



Overview of the Global Laboratory Initiative (GLI) Working Group

Dr Rick O'Brien (FIND)
Chair, Global Laboratory Initiative WG

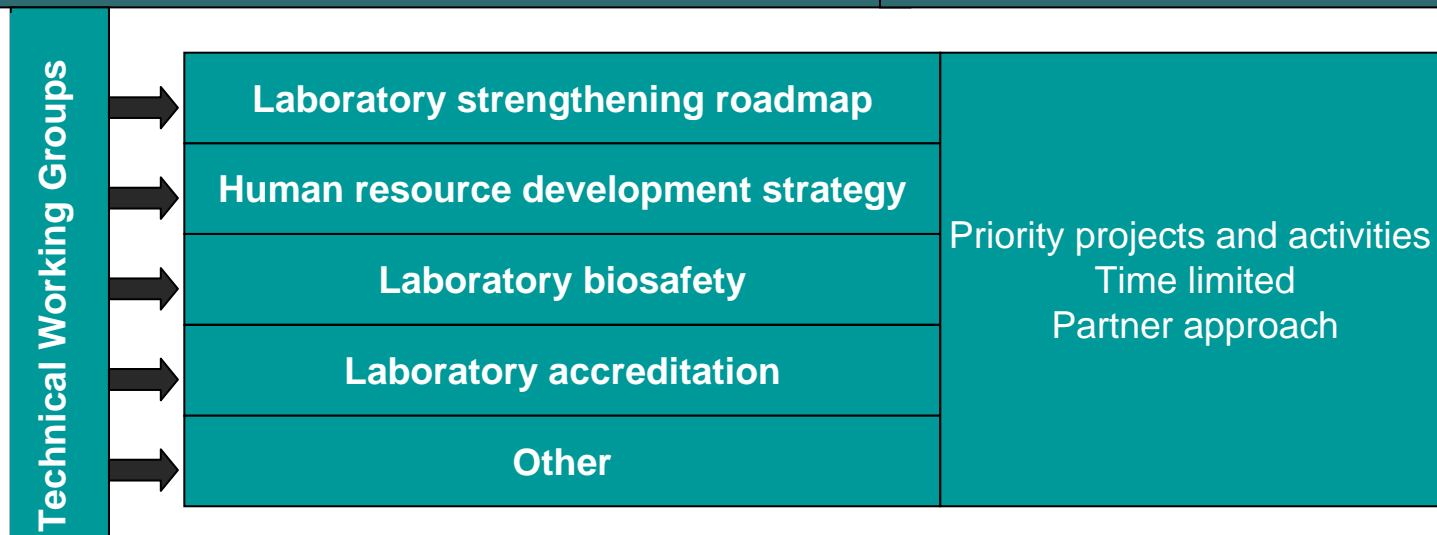
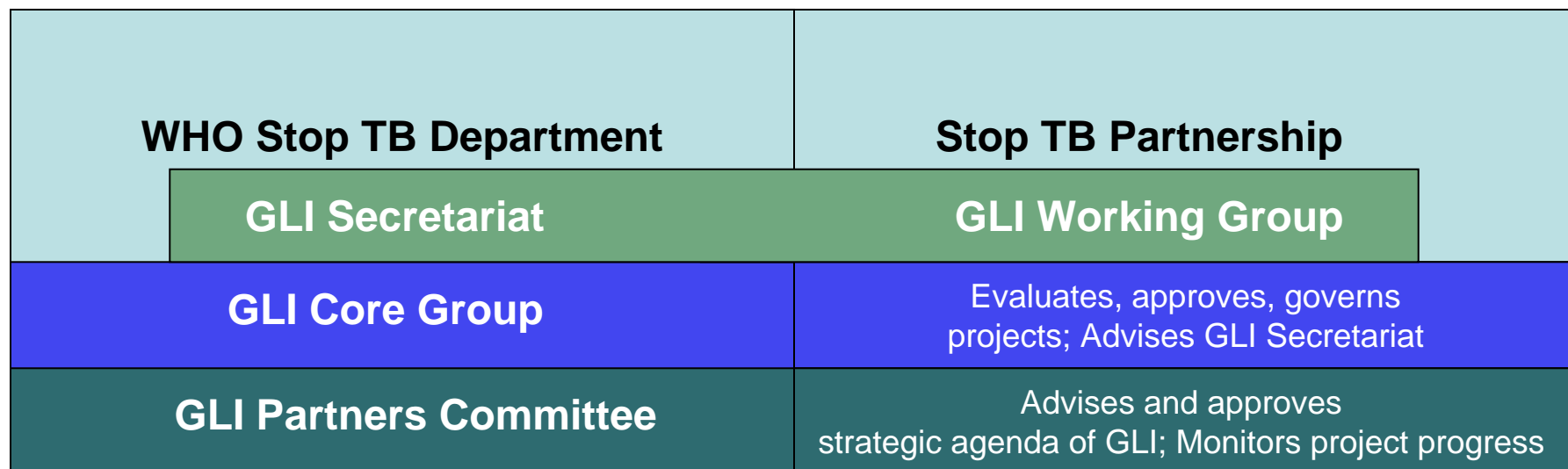
FIND and Partners Forum
Berlin, 12 November 2010



