The Global Fund
RDT Supplier Conference

Dubai
10-11 September 2015
Welcome
Who’s here today

- RDT Manufacturers

- Partners:

  BMGF, PMI, PEPFAR, FIND, UNICEF, UNITAID;UNAIDS, WHO

- Global Fund & PSA & PR

PFSCM, Ghana; Nigeria, Uganda
Today’s Objectives

1. To update you on the progress of The Global Fund’s sourcing strategies for RDT.

2. To create a platform for partner agencies to share key messages and forthcoming changes in the RDT market.

3. To obtain feedback from you.
<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>0900-0930</td>
<td><strong>Introductions, and Objectives</strong></td>
</tr>
</tbody>
</table>
| 0930-1000  | **The Global Fund, Procurement for Impact and the Market Shaping Strategy**  
Mariatou Tala Jallow |
| 1000-1020  | **Global Fund Quality Assurance Policy and Challenges**                    
Alain Prat, Global Fund QA Specialist |
| 1020-1045  | **Update on WHO PQ for HIV and Malaria Diagnostics**                      
Deirdre Healy, WHO GMP |
| 1045-1115  | **Coffee**                                                                |
| 1115-1145  | **WHO/GMP update on malaria RDT quality assurance activities and procurement recommendations**  
Jane Cunningham, WHO GMP |
| 1145-1215  | **The Diagnosis Aspects of Diagnostics Access Initiative and targets**    
Martina Brostrom, UNAIDS |
| 1215-1245  | **Global Fund Market Perspectives**                                       
Martin Auton, Aziz Jafarov The Global Fund |
| 1245-1400  | **Lunch**                                                                 |
| 1400-1445  | **The Global Fund E-Marketplace Objectives, Approach, Timeline and Supplier Requirements**  
Kivanc Cubukcu, Global Fund |
| 1445-1530  | **Global Fund Procurement Strategy and Supplier engagement**              
Martin Auton, Aziz Jafarov The Global Fund |
| 1530-1600  | **Wrap Up and Coffe**                                                     |
# One to One Meeting Schedule

<table>
<thead>
<tr>
<th>Time</th>
<th>Team 1</th>
<th>Team 2</th>
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<tbody>
<tr>
<td>10 Sept</td>
<td></td>
<td></td>
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<tr>
<td>16.00–17.00</td>
<td>Premier Medical</td>
<td></td>
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<tr>
<td>11 Sept</td>
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<tr>
<td>0900–1000</td>
<td>Calypte Biomedical Corporation</td>
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<td>1000–1100</td>
<td>AccessBio</td>
<td>Bio Focus Co., Ltd.</td>
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<tr>
<td>1100–1200</td>
<td>Alere Inc.</td>
<td>Standard Diagnostics</td>
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<tr>
<td>1200–1300</td>
<td>ICT International</td>
<td>OraSure Technologies</td>
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Global Fund Market Shaping Strategy and Procurement for Impact

Dr Tala Jallow
The Spend Profile

Between 2014 & 2016 the spend on the three diseases will be US$14.6 billion

<table>
<thead>
<tr>
<th>Disease</th>
<th>Spend</th>
<th>Percentage</th>
<th>No of Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS</td>
<td>$7.8bn</td>
<td>53%</td>
<td>105</td>
</tr>
<tr>
<td>Malaria</td>
<td>$4.3bn</td>
<td>30%</td>
<td>74</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>$2.6bn</td>
<td>17%</td>
<td>98</td>
</tr>
</tbody>
</table>

Key areas of spend: medicines and other health products & program implementation
### Annual spend for key products

<table>
<thead>
<tr>
<th>Product</th>
<th>US$ million</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIV</strong></td>
<td></td>
</tr>
<tr>
<td>ARV medicines</td>
<td>800</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>125</td>
</tr>
<tr>
<td>Prevention</td>
<td>40</td>
</tr>
<tr>
<td>Medicines for opportunistic infections</td>
<td>60</td>
</tr>
<tr>
<td><strong>TB</strong></td>
<td></td>
</tr>
<tr>
<td>Medicines</td>
<td>125</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>35</td>
</tr>
<tr>
<td><strong>Malaria</strong></td>
<td></td>
</tr>
<tr>
<td>Antimalarial medicines</td>
<td>75</td>
</tr>
<tr>
<td>LLINs</td>
<td>310</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>30</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1,600</td>
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</table>
Procurement for Impact (P4I)

P4I was established to increase access to health products by fundamentally changing the way the Global Fund works across the supply chain.

- Earlier involvement and closer collaboration with manufacturers
- Improving our purchasing capability and changing our contracting models
- Optimising the international supply chain to reduce cost
- Better planning & scheduling to support continuity of supply
- Delivering more products at the right time and place to more people
Our Approach has remained constant throughout

In determining our approach we deploy a standard methodology which does not end with the tender process.

**UNDERSTAND**

Going to the real places, meet the stakeholders and understanding the facts.

**DESIGN**

Defining a set of objectives based on findings and designing an approach to deliver them.

**ENGAGE**

Designing tenders and Engaging suppliers to meet our objectives.

**MANAGE**

Working with suppliers to drive continuous improvement.
An update on progress

Since the last Supplier Meeting, significant progress has been made in the way the Global Fund engages with its suppliers with implementation of the following:

• **January 2014**: Framework Agreements for LLIN

• **July 2014**: Framework Agreements for Artemisinin Combination Therapies (ACTs)

• **January 2015**: A new strategy and Framework Agreements for Antiretroviral medicines (ARVs)

• **June 2015**: New approaches in the selection and procurement of Viral Load and Early Infant Diagnosis Technologies
Projects in Progress:

- Rapid Diagnostic Tests: HIV and Malaria
- Medicines (Drugs) for opportunistic infections
- TB medicines
Going forward, the Global Fund is revising its Market Shaping Strategy, which guides health product sourcing.

**Market shaping supports health outcomes and access to critical health products by…**

…Leveraging the Global Fund’s position to facilitate healthier global markets for health products, today and in the future.

**Vision**

**Scope**

- Medicines or technologies that prevent, diagnose or treat the three diseases
- Focus on products where Global Fund can expect to shape the market (core health products eg, LLINs, ACTs, ARVs, diagnostics)
- May intervene on new products when the Global Fund can play a catalytic role in bringing new and/or cost-effective products to scale

**Dimensions of a healthy market**

- Innovation
- Availability
- Demand and adoption
- Quality
- Affordability
- Delivery

P4I will continue to be Sourcing’s vehicle to operationalize the MSS.
### Strategy emphasizes maintaining availability and affordability, investing in scaling innovations and sustainability

<table>
<thead>
<tr>
<th>Focus</th>
<th>Continuing vs. new</th>
<th>Strategic objectives (summary)</th>
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</table>
| Near-term market shaping     | Refine & institutionalize ongoing activities                                    | Ensure continued availability and affordability  
Market transparency and competition, strategic procurement, RSM  
Proactively extending benefits to all recipients |
|                              | Make targeted investments                                                       | Promote consistent quality standards  
Maintain and refine QA policies (diagnostics); support WHO |
| Building for the future      |                                                                                  | Support efforts to stimulate innovation  
Recognize innovation in sourcing strategies; engage partners |
| Foundational enablers        |                                                                                  | Accelerate adoption of new and/or cost effective products  
Partner on product scale-up roadmaps, target ERP, expand capacity for AMCs, optimize product selection |
|                              |                                                                                  | Prepare for country transition and long-term market viability  
Transition planning, grants to support PSM systems, in-country capacity building, process to assess further interventions |
|                              |                                                                                  | Strengthen key market shaping enablers  
Systems and tools to support forecasting & data management, further strengthening partnerships |
Several channels for Global Fund-financed procurements

The Global Fund

PPM
Procurement Agent
HIV/Malaria Manufacturers

GDF
Procurement Agent
TB Manufacturers

Country Procurement
National Systems
Procurement Agent
HIV/TB/Malaria Manufacturers

Principal Recipients

Several channels for Global Fund-financed procurements

The Global Fund

PPM
Procurement Agent
HIV/Malaria Manufacturers

GDF
Procurement Agent
TB Manufacturers

Country Procurement
National Systems
Procurement Agent
HIV/TB/Malaria Manufacturers

Principal Recipients
Context: Pooled procurement is a key tool for the Global Fund to shape markets

2009: Voluntary Pooled Procurement (VPP) created

- Mechanism to centrally procure health products to impact markets
- Recognizing need to address common procurement and/or risk-related grant performance issues
- From 2009 – 2011, responsible for:
  - Over US$ 700 million of health product orders from 47 countries
  - Savings of US$ 57 million vs. budgets
- Constrained by procurement process and disbursement of grant funds

2013: Transition to Pooled Procurement Mechanism (PPM)

