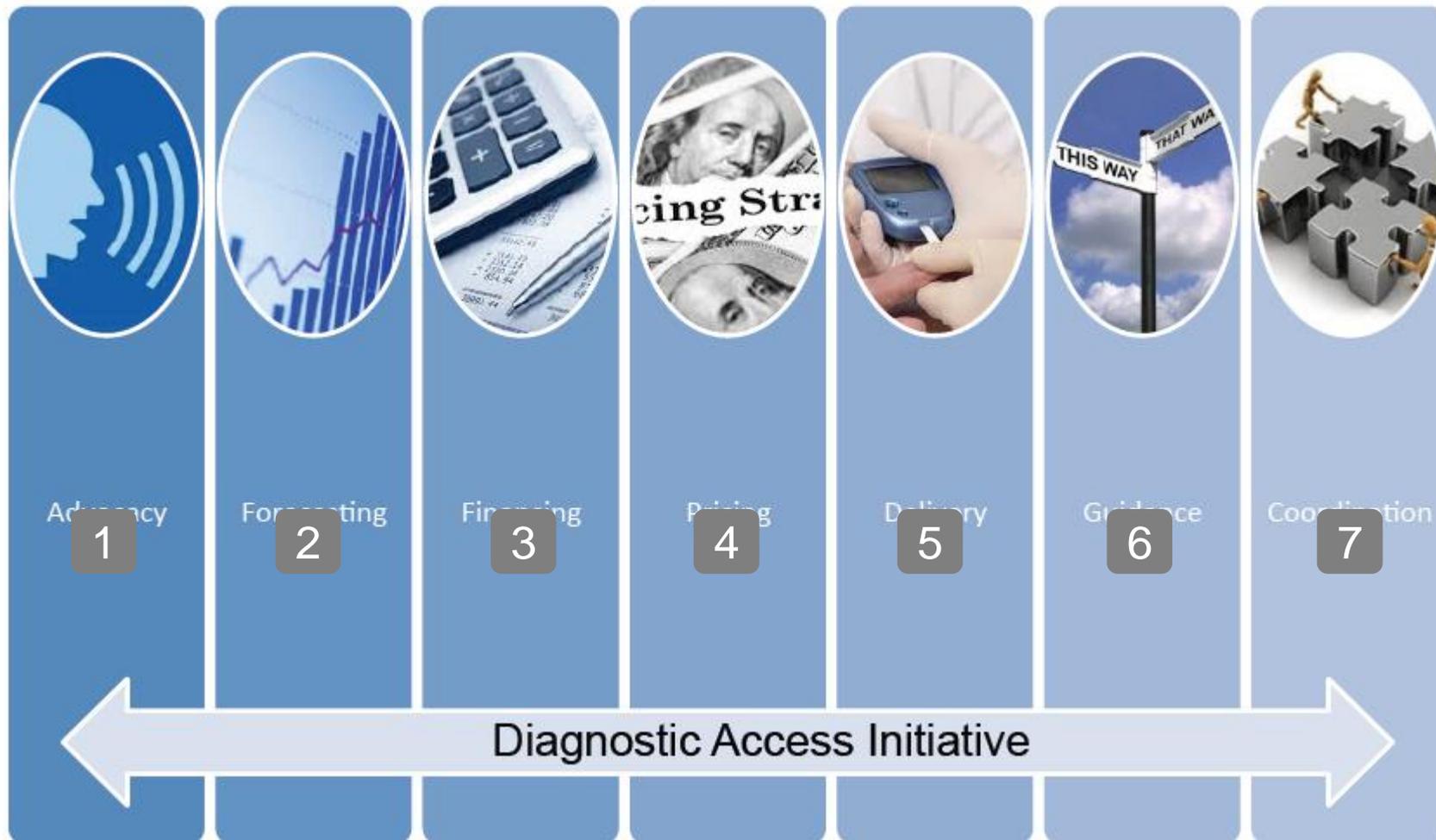
BILL & MELINDA GATES foundation



CIFF CHILDREN'S INVESTMENT FUND FOUNDATION



# THE SEVEN KEY PILLARS OF DAI

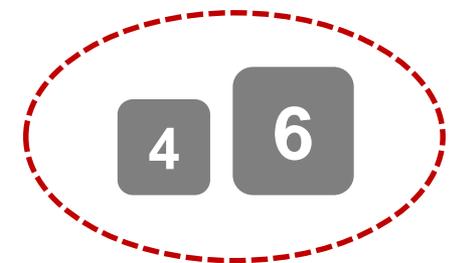


# THE KEY ACTIVITIES OF GDWG

The **GDWG** has **five main objectives** relevant to all DAI pillars but principally focused on delivering on DAI **Pillar 6: Normative Guidance** with close attention to **Pillar 4: Pricing**, for **selection, procurement & use of quality assured, affordable diagnostics**:

1. To strengthen communication, collaboration and coordination towards the optimal selection and use of quality-assured products;
2. To effectively respond in a timely and coordinated manner to urgent quality-related issues;
3. To provide aligned messages to global, regional, and country level users on quality assurance for product selection and testing implementation;
4. To provide aligned messages to manufacturers;
5. To advocate for diagnostic tests that are appropriate and affordable

[http://www.theglobalfund.org/en/procurement/updates/2014-11-28\\_Update\\_on\\_HIV\\_Global\\_Diagnostic\\_Working\\_Group/](http://www.theglobalfund.org/en/procurement/updates/2014-11-28_Update_on_HIV_Global_Diagnostic_Working_Group/)





# BI-LATERAL SNAPSHOT: GLOBAL FUND-PEPFAR PARTNERSHIP



	ARVs	Viral load	Other HIV diagnostics	Circumcision devices
Coordinated and coherent messages to suppliers	✓	✓	✓	✓
Synergistic strategies	✓	✓	Opportunity for improvement	✓
Direct engagement with suppliers & supplier visits	✓	✓	✓	✓
Improved demand visibility at global and national level	Opportunity for improvement	Opportunity for improvement	Opportunity for improvement	✓
Coordinated procurement	Paediatric ARVs	Opportunity		✓
Sharing non-confidential market and product information	✓	✓	Opportunity for improvement	✓

- Better planning & allocation of funds -- country level
- Leveraging scale in commodity procurement -- global level



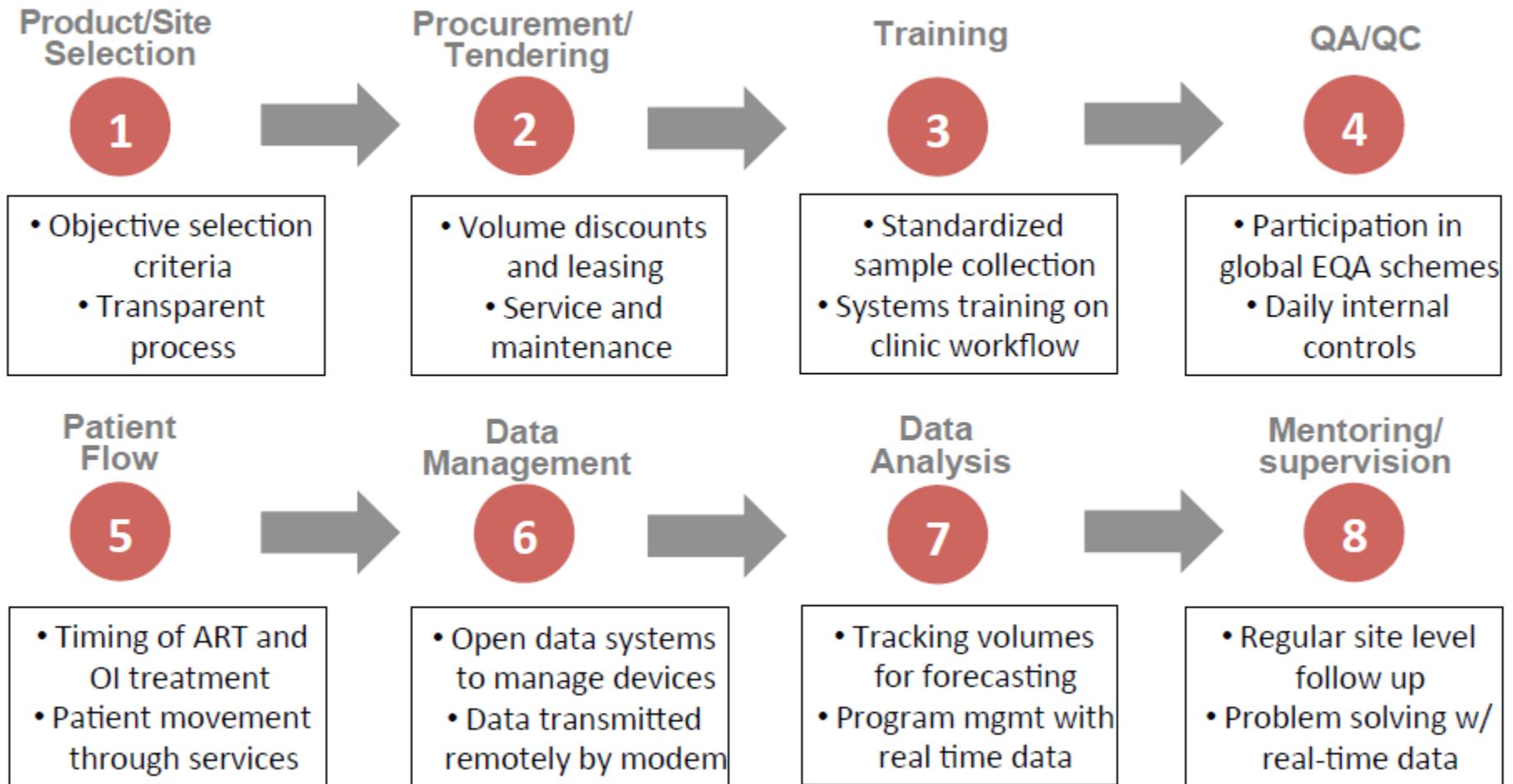
# PPP SNAPSHOT: UNITAID – POC DEVELOPERS