Stop TB Partnership Workgroups (WG)

- DOTS Expansion WG
- TB/HIV WG
- MDRTB WG
- New Diagnostics WG
- WG on New TB Drugs
- WG on New TB Vaccines
- Global Laboratory Initiative WG (Nov 08)

GLI structure & governance



GLI Core Group

- **Chair - Rick O'Brien**
- **WHO Secretariat – Chris Gilpin/Karin Weyer**
- **CDC – Tom Shinnick (Vice-Chair)**
- **Union – Armand Van Deun**
- **FIND - Vacant**
- **PEPFAR – John Nkengasong (CDC/GAP)**
- **USAID – Amy Piatek**
- **Civil society – Vijay K. Gupta/Tom Otwoma**
- **Satoshi Mitarai (NTP/NRLJapan)**
- **Dick van Sooligen (NTP/NRL Netherlands)**
- **Marie Alice Telles (NTP/NRLBrazil)**
- **Rumina Hasan (Pakistan)**
- **Past Chair - John Ridderhof**
- **Observers**
- **Liaisons with other WGs**

GLI Partners

- American Society for Microbiology (ASM)
- Association of Public Health Laboratories (APHL)
- Bill & Melinda Gates Foundation
- Centers for Disease Control and Prevention (CDC)
- CDC Global AIDS Programme (GAP)
- Fondation Merieux
- Foundation for Innovative New Diagnostics (FIND)
- International Union Against TB and Lung Disease
- PEPFAR
- USAID
- KNCV
- Merieux Alliance
- Management Sciences for Health (MSH)
- Mediciens Sans Frontiers
- Stop TB Partnership Working Groups (New Diagnostics, MDR-TB, DOTS Expansion/INAT)
- National TB Programmes
- WHO
- UNITAID
- *and growing...*



Global Laboratory Initiative

Platform of coordination and communication, providing the required infrastructure, focused on TB laboratory strengthening, in the areas of:

- Global policy guidance (norms, standards, best practices)
- Laboratory capacity development
- Interface with other laboratory networks, enabling integration
- Standardised laboratory quality assurance
- Coordination of technical assistance
- Effective knowledge sharing
- Advocacy and resource mobilisation

STP-GLI as an active facilitator of communication and provider of global infrastructure services synchronized to be a coherent network service

Key STP-GLI activities

Guidance

- Laboratory policies
- Laboratory manuals
- Training materials
- Resource mobilization
- National roadmap advice

Assurance activities

- Coordination of EQA
- Equipment specifications
- Global accreditation system
- Monitoring/evaluation

~100.000 smear lab centers
200.000-300.000 personnel

~8.000 advanced diagnostic centers
40.000 – 50.000 personnel

150 National Reference Labs

70 GLI Members

WHO GLI Office

7 STP WGs

Technical Agencies

Other Laboratory Networks

Other Diseases

Knowledge Sharing

- Coordinating TA, training
- Communication technologies
- Online knowledge resource network

Interface Connection

- Matchmaking projects between countries and implementing partners
- National “roadmaps”
- Advocacy
- Other disease networks

Capacity building

(expanding SRLN, building diverse and flexible national, regional, international consultants base, systematic and structured training)