- Market Shaping Strategy calls for policy changes to enable true consolidation of volumes
- Grew to 60 countries and about US$ 1 billion in 2013
- Global Fund can leverage pooled demand to shape markets, delivering benefits for countries and suppliers
  - **Countries**: improved value for money, risk reduction
  - **Suppliers**: greater visibility into demand, more predictable volume and lower transaction costs
ARVs and LLINs are largest categories purchased through the Global Fund’s pooled procurement mechanism

**Spend by category purchased through the Pooled Procurement Mechanism, 2013**

- ARVs: 414 USD $M (40%)
- LLINs: 382 USD $M (37%)
- ACTs: 39 USD $M (6%)
- Lab supplies: 34 USD $M (4%)
- HIV Dx: 34 USD $M (4%)
- Malaria Dx: 34 USD $M (3%)
- Other medicines: 34 USD $M (3%)
- Condoms: 8 USD $M (1%)
- Other: 4 USD $M (<1%)
- Total: 1,030 USD $M

Source: Global Fund pooled procurement data.
THANK YOU
Global Fund Quality Assurance Policy and Challenges

Alain Prat, Global Fund QA Specialist
Global Fund Quality assurance policy for Diagnostics and challenges

HIV and Malaria Manufacturers Engagement: 10th and 11th September 2015

Alain Prat, Quality Assurance Specialist
Pharmaceutical Products
(current version December 2010)

Condoms
(WHO Procurement Guidelines)

Global Fund Quality Assurance
for Health Products

Diagnostic Products
(current version July 2014)

Long Lasting Insecticidal Nets, IRS
(WHOPES recommendations & specifications)
Global Fund QA Policy for Diagnostics
Product Scope

• **Diagnostic Product**: means all durable and non-durable IVDs and imaging equipment and microscopes used in Global Fund-financed programs for diagnosis, screening, surveillance or monitoring purposes.

• **In Vitro Diagnostic Product (IVD) medical device**: means a medical device, whether used alone or in combination with other devices, intended by the Manufacturer for in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes including, reagents, calibrators, control materials, specimen receptacles, software, and related instruments, apparatus and other articles*

• Definitions not fully in line in international standards

• Interpretation needed regarding Dry Blood Spot (DBS) as IVD
Global Fund QA Policy for Diagnostics
Main Requirements

• Compliance with national requirements
  – National registration system
  – Specific quality standards (labelling requirements)
  – Regulatory system on IVD is globally week in LMIC and/or unrealistic for registration and licensing

• Comply with national guidelines (treatment guidelines and Diagnostics Guidelines, national algorithm)
  – Consistent with WHO Guidance or
  – Justifications in case of conflicting provisions between the two
Global Fund QA Policy for Diagnostics Manufacturing Requirements

• Compliance with Quality Management System standards for manufacturing site
  – IVD and imaging equipment
    • ISO 13485 or equivalent QMS recognized by one regulatory authorities of the founding members of the GHTF
    • No requirement on licensing, qualified person, variations

– Others Diagnostics Products (microscope)
  • ISO 9000 serie or equivalent QMS recognized by one regulatory authorities of the founding members of the GHTF
Global Fund QA Policies
Products Requirements

• Compliance with quality standards for products by considering existing internationally recognized assessment / evaluation processes
  • Recommended for use by WHO programs
  • Authorized for use by one of the Regulatory Authorities of the founding members of GHTF
  • Determined to be acceptance for procurement by Expert Review Panel for Diagnostics

• No reference is made to quality or performance studies guidelines for products as such but to regulatory mechanism
Global Fund QA Policies
Various Regulatory Mechanisms

• Based on harmonization initiative (GHTF members)
  – No assurance on the level of integration of the harmonized requirements (EU Standards versus CLSI for stability)
  – De facto if the RA is not a member then should it be considered as not robust
  – Inherent limitations to Global Harmonization (classification based on risk which may differ, stability requirements, intended purpose..)

• Based on Stringent Regulatory Authorities (SRA)
  • No evidence of robustness of the SRA
  • No assurance of the level of compliance to the above mentioned requirements (processes in place, resources allocated, involvement of third parties)

  • De facto different levels of assurance of the quality of the products
Global Fund QA Policy for Diagnostics
Expert Review Panel (ERP)

- A panel of experts hosted by WHO
- Two submissions per year
- Assesses the potential risks/benefits associated with the use of IVDs which are not PQ or RA approved
- Manufacturers are encouraged to submit their application to WHO or to the regulators of the founding members of the GHTF
- Abbreviated product dossiers submitted by manufacturers (questionnaire + annexes)
- No on-site QMS inspection nor GLP inspection
- Makes time limited recommendations: validity maximum 12 months
Global Fund QA Policy for Diagnostics
Global Fund IVDs List

- RDTs + Enzyme Immunoassays (EIAs) + HIV Supplemental assays + CD4 + HIV VL
- Malaria RDTS
- No list for TB Diagnostics
- Maintenance of the lists
- How to integrate N-Compliances
Global Fund QA Policy for Diagnostics
Monitoring quality and reporting non-conformities

• Lot testing is organized depending WHO guidelines in such case the PR should ensure that lot testing is performed
  – Pre-shipment lot testing: check a QC lot release certificate issued by the manufacturer or an independent regulatory body
  – Post shipment lot testing: Recipient can arrange lot-testing in line with relevant WHO policies and procedures
  – No requirement for recipient to conduct post-marketing surveillance

• PR should ensure that a mechanism is developed and maintained
  – for systematic reporting of defects related to diagnostic products to the RA
  – For facilitating communication in the event of defects
  – GF/QA very limited information on the NC identified in the field
Global Fund QA Policy for Diagnostics
GF Compliance monitoring system

- Mandatory system to report procurement transactions for diagnostic in the Price Quality Reporting online system (PQR)
- The Secretariat monitors compliance with QA requirements by organizing a monthly compliance review
  - Falsified EC Certificate identified during the last review

In case of non-compliance, follow up and corrective measures are required
Thanks for your attention
Global Fund QA Policy for Diagnostics
Relevant guidance is available on GF

- Global Fund’s QA policy for Diagnostic Products
- List of Malaria RDTs / List of HIV Diagnostics tests
- Price and quality reporting
- Guidance for best practice
- Quick Facts on Procuring Malaria Rapid Diagnostic Test Kits
- Global Fund Guidance for Procurement and Use of HIV Diagnostic Test Kits with Global Fund Grants

Update on WHO PQ for HIV and Malaria Diagnostics

Deirdre Healy, WHO GMP
WHO Prequalification of In Vitro Diagnostics

Global Fund HIV and Malaria Manufacturers Engagement
September 2015, Dubai

Deirdre Healy
Prequalification Team – Diagnostics
Department of Essential Medicines & Health Products
Role of WHO prequalification

- Facilitate access to safe, appropriate priority IVDs, medicines and vaccines

- Support two of WHO's six core functions
  - setting norms & standard/promoting their implementation
  - providing technical support, catalyzing change & building institutional capacity

- Contribute to achieving four of WHO's impact goals
  - reduce under-five mortality
  - reduce maternal mortality
  - reduce the number of people dying from AIDS, tuberculosis and malaria
  - eradicate polio
Prequalification of in vitro diagnostics programme

• Aims at promoting and facilitating access to safe, appropriate and affordable IVDs of good quality in an equitable manner

• Undertakes a comprehensive assessment of individual IVDs through a standardized procedure aimed at determining if the product meets PQ requirements.

• Focus is placed on IVDs for priority diseases

• Is coordinated through the department of Essential Medicines and Health Products, PQ Team
WHO Prequalification of IVDs

Scope:
- IVDs for **priority diseases** (HIV, hepatitis C, hepatitis B, HIV/TP, malaria, HPV) and their **suitability for use in resource-limited settings**

Impact:
- PQ findings provide **independent technical** information on safety, quality, performance of IVDs
- PQ findings used by UN agencies, WHO Member States and other organizations to **guide their procurement of IVDs**
Prequalification assessment

- Includes three components:
  - Review of a product dossier;
  - Performance evaluation, including operational characteristics; and
  - Manufacturing site(s) inspection.