Support to POC developers for “final mile” field validation, product registration, prequalification and commercialization (2013-2016)



# IMPLEMENTATION: PROCESSES REQUIRED FOR NEW PRODUCTS



# PRIORITY AREAS OF PARTNER ENGAGEMENT & HARMONIZATION

2

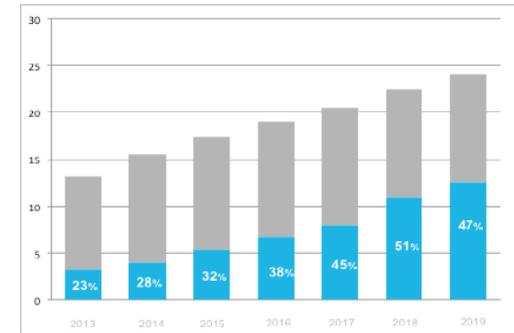
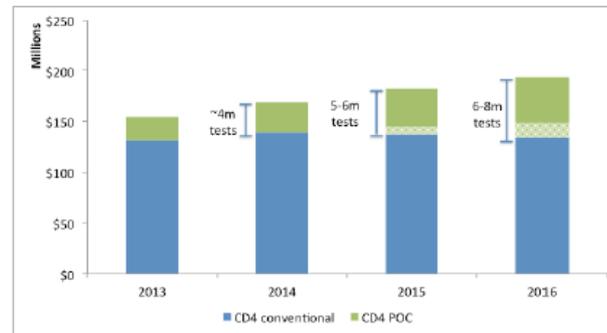
Financing for Market Shaping and Access Interventions

Coordinated and complementary **procurement** for optimal market shaping impact:

- ✓ Co-investment to achieve Dx volume thresholds
- ✓ Joint tenders/negotiations
- ✓ Pricing transparency



Forecasting and Order Visibility



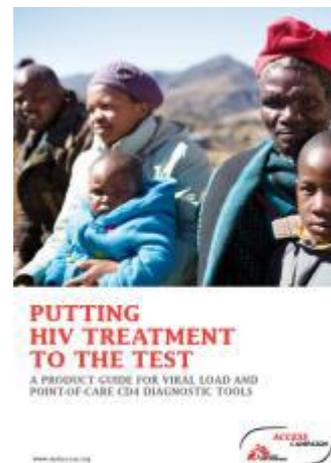
Laboratory System Capacity & Quality of Testing

Capacity assessments; laboratory strengthening (SLMTA, SLPTA); connectivity; EQA etc.