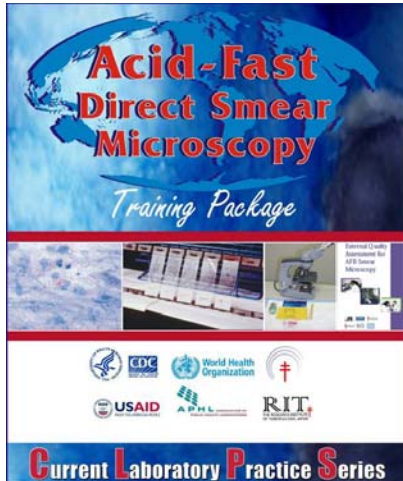
GLI strategic priorities

- Accelerating evidence-based policy development on diagnostics and laboratory practices
- Promoting a structured framework/roadmap for TB laboratory strengthening within the context of national laboratory plans at country level
- Developing a comprehensive set of tools, norms and standards based on international standards and best-practice
- Advancing laboratory strengthening through global, regional and local partnerships
- Developing multi-level laboratory human resource strategies to address the capacity crisis
- Accelerating new diagnostics into countries

GLI Projects are run on behalf of GLI, and adhere to a collaborative spirit

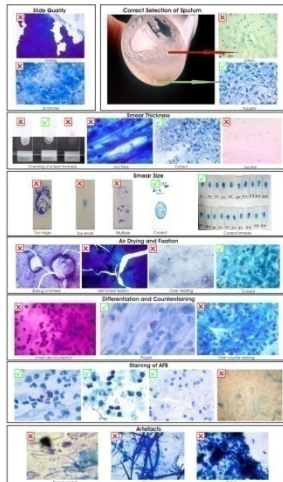
- Aligned with strategic agenda and priorities
- Complementarity with other projects
- Liaison to GLI secretariate established
- Project review process established
- Adequate partner representation requirements satisfied
- Information networks utilized

GLI Guidance, Tools, Programs



Quality Issues of AFB Smear Preparation and Staining Technique

- Important:
- 1) Always use good quality stains, chemicals, reagents, and new slides.
 - 2) Prepare and label staining solutions to pre standard operating procedures.
 - 3) Verify quality and maintain the record.
 - 4) Store all stains, chemicals, reagents, and solutions under appropriate conditions.
 - 5) Discard expired stains, chemicals, reagents, and solutions.



External Quality Assessment for AFB Smear Microscopy



TB CAP Toolbox

TB CAP Laboratory Tools

- [Introduction TB CAP](#)
- [Acknowledgements](#)
- [Introduction Laboratory Tools](#)
- [Overview of Laboratory Tools](#)

The Global Health Metrics, Office of Health, Infection, Disease and Nutrition (OHID), US Agency for International Development, financially supports the TB CAP through TB CAP under the terms of Agreement No. GHS-A-00-05-00037-00.

This media product is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of TB CAP and do not necessarily reflect the views of USAID or the United States Government.



Recent WHO laboratory policies



- Automated liquid culture and DST (2007): Use of liquid culture systems in the context of a comprehensive country plan for strengthening TB laboratory capacity; in a phased manner starting at [national/central reference laboratory level](#)
- Rapid speciation (2007): Strip speciation for rapid *Mycobacterium tuberculosis* from non-tuberculosis mycobacteria; established at [regional or central reference laboratory level](#) in combination with liquid culture
- Line probe assays (2008): Use of line probe assays for rapid detection of R resistance within the context of country plans for MDR-TB management, including development of country-specific screening algorithms and timely access to quality-assured second-line anti-tuberculosis drugs; do not eliminate the need for conventional culture and DST capability; should be phased in, starting at [national/central reference laboratory](#) or those with proven [molecular capability](#)
- Second-line drug susceptibility testing (2008): Reliable and reproducible for injectables and fluoroquinolones; to be conducted in [supranational or national/central reference laboratories](#) using standardised methodology and drug concentrations
- LED microscopy: (2009) alternative for fluorescence and conventional light microscope
- Selected non-commercial culture and DST methods (2009-2010) not alternatives for gold standards, but may provide interim solution
- Available at: <http://www.who.int/tb/dots/laboratory/policy/en/print.html>

2010 - Cepheid Gene Xpert

2010 - Serodiagnostics

2010 - Molecular testing for second line DST (deferred)