- Looks into quality, safety and performance through dossier review, performance evaluation and inspection
  - Dossier: safety and performance
  - Performance evaluation: performance
  - Inspections: quality
Prequalification of IVDs

Full prequalification assessment

Pre-submission form

Priority product

Yes

No

Dossier screening

Dossier incomplete

Dossier complete

Dossier review

Site inspection

Laboratory evaluation

Prequalification decision

Abbreviated prequalification assessment

Pre-submission form

Priority product

Yes

No

Full PQ assessment

Decision on abbreviated PQ assessment

Yes

No

Abbreviated site inspection

Laboratory evaluation

Prequalification decision
Prequalification: decision

- Final prequalification outcome depends on:
  - (Results of dossier assessment, acceptance of corrective action plan)
  - Results of site inspection, acceptance of corrective action plan
  - Meeting the acceptance criteria for the laboratory evaluation/Malaria RDTs must pass WHO/FIND product testing on regular basis

- WHO PQ Public Report is posted publicly and added to the list of WHO prequalified IVDs
  - Product is then eligible for WHO and UN procurement
  - 1st Joint tender ongoing for WHO, UNDP, UNICEF, UNFPA
PQ assessment findings as procurement driver

- Bulk procurement scheme - 1989
- National AIDS Control Programmes, blood transfusion services, UN agencies, NGOs, donor support HIV/AIDS projects
- Recommendations and guidelines to assist selection of kits
- http://www.who.int/diagnostics_laboratory/procurement/150730_products_eligible_for_proc.pdf?ua=1
Ineligibility for procurement

- If made obsolete by their manufacturer,
- If de-listed from the list of WHO prequalified products,
- If Field Safety Notice or Notice of Concern is active.
Trends in HIV RDT market

- HIV RDT market has always been highly consolidated
  - Dominated by Determine™ HIV-1/2 (Alere Medical) with 83% market share in 2014
  - Despite 12 HIV RDTs WHO prequalified, just 5-6 other RDTs make up the rest of the market

- National validated testing algorithms usually reviewed every 5 years
  - Maximum of 3 assays required

- Most public sector procurement goes to high prevalence settings
  - Therefore most likely to only require 2 assays

- So some predictability of what assays will be used in which order
  - 1st line, 2nd line, 3rd line assays
Post-prequalification phase

assess

PMS
> Complaint reporting
> Proactive lot testing

Changes notifications
> QMS, design, performance etc.

quality

safety

performance

Post-PQ
About post-market surveillance of IVDs

- Some quality, safety and performance issues may only arise after an IVD is placed on the market

- Requirements for post-market activities by manufacturers are listed in:

- Adequate post-market surveillance is necessary to detect, investigate and act on any issues that compromise individual health or public health related to use of an IVD
WHO normative guidance on PMS

- Roles/responsibilities of stakeholders

- Forms
  - IVD complaint report
  - Manufacturer complaint investigation report
  - Field Safety Corrective Action report
  - Lot testing data collection & report

- Notices
  - Field Safety Notice
WHO post-market surveillance of IVDs

Any class of IVD

Proactive PMS
Lot verification testing
Pre-distribution
Post-distribution

Evaluation of EQA/QC data

Reactive PMS
Complaint
Possible Field Safety Corrective Action
Possible issuance of Field Safety Notice
Proactive post-market surveillance of IVDs

- Lot verification testing
  - Independent of the manufacturer, so not lot release testing
  - Ensures that only lots meeting established criteria are delivered to users
  - Using a risk-based approach

- Evaluation of EQAS and QC testing results
  - Across sites using the same assay, same/different lot
Proactive PMS of IVDs: lot testing

- Lot verification by suitably qualified laboratory using SOPs so that each lot testing event is consistent

- Through **physical inspection** of packaging, labelling and instructions for use
  - Looking for breaches of packaging that might affect stability

- **Testing** of samples from each lot of the same IVD
  - Against a well-characterized panel of specimens, same panel for both pre-distribution and post-distribution lot testing

- Lot acceptance criteria must be in place (pass/fail) for both inspection and testing
Reactive post-market surveillance of IVDs

- Reporting of administrative and technical complaints by end-users/procurers/implementers
  - As soon as they become aware

- Ensures that any necessary FSCA is undertaken, and notified to users via a FSN
  - e.g. lot recall, modification of test procedure (IFU), etc.

Reactive PMS

Complaint

Possible Field Safety Corrective Action

Possible issuance of Field Safety Notice
Complaints and product alerts

- WHO publically lists only outstanding product alerts
  - WHO Notices of Concern for nonconformities during WHO PQ inspection
  - WHO Information Notices for Users to supplement field safety notices issued by manufacturers

http://www.who.int/diagnostics_laboratory/procurement/complaints/en/
WHO IVD complaint reporting form

- All verified complaints should be reported to the manufacturer, as soon as possible.

- Complaints that are classified as serious, moderate or a change in trend of mild adverse events should be reported to the relevant NRA, and WHO, as soon as possible.
Change reporting criteria for PQed IVDs

WHO PROCEDURE FOR CHANGES TO A WHO PREQUALIFIED IN VITRO DIAGNOSTIC

WHO Prequalification of In Vitro Diagnostics Programme
Prequalification of IVDs - Future developments

Dossier and Inspections

- WHO developing guidance documents for manufacturers

Lab evaluations:

- WHO has been supporting studies through WHO collaborating labs

Joint assessments

- Capacity building mechanism to strengthen NRAs and provide insight into PQDx assessment
- Sessions for regulators
- Support Collaborative registrations in country (WHO Collaborative Procedure)
Contact us

- By email
  - diagnostics@who.int

- Sign up to our mailing list
  - By emailing
    diagnostics@who.int

- Via our website
  - http://www.who.int/diagnostics_laboratory/en/
  - http://www.who.int/diagnostics_laboratory/postmarket/en/
WHO/GMP update on Malaria RDT Quality Assurance Activities and Procurement Recommendations

Jane Cunningham, WHO GMP
Update on malaria RDT quality assurance activities and procurement recommendations

J. Cunningham WHO/GMP

The Global Fund HIV and Malaria Manufacturers Engagement
10-11 September, 2015
Dubai
Historical overview

1990s
Few products on the market; WHO holds first consultation on malaria diagnosis

2003
WPRO, TDR, CDC - consultation to establish procedures for RDT evaluation scheme

2007
First lot testing at RITM; WHO recommends RDTs from ISO13485 certified suppliers and lot testing

2008
Launch of Round 1 - WHO product testing and WHO Prequalification of IVDs (HIV, TB, malaria)
PT = PQ lab evaluation

2009
Publication of Round 1 PT report
WHO develops recommended procurement criteria based on PT results
The WHO-FIND strategy for QA of RDT-based diagnosis involves three main stages:

1. **Product testing** (Stage 1): Evaluate product performance before purchase.
2. **Lot testing** (Stage 2): Confirm product quality on arrival in the country before dissemination to the field.
3. **QC at point of use** (Stage 3): Ensure that RDTs have maintained accuracy through transport and storage before use.

The strategy is supported by supply chain management and transport and storage considerations, as well as end-user training and instructions. Additionally, the availability of common reference standards is crucial for maintaining quality throughout the process.
Current Product Testing
Comparative evaluation of commercially-available antigen-detecting malaria rapid diagnostic tests – RDTs.

- Evidence of quality manufacturing
- RDTs to specimen bank with temperature monitor
  - Performance versus panel
  - Stability
  - Ease-of-Use assessment
- Review of results by technical group
  - Results released to manufacturers
- Longer-term stability test by manufacturer
- Final publication

5 years

$
Product Testing (at US CDC)

**Performance** – panel detection score, false-positive and invalid rates
- Phase 1 – 20 cultured *P.falciparum* samples; 2 lots; 1 RDT @2000p/µl ; 2 RDT @ 200p/µl + 20 clean negative samples (*new Round 6*)
- Phase 2
  - *P.falciparum* (100), *P.vivax* (35), 2 lots; 1 RDT @2000p/µl ; 2 RDT @ 200p/µl
  - negative samples (100; mixed clean and other disease conditions)
- Antigen concentrations (HRP2, pLDH, aldolase) not statistically different in panel samples between Rounds 1-5

<table>
<thead>
<tr>
<th></th>
<th>HRP2</th>
<th>Pf LDH</th>
<th>Pf aldolase</th>
<th>Pv LDH</th>
<th>Pv aldolase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum</td>
<td>0.6 ng/mL</td>
<td>0.2 ng/mL</td>
<td>0 ng/mL</td>
<td>1.6 ng/mL</td>
<td>1.7 ng/mL</td>
</tr>
<tr>
<td>Maximum</td>
<td>74 ng/mL</td>
<td>53.5 ng/mL</td>
<td>9.9 ng/mL</td>
<td>47.9 ng/mL</td>
<td>15 ng/mL</td>
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**Heat stability** (4°C, 35°C, 45°C; 75% humidity x 60 days)

**Ease of use assessment**
- blood safety, instructions quality, no. timed steps, RDT anomalies (from Round 5)
Example results: Pf PDS @ 200 and 2000p/µL
Rounds 1-7

- **Published Rounds 1-5**
  - 206 RDTs evaluated (147 unique products)

- **Round 6**
  - 41 RDTs (30 combo; 11Pf only) 22 manufacturers
  - Analysis being finalized – report October-November 2015

- **Round 7**
  - Expression of interest – 85 products
  - Limit to 2 products per manufacturer (plus compulsory resubmissions)
Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests

March 2015

Annex 1. Performance of malaria RDTs in rounds 2–5 of WHO malaria RDT product testing
Annex 2. Changes in malaria RDT manufacture and corresponding required product performance assessment

Annex 3. Notifications of product variations to the WHO malaria RDT product testing programme in 2013 (round 5): required assessment and outcome
WHO/GMP Procurement criteria & WHO Prequalification

