

Global HIV Diagnostic Working Group

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Why a need for such a Working Group?

- Faced with **several problems related to the quality of RDTs** along the procurement pathway, several agencies decided to share QA concerns and approaches
- **Diversity** of QA strategies among stakeholders
- **Little communication** among stakeholders and between stakeholders and manufacturers
- **Informal and irregular interactions between stakeholders** were not productive enough

Feedback to manufacturers (2012)*

Procuring quality HIV Diagnostic Tools

Meeting with manufacturers, implementers and agencies

31st January 2012 The Global Fund - Geneva

1. Agencies/QA programs are **communicating** and collaborating among themselves
2. **Quality Assurance of MD is fundamental** to provide proper medical care, as well as for sustainability of testing programs
3. **Unequivocal identity** for products/ **Traceability** and **transparency** for products need to be assured
4. **Proactive** communication/notification from manufacturers on changes is expected
5. **Trust** is fundamental (agencies, programs, manufacturers)
6. Recognition from our side: we need (agencies/programs) to clearly communicate available procurement data/ to provide more precise data on forecasting

** From MSF, WHO-DLT, USAID/PEPFAR/CDC, SCMS/PFSCM, UNICEF, The Global Fund*

Following step:

- **Need**

- to increase communication and harmonized approaches on QA but also on additional areas : procurement, market dynamic, communication with manufacturers /with countries
- to involve a wider range of partners

- In February 2013 the first meeting lead to the launch of the

HIV Global Diagnostic Working Group (GDWG)

A forum to share information and to align actions and communications with respective constituencies.

Goal of the GDWG

To **promote** communication, collaboration and coordination

- for equitable access to affordable, **quality-assured** IVDs
- for more effective diagnosis of HIV infection and management of HIV-related disease in developing countries.

Objectives

The GDWG has five main objectives

1. To strengthen communication, collaboration & 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

Membership

Member organizations meet **all** of the following criteria:

- **Involvement in and commitment to international QA standards** for product market entry, selection, assessment, procurement, delivery and use
- **Global or regional mandate/involvement in HIV-related IVDs**
- **Expertise in IVD market dynamics**
- **Without any conflict of interest** with the objectives of the group
- **Committed to reciprocity**: the organization should be able to contribute to the goals of the group

Current members

- African Society for Laboratory Medicine (ASLM)
- Centre for Disease Control (CDC)
- The Bill and Melinda Gates Foundation (BMGF)
- The Clinton Health Access Initiative (CHAI)
- The Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM)
- Médecins sans Frontières (MSF)
- President's Emergency Plan AIDS Relief (PEPFAR)
- United Nations Children's Fund (UNICEF)
- UNITAID
- USAID
- World Health Organization (WHO) – Pre-qualification of *in-vitro* Diagnostics Program and HIV Department

Ad hoc Invitees : for specific sessions, based on need for technical input

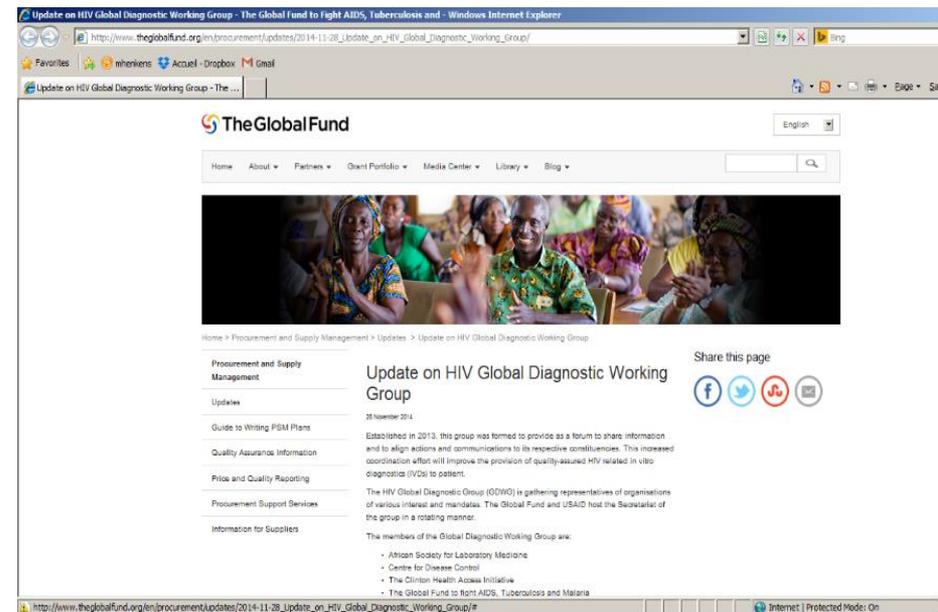
- Regulatory bodies
- Manufacturers
- Procurement service agents
- Other relevant expertise

Outcomes

- A. Improved communication between member agencies
- B. Increased exchange of critical information on products
- C. Move to alignment of QA policies

Web page currently hosted by the GFATM

http://www.theglobalfund.org/en/procurement/updates/2014-11-28_Update_on_HIV_Global_Diagnostic_Working_Group/



Next steps include:

- Continuation of ERPD implementation
- Development & implementation of tools for selection and procurement
- Creation of a repository for guidance and technical documents for country programs
- Definition of GDWG's role vis a vis DAI and collaborate accordingly
- Improvement of GDWG website to be hosted in an independent manner (not hosted by a specific agency)

- Thank you to all working group's members and especially to the Secretariat for the support in preparing this presentation on behalf of the whole group
- Thank you for your attention
- Questions should be addressed to all group's members.