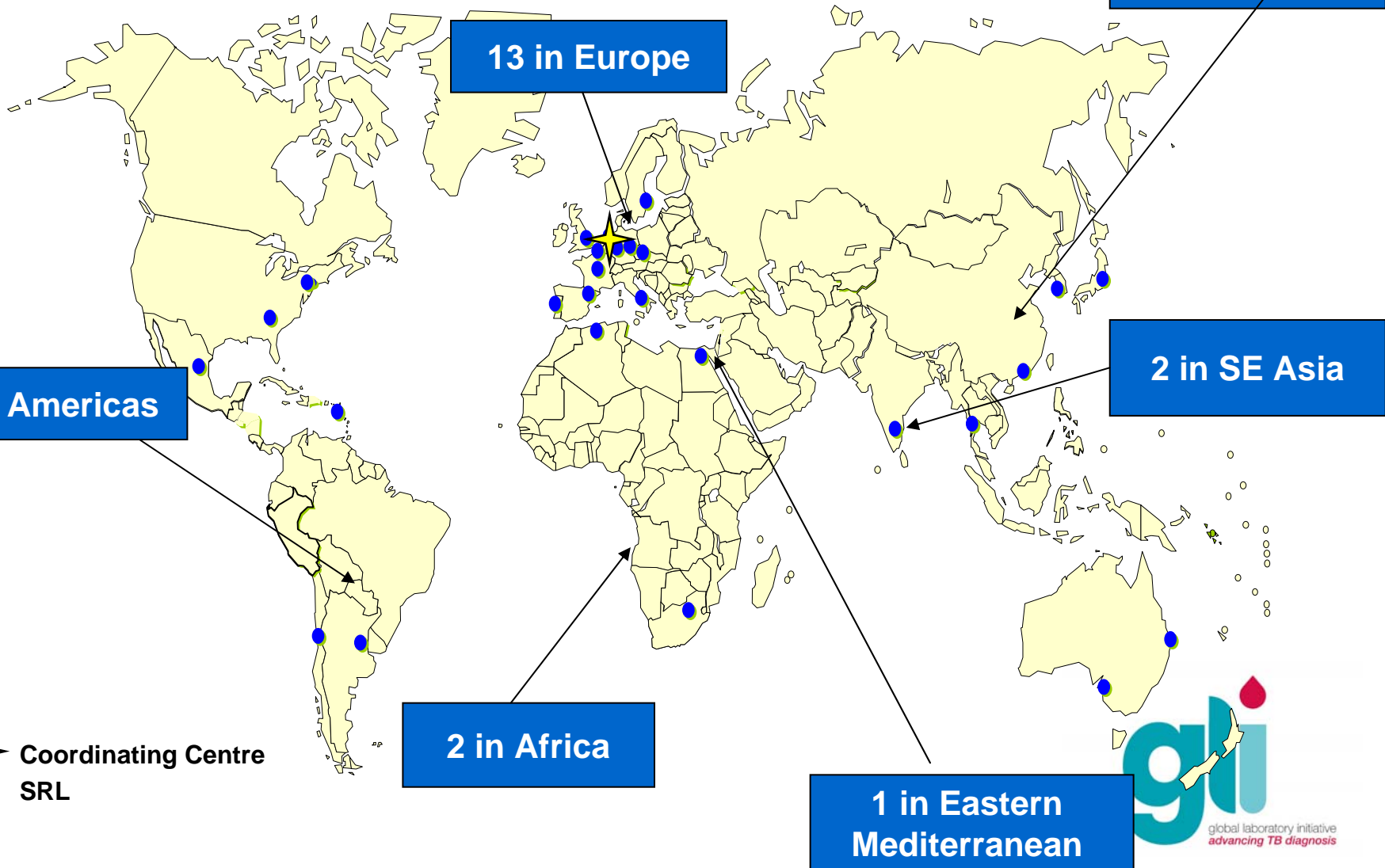
2010 - IGRAs







SRLN

TB SUPRANATIONAL REFERENCE LABORATORY NETWORK



 Coordinating Centre
 SRL



Roadmaps for TB Laboratory Strengthening

Assuring effective policies and plans for TB diagnostics strengthening are included in system-wide plans

**Guidance for Development of
National Laboratory Strategic Plans**

Produced with the collaboration of:

WHO-AFRO
WHO-GENEVA
U.S. Centers for Disease Control and Prevention
The Association of Public Health Laboratories
The American Society for Clinical Pathology
The Bill and Melinda Gates Foundation
The Clinton Foundation
The Global Fund