A) For the detection of Pf in all transmission settings the Panel detection score (PDS) against Pf samples should be at least 75% at 200 parasites/uL

B) For the detection of Pv in all transmission settings the Panel detection score (PDS) against Pfv samples should be at least 75% at 200 parasites/uL

C) The false positive rate should be less than 10%

D) The invalid rate should be less than 5%

Only products meeting performance criteria outlined in A, B, C, D are recommended for procurement

- After 6 rounds of testing 50-60 products (Pf only and combination tests, few pan-only, meet these criteria)
- This includes 10 WHO prequalified products (6 Pf tests; 3 combination tests (2 Pf/pan; 1 Pf/Pv, 1 pan-only test)
  [Link](http://www.who.int/diagnostics_laboratory/evaluations/150729_prequalified_products_list.pdf?ua=1)
FIND Interactive Guide – Updated to include new filters*

- Web based database of product testing results (Rounds 1-5)


* Buffer drops, reading time, target antigens
Proportion of RDT procurement by Panel detection score (GF (PPM and PQR), PMI, UNICEF & WHO)

Data represent approximately 60% of estimated market based on manufacturers sales data.
Lot testing

- Institut Pasteur, Cambodia (IPC)
- Research Institute of Tropical Medicine, Philippines (RITM)
Initial Testing

**Initial QC testing**

* Use 48 RDTs, and use QC samples from 4 different Pf cases (A, B, C, D), 4 different Pv cases (E, F, G, H) and 10 different malaria parasite negative cases (I-R).

Long term testing (37°C): 6 months prior to expiry

**Long-term QC testing**

† Use only 8 RDTs, and use QC samples from 2 different Pf cases (A, B), 2 different Pv cases (E, F) and 2 malaria parasite negative cases (I,J) used in the initial QC testing (if possible).

Lot testing request form sent to LT coordinator

Shipment of RDTs

Observations
Testing with initial samples

≥1 sample fails?

NO → Send PASS report w/in 5d

YES

Repeat testing with different sample(s)

Cross-check failed samples with stock RDTs: must be positive to proceed!

Repeat testing fails?

NO → Send PASS report w/in 5d

YES → Send DEFERRED report and Send RDTs for confirmatory testing

Confirmatory testing fails?

NO → Send PASS report

YES → Send FAIL report
Malaria RDT lots tested per year

Number of new Malaria RDT lots tested per year

Source: WHO, FIND
Results summary (2007-2015 (June))

<table>
<thead>
<tr>
<th>Year</th>
<th>Nº new Products</th>
<th>Nº new Manufacturers</th>
<th>Nº RDT lots tested</th>
<th>Nº Long Term Testing Carried out</th>
<th>Nº Initial Failures**</th>
<th>Nº Long term Failures**</th>
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<td>7</td>
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<td>4</td>
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<td>528</td>
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<td>Jan-End June 2015</td>
<td>4</td>
<td>2</td>
<td>476</td>
<td>660</td>
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<td>20</td>
<td>4095</td>
<td>3840</td>
<td>12</td>
<td>19</td>
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</table>

• **Long term failures noted the year when an RDT lot was received (routine testing only)

Source: WHO, FIND
Initial reports from lot testing labs:
- “Only a small amount of liquid buffer was left at the tip of the vial” and it wasn't enough to run through the test cassette.”
- “Variation of buffer volume among the ampoules”

Further investigation (2014): 55 lots of nine different test kits from three manufacturers

- For PQ’d products (and those in its portfolio) WHO PQ has the mandate to investigate product complaints and follow closely that manufacturers conduct root cause analysis; issue field safety notices and conduct field corrective action
- WHO information note to users issued (01/15) and all manufacturers have sourced new material and have submitted validation data under the WHO PQ change notification procedure
<table>
<thead>
<tr>
<th>Countries</th>
<th>Lot size</th>
<th>Countries</th>
<th>Lot size</th>
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<td>NIGERIA</td>
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<td>14'300'000</td>
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<td>AFGHANISTAN</td>
<td>500'000</td>
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<td>GUINEA</td>
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<td>GUATEMALA</td>
<td>500'000</td>
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<td>MALAWI</td>
<td>4'685'225</td>
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<td>BANGLADESH</td>
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<td>GAMBIA</td>
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<td>3'202'475</td>
<td>CAMBODIA</td>
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<td>ZIMBABWE</td>
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<td>1'910'000</td>
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<td>LIBERIA</td>
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<td>PHILIPPINES</td>
<td>10'000</td>
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<td>DRC</td>
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<td>CAMEROON</td>
<td>1'500'000</td>
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<td>31'207'445</td>
</tr>
</tbody>
</table>

Total: 140 million RDTs – nearly half of total market

In 2015, 97% of lots tested are for 4 manufacturers & 8 products

Source: WHO, FIND
The future – product testing

Product testing

- Reporting of anomalies
- ISO 13485 authenticity verification
- Manufacturing status of products evaluated
- Adherence to international standards and best practices for labelling RDTs and instructions for use
- New panels
  - Reduced #
  - Pf culture
  - Primate Pv
  - LOD against recombinants
The future – lot testing

Lot testing

- Decentralization of lot testing using recombinant antigen panels
- Maintenance of Pf culture and wild-type Pv samples for cross checking diminished performance trends in the field
  - Move away from parasites/µL to range of antigen concentrations
The future ---- procurement recommendations

- Reaching out beyond NMCP to regulators – raising awareness of product testing data
- Current criteria purely based on performance in product testing
  - Performance has improved and prices gone down
  - Room for improvement – assessment of QMS, enhance post market surveillance
- Increasing number of prequalified RDTs, including products and manufacturers with majority of current market share
- WHO considering the impact of a change to a requirement for prequalification as recommended procurement criteria on product quality, price and supply

**Risks:**
- Market concentration may not diminish and risk supply security increases
- Insufficient capacity to meet demand – will new suppliers come; will existing one continue to expand?
- Timeline for change – can manufacturer make it...will they try?; no experience with new PQ model
- Change is not adopted by all major procurers

  - Results will be shared initially with major procurers
  - Modified criteria would be considered by MPAC in March 2016
  - Lead time to allow manufacturers to get into prequalification pipeline.
Thank you & acknowledgements

cunninghamj@who.int

+41 22 791 2230
The diagnosis aspects of the Diagnostics Access Initiative

HIV and Malaria Manufacturers engagement
10 September 2015
2015 treatment coverage

Number of people receiving antiretroviral therapy, 2000–2015

“15 BY 15”
A GLOBAL TARGET ACHIEVED

UNAIDS
Ambitious, but achievable, new target

- 90% diagnosed
- 90% on treatment
- 90% virally suppressed
ENSURING THAT 90 % OF PEOPLE LIVING WITH HIV KNOW THEIR HIV STATUS
Evolving context

- Therapeutic and prevention benefits of ART
- Pathway to ART, EMTCT, PrEP, PEP, TB and possibly MC
- Community based testing – capacity, efficacy and cost
- All people knowing their status vs early diagnosis
- VCT still predominant in implementation
- Lost prevention dividence
17.1 million people do not know their HIV status.
People living with HIV aware of their status/diagnosed

54% Adults

32% Children
HIV treatment cascade for people aged 15 years and over in sub-Saharan Africa, 2014

Sources and methods:
1. UNAIDS 2014 estimates.
3. UNAIDS 2014 estimates.
4. GARPR 2015, representing the weighted average of 27 countries.

- People not covered
- People covered
Regional trends of median HIV testing and status awareness by gay and other men who have sex with men, last 12 months, 2011–2014

Source: GARPR 2015.
Diversity in progress towards the first 90

Awareness estimates of HIV status among PLHIV in selected countries

Percentages

Ever tested for HIV among people living with HIV in Africa

Source: DHS
DIAGNOSTICS ACCESS INITIATIVE to achieve final HIV treatment targets
The new testing paradigm

Advocacy and communications

Policy and Programming

Technology and innovation
# Testing Approaches for Identifying PLHIV

<table>
<thead>
<tr>
<th>Delivery Channel</th>
<th>Population</th>
<th>Expected Yield</th>
<th>Cost</th>
<th>Linkage to Care</th>
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</thead>
<tbody>
<tr>
<td>Provider Initiated</td>
<td>Patients with symptoms</td>
<td>High</td>
<td>Low</td>
<td>Good</td>
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<td></td>
<td>Partners of PLHIV</td>
<td>High</td>
<td>Medium</td>
<td>Good</td>
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<td></td>
<td>TB patients</td>
<td>High</td>
<td>Low</td>
<td>Good</td>
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<td>STI patients</td>
<td>High</td>
<td>Low</td>
<td>Good</td>
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<td>Other health care visits</td>
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<td>Pregnant women</td>
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<td>Outreach</td>
<td>Family planning clients</td>
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<td>Fair</td>
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<td>Fixed VCT centers</td>
<td>Key populations</td>
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<td>Good</td>
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<td>Mobile vans</td>
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<td>Door-to-door</td>
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<td>Self-test</td>
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<td>Low</td>
<td>Poor</td>
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</table>
Testing yield by channel / group

Mozambique

Nigeria

Partners of PLWH newly identified
TB patients
MSM
IDU
FSW
STI patients
Out- & in-patients w. AIDS symptoms
ANC & Family Planning
Other men 15-49 years
Other women 15-49 years
Overall

Senegal

Overall
Resource needs for testing

**Mozambique**

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**Nigeria**

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<td>Out- &amp; in-patients w. AIDS symptoms</td>
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**Senegal**

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</tbody>
</table>
Cost-effectiveness: programmatic pathways

Mozambique

Cumulative costs, 2016-2020 (US$)

Cumulative PLWH newly identified, 2016-2020

Nigeria

Cumulative costs, 2016-2020 (US$)

Cumulative PLWH newly identified, 2016-2020

Senegal

Cumulative costs, 2016-2020 (US$)

Cumulative PLWH newly identified, 2016-2020

Highly dependent on assumed unit costs.
Annual per patient cost

$112
Per person diagnosed

$177
Established adult ART

Source: UNAIDS estimates 2015
Studies show that current generation RDTs can have significant performance gaps, both in-facility and in the community.