# PRIORITY AREAS OF PARTNER ENGAGEMENT & HARMONIZATION

Normative Guidance



Product Selection & Placement

Highest volume sites → Lowest volume sites



 Suited to laboratory based

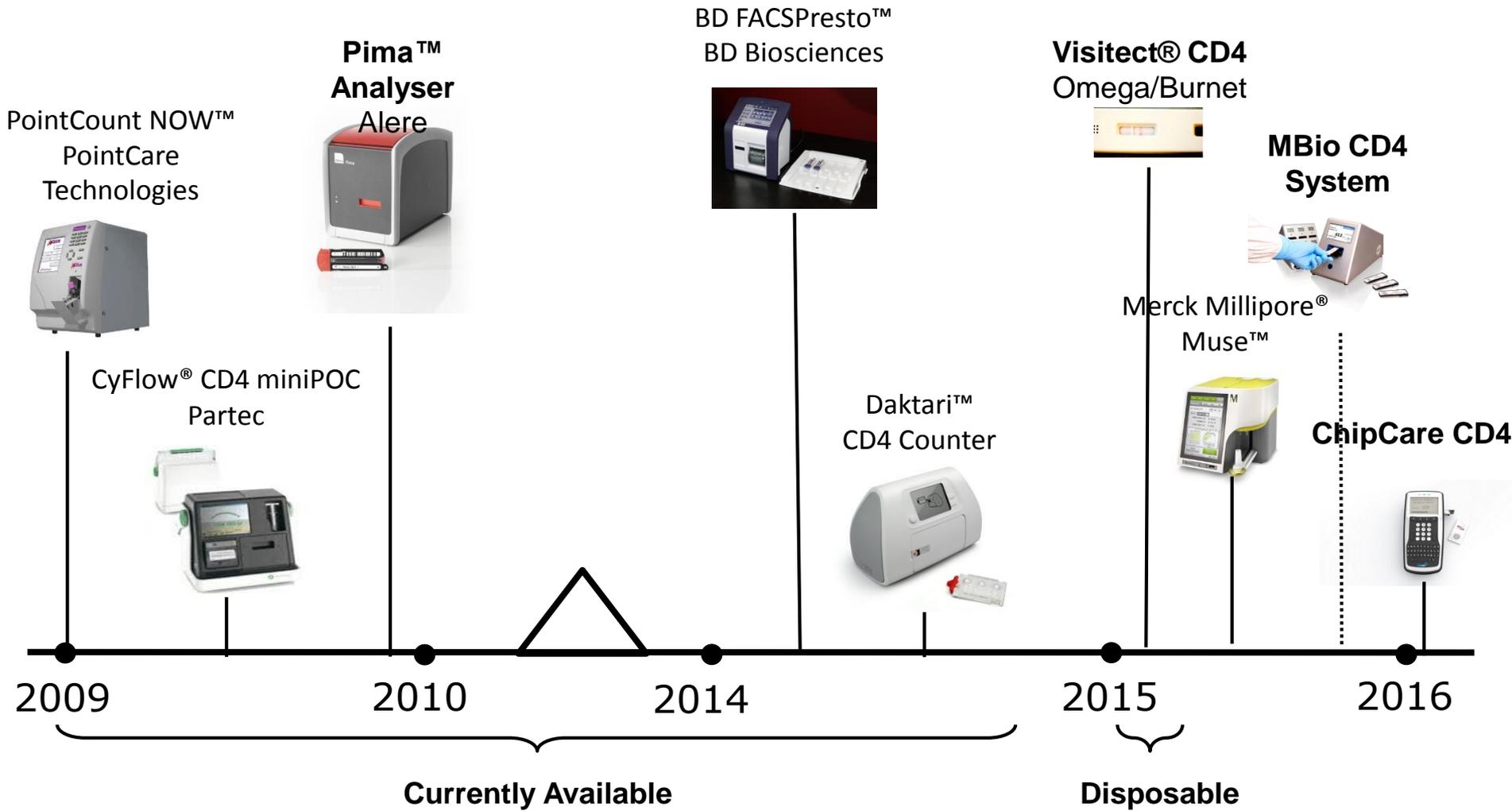


 Suited to POC

Quality Assurance



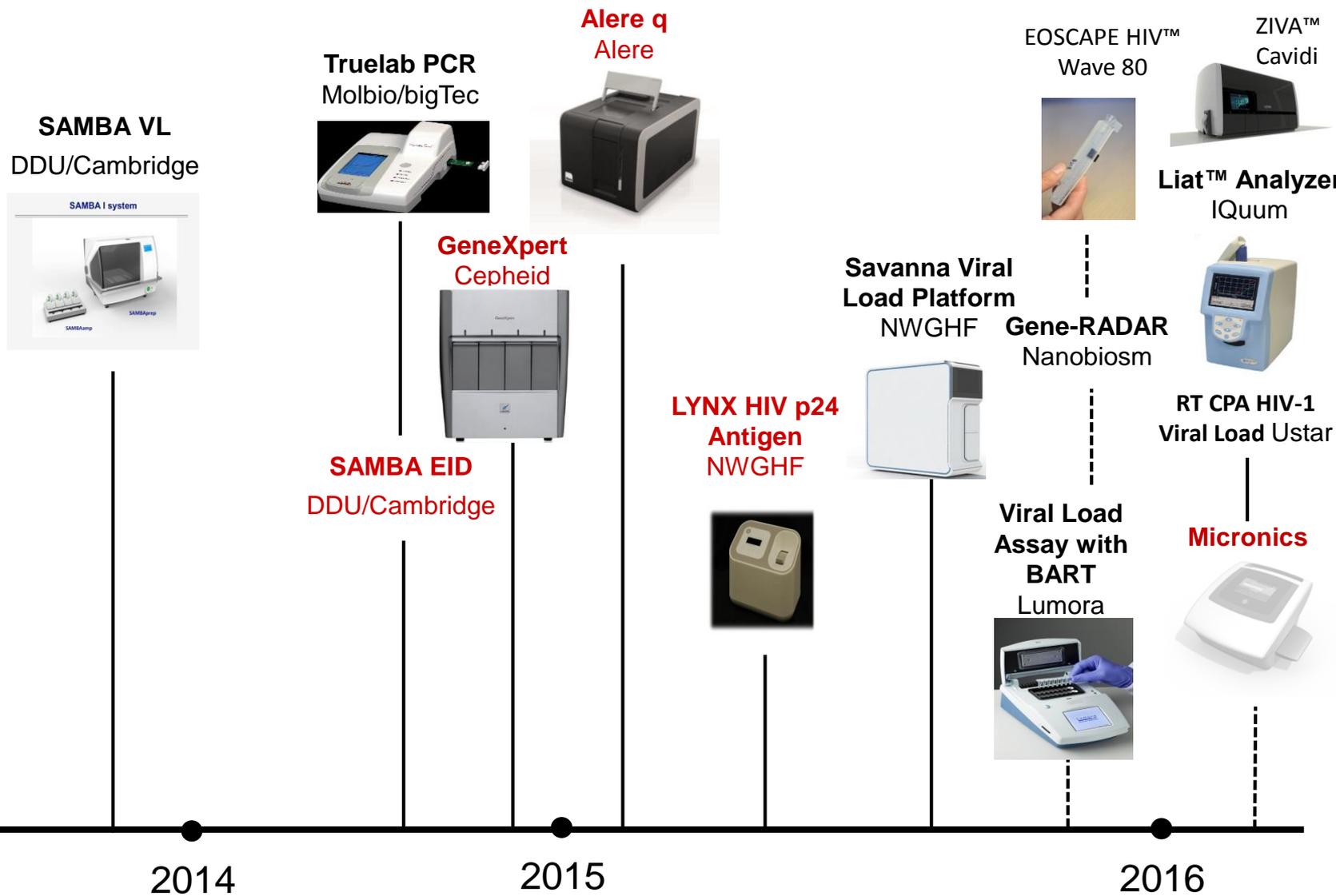
# NEW DIAGNOSTICS PIPELINE: CD4 – AVAILABLE AND PIPELINE



\*Estimated as of November 2014 - timeline and sequence may change. --- company.

No market launch date set by

# NEW DIAGNOSTICS PIPELINE: VIRAL LOAD & EID – AVAILABLE AND PIPELINE



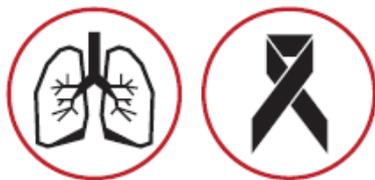
\*Estimated as of November 2014 - timeline and sequence may change.  
Platforms in red have specific EID assay.

No market launch date set by

## INNOVATIONS FOR CURRENT LAB-BASED DX



**Connectivity:** For rapid transmission of results, service and maintenance, surveillance



**Multiplex platforms:** Multi-purpose platforms capable of running assays for HIV, STIs, TB, HCV etc.



**Sample transportation:** Innovations in sample types and transport methods to reduce TAT and improve sensitivity/specificity

Thank you!

## ACKNOWLEDGEMENTS