Harmonization of Global Support for Laboratory Strengthening

October 28-30, 2009
Atlanta, Georgia USA

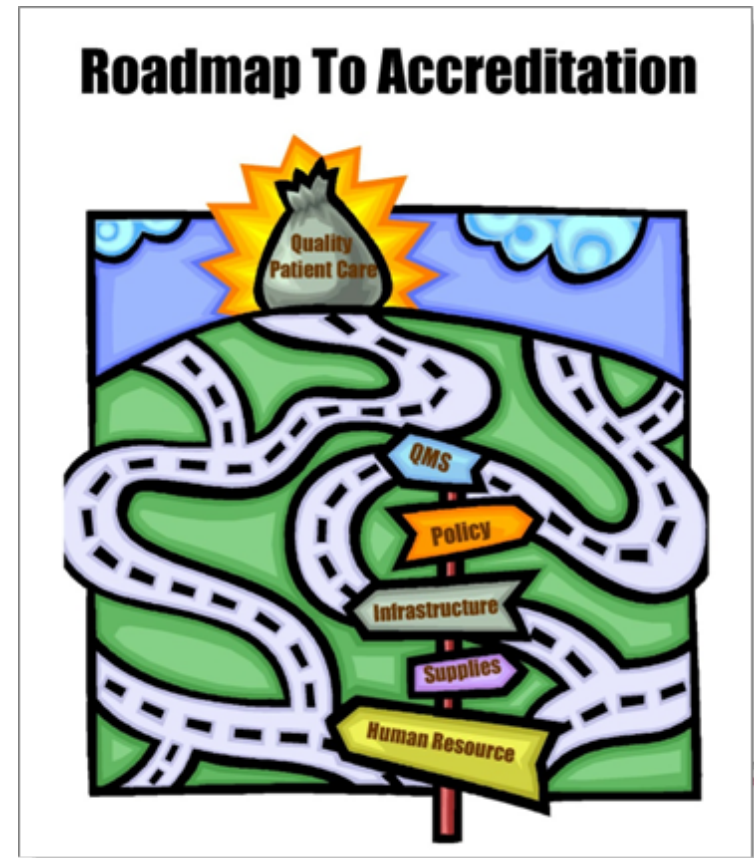
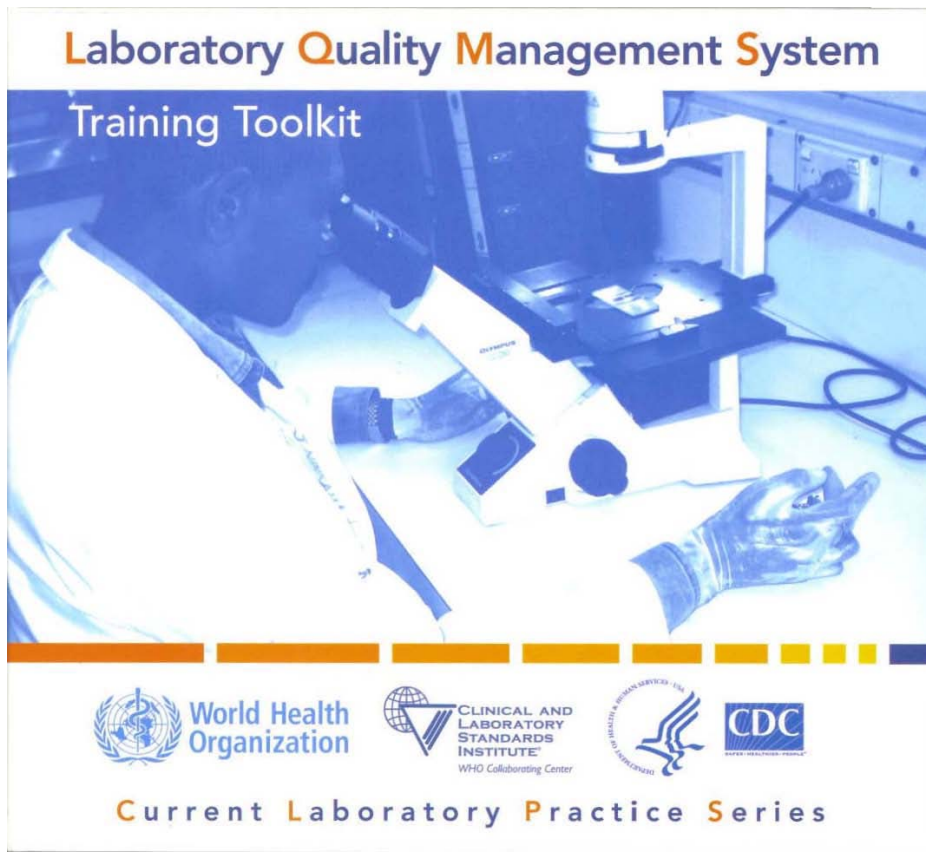
Purposes of Meeting:

1. To consider strategies and a framework for harmonizing approaches by international partners in their efforts to strengthen laboratory capacities and to produce sustainable laboratory systems, especially in resource-limited settings.
2. To discuss formation of a partnership provisionally referred to as the “Global Alliance for Laboratory Strengthening.”
3. To outline next steps for the meeting “The Public Health Lab of the Future” scheduled for July 2010: to identify a theme for the meeting, to explore topic areas where there is a need for harmonization and collaboration across programs, and to develop an agenda for what will be the first-ever meeting to look at global harmonization for laboratory strengthening.