### Accuracy of Different Testing Algorithms in the Field

<table>
<thead>
<tr>
<th>Country (study, year)</th>
<th>Strategy</th>
<th>Algorithm</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Driver of low accuracy</th>
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</thead>
<tbody>
<tr>
<td>Uganda (Gray, 2007)</td>
<td>Mobile Lab</td>
<td>1) Determine 2) Stat-Pak</td>
<td>97.6%</td>
<td>90.4%</td>
<td>Weak bands: cross-reactions, over-development?</td>
</tr>
<tr>
<td>Cameroon* (Aghoken, 2009)</td>
<td>Facility</td>
<td>1) Determine 2) ImmunoComb</td>
<td>100%</td>
<td>91.5%</td>
<td>Quality control issues: use test after expiration date &amp; suboptimal shipment</td>
</tr>
<tr>
<td>Cameroon** (Aghoken, 2009)</td>
<td>Facility</td>
<td>1) RetroCheck 2) SD Bioline</td>
<td>94.7%</td>
<td>98.8%</td>
<td></td>
</tr>
<tr>
<td>South-Africa (Wolpaw, 2010)</td>
<td>Facility</td>
<td>Not available</td>
<td>93.5%</td>
<td>N/A</td>
<td>Suboptimal use: risk in high-burden LRS</td>
</tr>
<tr>
<td>Malawi (Molesworth, 2010)</td>
<td>Door-to-door</td>
<td>1) Determine 2) UniGold</td>
<td>99.6%</td>
<td>100%</td>
<td>Not applicable</td>
</tr>
<tr>
<td>South-Africa (Jackson, 2013)</td>
<td>Door-to-door</td>
<td>1) SD Bioline 2) Sensa</td>
<td>98.0%</td>
<td>99.6%</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Source: CHAI
Manufacturers are developing oral fluid RDTs

<table>
<thead>
<tr>
<th>Product (supplier)</th>
<th>Mechanism</th>
<th>Sensitivity</th>
<th>FDA</th>
<th>CE</th>
<th>WHO PQ</th>
<th>LR Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>• OraQuick Advance</td>
<td>• Rapid Immunoassay</td>
<td>• 99.3%</td>
<td>✓</td>
<td>✓</td>
<td>In progress</td>
<td>~$5-7</td>
</tr>
<tr>
<td>(OraSure, USA)</td>
<td>• Swab gums with test stick; put into test tube</td>
<td>• 99.8%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• DPP® HIV ½ Assay</td>
<td>• Rapid Immunoassay</td>
<td>• 98.9%</td>
<td>✓</td>
<td>✓</td>
<td>In progress</td>
<td>~$3</td>
</tr>
<tr>
<td>(Chembio, USA)</td>
<td>• Swab gums with stick; put into test tube</td>
<td>• 99.9%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• AWARE™ HIV-1/2 OMT</td>
<td>• Immunoassay</td>
<td>• 99.2%</td>
<td>In progress</td>
<td>In progress</td>
<td>Unknown</td>
<td></td>
</tr>
<tr>
<td>(Calypte, USA)</td>
<td>• Swab gums with stick; put into test tube</td>
<td>• 99.9%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Asanté™ HIV-1/2 Oral Fluid RDT</td>
<td>• Immunoassay</td>
<td>• 100%</td>
<td>Unknown</td>
<td>Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Sedia, USA)</td>
<td>• Swab gums with stick; put into test tube</td>
<td>• 100%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• One Step HIV 1/2 Oral Fluid</td>
<td>• Lateral Flow Test</td>
<td>• 99.6%</td>
<td>In progress</td>
<td>Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Wondfo, China)</td>
<td>• Swab gums with stick; put into test tube</td>
<td>• 100%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• OralWell Oral Fluid HIV ½</td>
<td>• Lateral Flow Test</td>
<td>• 98.3%</td>
<td>Unknown</td>
<td>Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>screening</td>
<td>• Swab gums with stick; put into test tube</td>
<td>• 99.9%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Jingsu Well, China)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Aibokang Oral Fluid HIV ½</td>
<td></td>
<td></td>
<td>Unknown</td>
<td>Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screen Test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Beijing Jiele, China)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Union Oral Fluid HIV ½</td>
<td></td>
<td></td>
<td>Unknown</td>
<td>Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antibody Kit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Chengdu Un, China)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• HIV 1/2 antibody Dot ELISA</td>
<td></td>
<td></td>
<td>Unknown</td>
<td>Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>rapid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Wantai, China)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
AtomoRapid (by AtomoDiagnostics) is an all-in-one device that allows for sample collection without pipetting

<table>
<thead>
<tr>
<th>Sample type</th>
<th>Whole Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>Sensitivity = 99.8% ; Specificity = 99.7%</td>
</tr>
<tr>
<td>SRA status</td>
<td>CE mark expected early 2015</td>
</tr>
<tr>
<td>Price</td>
<td>$1.4 - $2 (scale up could bring price to $1.2-$1.25)</td>
</tr>
</tbody>
</table>

**Manufacturer description**

- Launched in 2008 to develop a blood test as simple as a pregnancy test
- Have deal with a US company about adapting the platform for home test use
- Recently signed a MoU with a large listed Chinese healthcare company
- Also provide device for Malaria and OEM

**Product description**

- First integrated (all-in-one) test device for rapid blood testing
- No pipetting required as the device contains a needle which draws blood directly from the patient
- Can be used with various WHO PQ test strips
- Sold as a device or as a finished product with test strip included (INTEC HIV test)

**Ease of use features**

- **Reduced number of steps**: all-in-one integrated device, no pipetting required
- **Reduced user-error**: no interference of specimen with environment

---

*Atomo Diagnostics is currently in the process of developing a self-test version of their device*

Source: CHAI
### The INSTI Test (by Biolytical) delivers results in 60 seconds

<table>
<thead>
<tr>
<th>Sample type</th>
<th>Whole blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sens/spec</td>
<td>Sensitivity: 99.6%; Specificity: 99.3%</td>
</tr>
<tr>
<td>SRA status</td>
<td>WHO PQ, FDA approved, CE marked</td>
</tr>
<tr>
<td>Price</td>
<td>$3 (WHO price)</td>
</tr>
<tr>
<td>Manufacturer description</td>
<td>• Privately-owned Canadian Company</td>
</tr>
<tr>
<td></td>
<td>• R&amp;D program and pipeline includes INSTI™ tests for diseases such as Hepatitis C and Syphilis</td>
</tr>
<tr>
<td>Product description</td>
<td>• Flow-through in vitro qualitative Immunoassay</td>
</tr>
<tr>
<td></td>
<td>• INSTI™ is considered as an initial test only</td>
</tr>
<tr>
<td></td>
<td>• The kit is designed to produce a very rapid result, and therefore be interpreted immediately</td>
</tr>
<tr>
<td>Test algorithm</td>
<td>1. Sampling blood with a fingerprick</td>
</tr>
<tr>
<td></td>
<td>2. Put blood into buffer liquid container</td>
</tr>
<tr>
<td></td>
<td>3. Put 3 different buffer liquids onto the container (in the right order)</td>
</tr>
<tr>
<td></td>
<td>4. Wait 60sec to read the results</td>
</tr>
<tr>
<td>Ease of use features</td>
<td>• Reduced time to reading the results: 60sec to perform the test</td>
</tr>
</tbody>
</table>

BioLytical is currently exploring ways to lower cost and reduce complexity

Source: CHAI
HIV Self-testing

- Available since 1990s
- UNAIDS policy since 2004
- Private non-medical affair
- Convenience and comfort with instant robust results
- Circumvent barriers
- Preferred modality
- heterosexual men, young people, health workers in high prevalence settings, and key populations
More RDT manufacturers are in the process of developing a product for Self-Testing, both oral fluid and blood-based