GLI Accreditation Process/Proposals

- Identify TB laboratory requirements for QMS frameworks
- Develop an accreditation process for AFB Microscopy Networks

WHO AFRO Stepwise Accreditation Program



TBCAP Tools

[<< home](#)

Overview of Laboratory Tools

1. Standard Operating Procedures (SOPs)

[Introduction](#)

[Table of contents](#)

2. Guidelines and specifications for managing TB laboratory equipment and supplies

[Introduction](#)

[Table of contents](#)

3. External Quality Assurance Package

[Introduction](#)

[Table of contents](#)

4. Management Information System

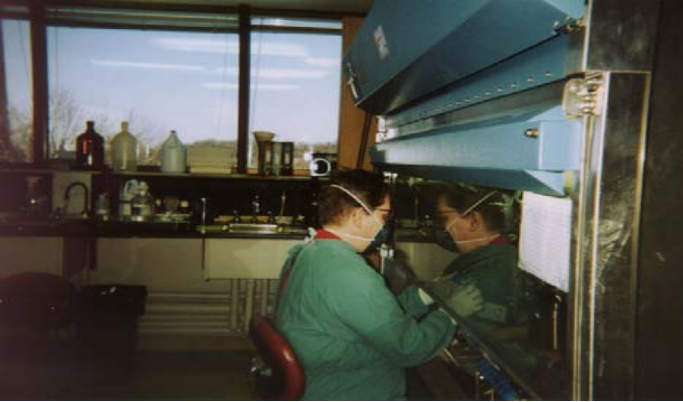
[Introduction](#)

[Table of contents](#)

5. Culture & DST Package

[Introduction](#)

[Table of contents](#)



Biosafety Initiatives

- CDC/WHO Technical consultation, Atlanta, Sept 08
- Recommendations and guidance for simple “Ventilated Workstations” for smear microscopy
- Guidance and training on TB laboratory biosafety (TBCAP)



Expert Consultation: Developing Specifications for TB Smear Preparation “Ventilated Workstations”

APHL/CDC/USAID/WHO

September 15-16, Atlanta, USA

VENTILATED WORKSTATION

For AFB Smear Microscopy



Manufacturing, Validation and User guide.

LOGO CDC

LOGO WHO

LOGO APHL



EXPAND-TB

EXPanding Access to New Diagnostics for TuBerculosis



Background

- Initial project
 - UNITAID Board approval: April 2008,
 - Project Agreement signed: December 2008
 - 16 countries; ~74,000 patients
 - Time frame: 2009 – 2011
- Expansion project
 - UNITAID Board approval: May 2009
 - Project Agreement expected: December 2009
 - 11 additional countries; ~56,000 additional patients
 - Time frame: 2009 – 2013
- Revised Project Plan to cover 27 countries, ~129,000 patients, time frame 2009 - 2013





- Accelerated uptake of new MDR-TB diagnostics in 27 countries, 2009 - 2013 (additional 15 planned by 2012)
- State-of-the-art commodities (instruments, tests, reagents) funded by UNITAID
- Leverage other local partners to address non-commodity components (infrastructure, training, etc.)
- Long-term mentoring and TA: in-country hands-on support to optimise technology and knowledge transfer, closely linked to capacity building
- Full ownership of MOH, NTP, Laboratory
- Integrated laboratory approach (notably TB and HIV)
- Adjustment based on growing evidence ('learning by doing')

Global Laboratory Initiative Looking Toward the Future

- Review strategic priorities: HR development, lab accreditation
- Fully engage current GLI members and partners in its work and expand individual and constituent membership in GLI
- Promote the integration of TB laboratory services within public health laboratories and expand role of GLI in overall context of health systems strengthening
- Improve coordination and harmonization of technical assistance for TB laboratory strengthening at the country level
- Ensure full participation of GLI in other STB Partnership WGs
- Advocacy and resource mobilization for strengthening TB laboratory services