**OVERVIEW OF PIPELINE PRODUCTS FOR HIV SELF-TESTING**

<table>
<thead>
<tr>
<th>Product (supplier)</th>
<th>Specimen</th>
<th>Business objectives</th>
<th>Regulatory Status</th>
<th>Other RDTs from manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Aware™ (Calypte, USA)</td>
<td>Oral Fluid</td>
<td>• <strong>TBD</strong></td>
<td>In process of obtaining FDA approval</td>
<td>• Aware HIV-1/2 OMT</td>
</tr>
<tr>
<td><strong>2</strong> Asante HIV Self Test (Sedia, USA)</td>
<td>Oral Fluid</td>
<td>• <strong>TBD</strong></td>
<td>TBD</td>
<td>• Asanté HIV-1/2 Oral Fluid Rapid Test</td>
</tr>
<tr>
<td><strong>3</strong> DPP HIV1/2 (self test version)</td>
<td>Oral Fluid, Whole Blood</td>
<td>• <strong>TBD</strong></td>
<td>In process of obtaining FDA approval</td>
<td>• HIV 1/2 STAT-PAK&lt;br&gt;• SURE CHECK HIV 1/2&lt;br&gt;• DPP HIV 1/2</td>
</tr>
<tr>
<td>(Chembio, USA</td>
<td>Fiocruz, Brazil*)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>4</strong> Self Test (Developer in Toronto, Canada)</td>
<td>Whole Blood</td>
<td>Target SSA market</td>
<td>• <strong>TBD</strong></td>
<td>• <strong>TBD</strong></td>
</tr>
<tr>
<td><strong>5</strong> Self Test (Buchanan, USA)</td>
<td>Whole Blood</td>
<td>Target SSA market</td>
<td>• <strong>TBD</strong></td>
<td>• <strong>TBD</strong></td>
</tr>
<tr>
<td><strong>6</strong> Self Test (Alere, USA)</td>
<td>Whole Blood</td>
<td>Target SSA market</td>
<td>Process development ready by 2015</td>
<td>• Determine</td>
</tr>
<tr>
<td><strong>7</strong> AtomoRapid (AtomoDiagnostics, Aus)</td>
<td>Whole Blood</td>
<td>Target SSA market</td>
<td>In process of obtaining FDA approval</td>
<td>• AtomoRapid</td>
</tr>
</tbody>
</table>

Source: CHAI
TURN NO ONE AWAY
Our new human rights challenge
The share of Lab portfolio varies by country

- Malawi: 4%
- Ethiopia: 9%
- Rwanda: 6%
- Zambia: 5%
- RSA: 15%

Source: ASLM
PMI and PEPFAR Update
PEPFAR Procurement and Quality Assurance of HIV Rapid Diagnostics Tests

Dianna Edgil, PhD
GFATM Malaria and HIV RDT Suppliers Meeting
September 10-11, 2015
PEPFAR’s Evolution
From Emergency Response to Sustainable Impact for an AIDS-free Generation

2003-2007: PEPFAR 1
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Delivering prevention, care and treatment services
Building and strengthening health systems to deliver HIV services

2008-2012: PEPFAR 2
Shift to sustainable response
Shared responsibility and country driven programs
Scaling up core interventions (ART, PMTCT, and VMMC) for impact

2014-2018: PEPFAR 3
Sustainability and shared responsibility
Quality, oversight, transparency and accountability for impact
Accelerating core interventions for epidemic control

A New Era of Accountability, Transparency, and Solidarity to Accelerate IMPACT
Epidemic control PEPFAR 3.0

① Impact agenda

② Sustainability agenda

③ Partnership agenda

④ Efficiency agenda

① Human rights agenda
PEPFAR Figures

Over life of PEPFAR

• 7.7 million on ART
• 6.5 million men received VMMC
• Training to 140,000 new health care workers.

Over FY 2014

• 56.7 million received counseling and testing (FY14)
  – 749,313 received PMTCT
  – 95% were born HIV free
• Care and support for 5 million orphans and vulnerable children
Prioritize Subnational Units
“We are at a critical juncture in the fight against HIV/AIDS. After three decades of hard won progress against the disease the dream of an AIDS-free generation is within our grasp. The good news is that we know what works. We have developed and implemented effective HIV prevention programs and are providing lifesaving treatment to millions of people...around the world.”

Ambassador Deborah L. Birx, US Global AIDS Coordinator
The New Global Health Supply Chain (GHSC) Program

1. Procurement & Technical Assistance Single-Award IDIQ
2. HIV RTK Procurement Remote Medical International
3. Technical Assistance Axios Chemonics LMI PwC
4. Quality Assurance FHI 360
5. Business Intelligence and Analytics IntelliCog
6. Research and Innovation Award
A New Era of Accountability, Transparency, and Solidarity to Accelerate IMPACT

Number of patients tested by PEPFAR-funded programs

Millions

Number of Patients Tested

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Patients Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>7 million</td>
</tr>
<tr>
<td>2007</td>
<td>10 million</td>
</tr>
<tr>
<td>2008</td>
<td>18 million</td>
</tr>
<tr>
<td>2009</td>
<td>25 million</td>
</tr>
<tr>
<td>2010</td>
<td>30 million</td>
</tr>
<tr>
<td>2011</td>
<td>35 million</td>
</tr>
<tr>
<td>2012</td>
<td>40 million</td>
</tr>
<tr>
<td>2013</td>
<td>50 million</td>
</tr>
<tr>
<td>2014</td>
<td>60 million</td>
</tr>
</tbody>
</table>
SCMS Lab Procurements: 2014

SCMS Delivered Value 2014
Selected diagnostic areas

- Flow Cytometry (CD4), $26.5, 35%
- HIV RDT, $41.7, 56%
- Molecular (Viral load), $6.9, 9%
Procurement Criteria for HIV Rapid Test Kits

- Must be included on national HIV testing algorithm or on national list of approved tests for country of use
- Must be registered in country of use
- Must meet USAID approval criteria


1. FDA-Approved
2. WHO Prequalified / CDC Evaluated
3. USAID-Evaluated (For Priority HIV or Non-HIV Diagnostics)

USAID List of Approved HIV/AIDS Test Kits is found at

Alignment with WHO PQ (Sept. 2014 - present)

• Revised HIV rapid test kit (RTK) approval process:
  – to avoid duplication of efforts
  – to develop a harmonized list for country decision-making

• Aligned Process:
  – Submit a pre-submission form to WHO PQ. See following link: [http://www.who.int/diagnostics_laboratory/evaluations/Application/en/](http://www.who.int/diagnostics_laboratory/evaluations/Application/en/)
  – A product dossier will be requested by WHO for review and approval;
  – WHO will schedule a manufacturing site inspection;
  – CDC will perform the technical evaluation as per protocol. (Note: This step can proceed in tandem with the inspection.)

• An RTK meeting all three requirements (dossier review, site inspection, technical review) will be approved by USAID and appear on the WHO PQ list.

• An FAQ providing further information on these changes is in process
Further Requirements for Manufacturers

1. USAID will publish the evaluation results for all submitted RTKS.
2. USAID may re-evaluate any approved test kit (est. 3-5 years).
3. USAID requires written notice within 30 days and prior to supplying an approved test of:
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   – Any change in manufacturing or component manufacturing sites;
   – Any service bulletins, safety notices, recall notices, etc.
4. USAID will be provided with the results of site inspection(s) by a 3rd party performed at any time during or after the approval process.
5. For submitted or approved products, USAID may inspect or participate in site inspections of the Manufacturer’s facilities and/or any component facilities.
6. For approved products, USAID will be notified of any possible counterfeiting, piracy, or unauthorized sales by third parties of any test.
Alignment with GF

- Difference: CE Marking not acceptable for procurement
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- PEPFAR will participate in the ERP-D to inform procurement decisions
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- Initiated PMS for all procurements (SCMS) for PEPFAR programs in 2010.
  - Test every lot procured upon entry into country of use
  - Sample size: 60 tests per lot
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  - UMD performs testing; failed lots confirmed by CDC
- Under GHSC-QA, FHI360 will continue lot testing
  - Sampling and testing policy under review
- GHSC-QA will maintain a passive, online reporting system
A New Era of Accountability, Transparency, and Solidarity to Accelerate IMPACT

Thank You!

USAID:
Vincent J Wong, MSc
Email: vwong@usaid.gov

Dianna Edgil, Ph.D.
Email: dedgil@usaid.gov

CDC:
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Email: bparekh@cdc.gov
$755 million worth of health commodities supplied to 38 countries

- ARV* (55%)
- LAB (20%)
- DRUG (6%)
- TEST (10%)
- MC (6%)
- OTH (3%)

* 95% generic formulations
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The Global Fund E-Marketplace
Objectives, Approach, Timeline and Supplier Requirements

Kivanc Cubukcu, Global Fund
Developing the e-Marketplace of the future
Supplier update

September 8th, 2015
Agenda

• e-Marketplace introduction and current status
• Changes in the procurement process
• Next steps and questions
The e-Marketplace is an online platform that allows buyers to enter and process orders in a highly automated and transparent manner.

- Search and compare products, lead-time, quality across products
- Increased market transparency
- Select desired specifications, order terms and place order
- Implementers more autonomous in decision-making
- Track and trace order, direct payment
- Automation and acceleration

In the initial phase, e-Marketplace is designed to provide an automated solution of the PPM process of the Global Fund.

SOURCE: Project team
**The e-Marketplace can streamline and accelerate procurement processes for PRs through 3 mechanisms**

The e-marketplace offers 3 **procurement mechanisms** to cover the procurement spend of The Global Fund.

<table>
<thead>
<tr>
<th>E-marketplace mechanisms</th>
<th>Description of mechanisms</th>
<th>Selected examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>e-ordering from LTAs</strong></td>
<td>• Electronic ordering process leverages internal catalogues that are the result of Global Fund tenders (e.g. selectable items based on LTAs)</td>
<td>LLINs, ACTs, ARVs, Malaria/HIV diagnostics</td>
</tr>
</tbody>
</table>
| **e-catalogues**         | • Electronic ordering process leveraging external catalogues that reflect items and prices agreed with The Global Fund  
                           • Standard specifications & competition driven prices of products | Vehicles, laboratory supplies, condoms, TB diagnostics |
| **e-RFQs and e-auctions**| • PR managed electronic quotation process for products and services that can be accompanied by e-auctions allowing real-time bidding visible to all suppliers | Non-core drugs |

**SOURCE:** Project team
In all phases of the e-Marketplace there is a wide range of benefits to buyers, suppliers and partners at a global scale

- **e-Marketplace will improve the efficiency of the procurement process** by streamlining & standardizing processes, increasing the quality of requests and more transparent communication.

- **Increased market visibility and decrease transaction costs**.

- **PRs do not need to build up complex and costly procurement systems**.

- **Number of manual processes limited and lead times of the ordering process shortened**.

- **Access to new innovative products will be facilitated** as new suppliers and innovative product are added to the e-MP.

- **All suppliers on the platform will be screened** by the organization to ensure they meet our quality assurance policy for health products.

- **e-Marketplace will leverage LTA conditions and reduced prices** other products like PCs and vehicles will be available at competitive prices as well.

**SOURCE:** Project team
The e-Marketplace is a voluntary platform for all PRs of the Global Fund

- The e-Marketplace is planned to be launched in Q1 2016, starting with e-order from LTA and followed by e-catalogue and e-RfQ/e-auction sequentially throughout 2016
- The e-Marketplace will be available for current PPM PRs and non-PPM PRs of the Global Fund. A staggered approach to enrollment of PRs will be taken
- In the initial phase, the e-marketplace will serve to automate existing PPM processes
- The e-Marketplace will be spun-off as a separate entity (not before H2 2017) – during the transition phase (until spin-off), e-marketplace will be available for TGF funds only

SOURCE: Project team
e-Marketplace will launch with LLINs in Q1 2016, followed by ACTs, diagnostics, ARVs, condoms, and vehicles

<table>
<thead>
<tr>
<th>Category launch prioritization</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Q1</td>
<td>Q2</td>
</tr>
<tr>
<td><strong>e-order from LTA</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- LLINs (Bed nets)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ACTs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Diagnostics – Malaria (RDTs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ARVs</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>e-order from catalogues</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Condoms and vehicles</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>e-RFQ/e-auction</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1Additional product categories which could be included in the 2016 launch could be diagnostics for HIV, Malaria and TB

SOURCE: Project team
Agenda

- e-Marketplace introduction and current status
- Changes in the procurement process
- Next steps and questions
Implementation of the e-Marketplace as the Global Fund’s main procurement tool will not change key processes for you as a supplier

<table>
<thead>
<tr>
<th>Process</th>
<th>Current</th>
<th>e-Marketplace</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTA negotiations &amp; demand forecast</td>
<td>• PPM negotiating LTAs and forecasting yearly demand^1</td>
<td>• No changes</td>
</tr>
<tr>
<td>Order management</td>
<td>• PSA issues PO to suppliers (manufacturer + logistics) and manages orders</td>
<td>• No changes</td>
</tr>
<tr>
<td>Claim management</td>
<td>• Claims managed by the PSA in alignment with PPM</td>
<td>• No changes</td>
</tr>
<tr>
<td>Invoicing &amp; Payments</td>
<td>• Invoices will be provided to and paid by the PSA</td>
<td>• No changes</td>
</tr>
<tr>
<td>Reporting</td>
<td>• Order data is made available through the PSA</td>
<td>• Historic order data is available electronically in the eMP</td>
</tr>
</tbody>
</table>

The PSA will still remain the entity through which the supplier interactions occur

---

1 Country teams at grant level, aggregation by Sourcing team
Agenda

- e-Marketplace introduction and current status
- Changes in the procurement process
- Next steps and questions
Global Fund Procurement Strategy and Supplier Engagement

Martin Auton, Aziz Jafarov: The Global Fund
Background and introduction

This presentation defines the proposed supplier engagement strategy for RDTs for malaria and HIV.

It considers the current market, lessons learned and potential future developments.

From these an engagement model is proposed that manages the transition from the current position to one where there is increased transparency, more competition and better products.
Our approach to developing a Sourcing Strategy

A connected process to maximise value (which is not limited to purely cost)

UNDERSTAND

Going to the real places, meet the stakeholders & understanding the facts.

DESIGN

Defining a set of objectives based on findings & designing an approach to deliver them

ENGAGE

Designing tenders to meet our objectives

MANAGE

Working with suppliers to drive continuous improvement
The analysis phase
A structured, fact based diagnostic that evaluates 4 sets of criteria

The Product, it’s cost structure and market dynamics
- In depth analysis of API / FF; packaging and country specific requirements.
- Understanding of relative drivers, supply chain integrity and volatility

The Supply base, their capabilities and challenges
- On site analysis with face to face discussions
- Provides insight to supplier strategy, commitment and issues

The demand profile and opportunities for partner alignment
- Reliable and up to date demand forecast through PPM countries;
- Coordination of demand across agencies; partnering where objectives and legislative processes permit

Historical challenges and future direction
- Learning from the past to avoid previous mistakes
- Understanding the future development path to ensure our strategy is aligned
The analytical approach

We adopted a combined approach across Malaria and HIV in an analysis that contained a number of elements

- Visits to manufacturers that account for more than 80% of the combined U$80m PPM spend a year
- Close engagement with partner agencies and WHO on quality and demand
- Multiple opportunities for suppliers to provide feedback
Global Fund Historic Demand and Future Forecast 2016-2017: Malaria
Global Fund (PPM) - P.f. an combo Malaria RDTs prices 2010-2014
Demand and Regulatory Analysis: Malaria

1. More harmonisation is needed in operational characteristics.

2. Lack of end user confidence.

3. Two forms of pre-approval predominate, PQ likely to become the standard.

1. Current packaging formats seem to drive increased wastage

2. Large volumes procured with opportunities for supply chain efficiency.

3. Demand pattern not supported by technical advice.
Market Share: Malaria

Total of six suppliers supplied through PPM mechanism

The market is dominated by three suppliers

The combined volumes for the three main suppliers is over 99%

- Access BIO, L.C.
- Premier Med. Corp Ltd.
- Standard Diagnostics
- Others
Historic demand: HIV

WHO 2014

- 150 million people tested resulting in more than 3 million people being diagnosed with HIV
- Estimated 51% people with HIV know their status

Global Fund

- Low level of reporting into PQR of non-PPM Global Fund volumes
- PPM volumes show significant growth since 2010 to almost 50 million tests in 2015
**Future demand: HIV**

**UNAIDS:** 90% of all people living with HIV to know their status

**WHO:** volumes will increase by 35-45% between 2013 and 2018

*WHO forecast of global demand for 2014–2018; July 2015*
Demand and regulatory analysis: HIV

1. Testing strategies and algorithms are complex to establish, update and implement

   • 2/3 of testing strategies not aligned to WHO guidelines
   • Misdiagnosis not infrequent in some settings
   • Limited re-validation – same algorithm for a decade
   • Infrequent re-testing before ARV initiation
   • Not all tests always available for testing strategy
Demand and regulatory analysis: HIV (contd)

2. Need for innovation – including: sensitivity/specificity; ease of use; design, shelf life; lay and self-testing; linkages to care

3. Most GF-eligible WHO prequalified; others in PQ process and/or CE/FDA

4. Two HIV RDTs have had procurement eligibility removed in the last 4 years

5. Not all innovations are all positive, some downsides
Market share and pricing: HIV

- Highly concentrated demand with around 7 main suppliers for many years
- Pricing ranging from USD 0.5 – 1.60/test depending on brand

Number of manufacturers (procurement data analysis)

<table>
<thead>
<tr>
<th>Year</th>
<th>Manufacturers</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>7 manufacturers</td>
<td>UNITAID</td>
</tr>
<tr>
<td>2010</td>
<td>9 manufacturers; 7 with &gt; 100,000 tests/year</td>
<td>UNITAID</td>
</tr>
<tr>
<td>2014</td>
<td>12 manufacturers; 7 with &gt; 100,000 tests/year</td>
<td>Global Fund PPM</td>
</tr>
</tbody>
</table>
Supply market analysis: combined

1. Many suppliers not participating (for whatever reason) limiting competition and introducing supply security risks

2. Limited number of tests “available” considering testing strategy needs a series of 3 different tests for HIV.

3. Even within participating manufacturers there is significant over capacity

4. Majority of manufacturing is in high cost locations and some distance from the majority of customers. This, combined with short shelf lives increases cost and risk of wastage

5. Inconsistent product offerings and pricing requiring ad-hoc negotiations

6. Distributor model can add complexity and sometimes substantial cost
**Supplier feedback: HIV**

**HIV Diagnostic Manufacturers Engagement, Geneva, September 2014**

*Product quality assurance requirements:*
- Regulatory complexity is increasing and country registration requirements are limiting penetration

*WHO guidance*
- WHO guidance issued but further communication are needed for some aspects

*Product selection and placement guidance*
- Current selection policy sufficient but issues of non compliance

*Forecasting and order visibility*
- Need better forecasts with improved granularity by country

*Laboratory system capacity and quality of testing*
- Need greater support to infrastructure and training programmes

*Logistics*
- Pickup challenges; would like opportunities to quote different incoterms including freight
Our summarised findings
A commonality of issues across Malaria and HIV confirms a common approach.

Malaria

- Brand specific demand
- Demand profiles probably lead to high wastage
- Little harmonization (despite efforts)
- Perception of test reliability
- Changes to product qualification

HIV

- Complex Testing Algorithms

Demand

- Supply

Significant over-capacity in manufacturing sector

More Competitive

- Less Competitive

New Technology

Very short shelf life

Small number of suppliers predominating- supply chain risk
Our Analysis of What is Required

Supporting Optimal Product Selection
- Improved guidance and (public) visibility of information on selection & implementation
- Greater understanding of similarities vs. differences
- Packaging and labelling simplification & improvements

Establishing a Supplier Engagement Model
- Establish direct contracts
- Agree targets for continuous improvements
- Regular performance measurement and review including with partners

Quality and regulatory
- Refine, strengthen and/or clarify QA eligibility and product selection guidance (as appropriate)
- Country registrations

Drive innovation to meet program needs & targets
- Design improvements and new products to support
  - implementation of WHO recommendations
  - achieving coverage targets
  - combination testing
  - linkages to care and treatment
  - value specialist products

Understand total cost of acquisition
- Cost reduction through design improvements and efficiencies
- Standardization & transparency in distribution models and costs
- Encouraging lower cost manufacture and supply of RDTs and accessories
- Broadening the supply base to increase the competitive dynamic
Our priorities in Phase 1 (2016)

Supporting Optimal Product Selection
- Improved guidance and (public) visibility of information on selection & implementation
- Greater understanding of similarities vs. differences
- Publishing product level information
- Packaging and labelling simplification & improvements

Establishing a Supplier Engagement Model
- Establish framework agreements
- Agree targets for continuous improvements
- Regular performance measurement

Understand total cost of acquisition
- Identification of those aspects where the Global Fund will request partner support or implementation
- Cost reduction through design improvements and efficiencies
- Standardization & transparency in distribution models and costs
- Encouraging lower cost manufacture and supply of RDTs and accessories
- Broadening the supply base to increase the competitive dynamic
- Recognize the value of interchangeability

This approach will be based on collaboration other major buyers and partners”
Our approach to implementation

To achieve our objectives in phase 1 we will undertake a series of activities.

*Phase 1 By Q3 2016*

<table>
<thead>
<tr>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issue a tender for all products</td>
</tr>
<tr>
<td>Establish Framework Agreements with panel suppliers through an evaluated tender process.</td>
</tr>
<tr>
<td>Implemented programs to increase customer awareness and drive informed decisions on selection and procurement</td>
</tr>
<tr>
<td>Contract reviews based on quality, delivery (OTIF) and cost/price performance</td>
</tr>
<tr>
<td>Issued an RFI to support information gathering to support selection and procurement decisions including price, specifications, performance etc</td>
</tr>
<tr>
<td>Commence performance monitoring</td>
</tr>
</tbody>
</table>

Phase 2 objectives will be agreed by the end of Q1 2017
A Diagrammatic Representation

- **Single Tender**
  - Some disease specific evaluation criteria

- **Customer Awareness Programme**

- **Freight Strategy Implementation (separate)**

- **Request for Information**
  - Q1 2016
  - Malaria
  - HIV
  - Evaluation

- **Selected Panel Suppliers**
  - Framework Agreements
  - Phase 1

- **Performance Assessment and Development Evaluation**
  - Q1 2017
  - Phase 2

**Timeline**
- Q1 2016
- Q1 2017
Influencing the demand dynamics: Malaria and HIV

- Refine and strengthen Global Fund selection and procurement guidance, requirements and tools
- Publication of product information to guide optimal selection and implementation
- Recognize value of interchangeability
The initial tender

Currently targeted to be issued end Q1 2016

Responses will be required on pre-formatted templates and will include a requirement for cost breakdowns.

Evaluation criteria will be published in the tender

Initial workshops to define Phase 2

Phase 2 Development targets will be agreed during Phase 1.
Framework Agreements

Framework Agreement Key Elements:

1. Direct with the Global Fund

1. Duration 2 years

2. Quarterly Reviews to monitor progress

3. Performance Management

1. Process to include new suppliers

2. Draft copies will be issued with initial tender
Other technical and ethical considerations

As part of its strategy to ensure ever increasing standards of business the Global Fund will require RDT suppliers to participate in Social and Environmental Assessments.

These will be conducted by a third party and will assess suppliers’ policies, controls and standards in a range of areas.

The assessment results will contribute to the formulation of Phase 2.
Suppliers will be Expected to work in new Ways

- Suppliers will be expected to work with us in new ways.
- Change will be long term we will expect commitment.

- We will require openness and transparency.
- We will for detailed cost breakdowns.
- We will respect the confidentiality of this information.
- We expect the highest standards in business behaviour.

- We will expect suppliers to be pro-active.
- We want to make use of supplier expertise.
- Where appropriate we will reward new innovations and technical developments.

- Performance will be Managed.
- Performance will become a differentiator.
- Quality and delivery will be the initial indicators.
- We will also be commencing assessments of social and environmental performance.
A Tentative Timeline

- Supplier Conference
- Tender Issue
- Framework Agreements Signed
- Review/Implementation of Phase 2

Tender Preparation
- Responses Prepared and Submitted
- Tender Evaluation and Panel Supplier Selection

Phase 1

Timeline:
- 2015
  - Sep
  - Nov
  - 2016
  - Mar
- 2016
  - May
  - Jul
  - Sep
  - Nov
- 2017
  - Sep
  - Nov
  - Mar
Thankyou.
### Working definition of a healthy market harmonized with UNITAID

**Applies to markets for medicines or technologies to effectively prevent, diagnose or treat a disease or condition.**

Need to assess dynamics, potential trade-offs and set priorities in a given market.

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Description of healthy market</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Innovation</strong></td>
<td>• There is a robust pipeline of new products, regimens or formulations intended to improve clinical efficacy, reduce cost, or better meet the needs of end users, providers or supply chain managers</td>
</tr>
<tr>
<td><strong>Availability</strong></td>
<td>• New and/or superior evidence-supported, quality-assured products are rapidly introduced in the market and made available to those in LMICs. Adequate and sustainable supply exists to meet global needs</td>
</tr>
<tr>
<td><strong>Demand and adoption</strong></td>
<td>• Countries, providers (e.g., healthcare providers, retailers) and end users rapidly introduce and adopt the most cost-effective products (within their local context)</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td>• Products are available at an internationally recognized standard of quality and there is reliable information on the quality of the product. This includes not only the quality of the final, finished product, but also the quality of starting and intermediary materials¹</td>
</tr>
<tr>
<td><strong>Affordability</strong></td>
<td>• Products are offered at the lowest possible price that is sustainable for suppliers and does not impose an unreasonable financial burden on governments, donors, individuals or other payers</td>
</tr>
<tr>
<td><strong>Delivery</strong></td>
<td>• Supply chain systems (including quantification, procurement, storage and distribution) function effectively to ensure that products reach end users in a reliable and timely way²</td>
</tr>
</tbody>
</table>

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¹ For the Global Fund, this is operationalized through the existing Quality Assurance Policies.
² For the Global Fund, issues related to Delivery are typically handled by Health Product Managers in the Grant Management Division. This area is also being addressed through a supply chain strategy currently in development.