



Achievements/Update of the Global Laboratory Initiative

Dr John Ridderhof (CDC)
Chair (outgoing), Global Laboratory Initiative WG
October 4, 2010
Veyrier-du-Lac, France

Stop TB Partnership Workgroups

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

GLI core group

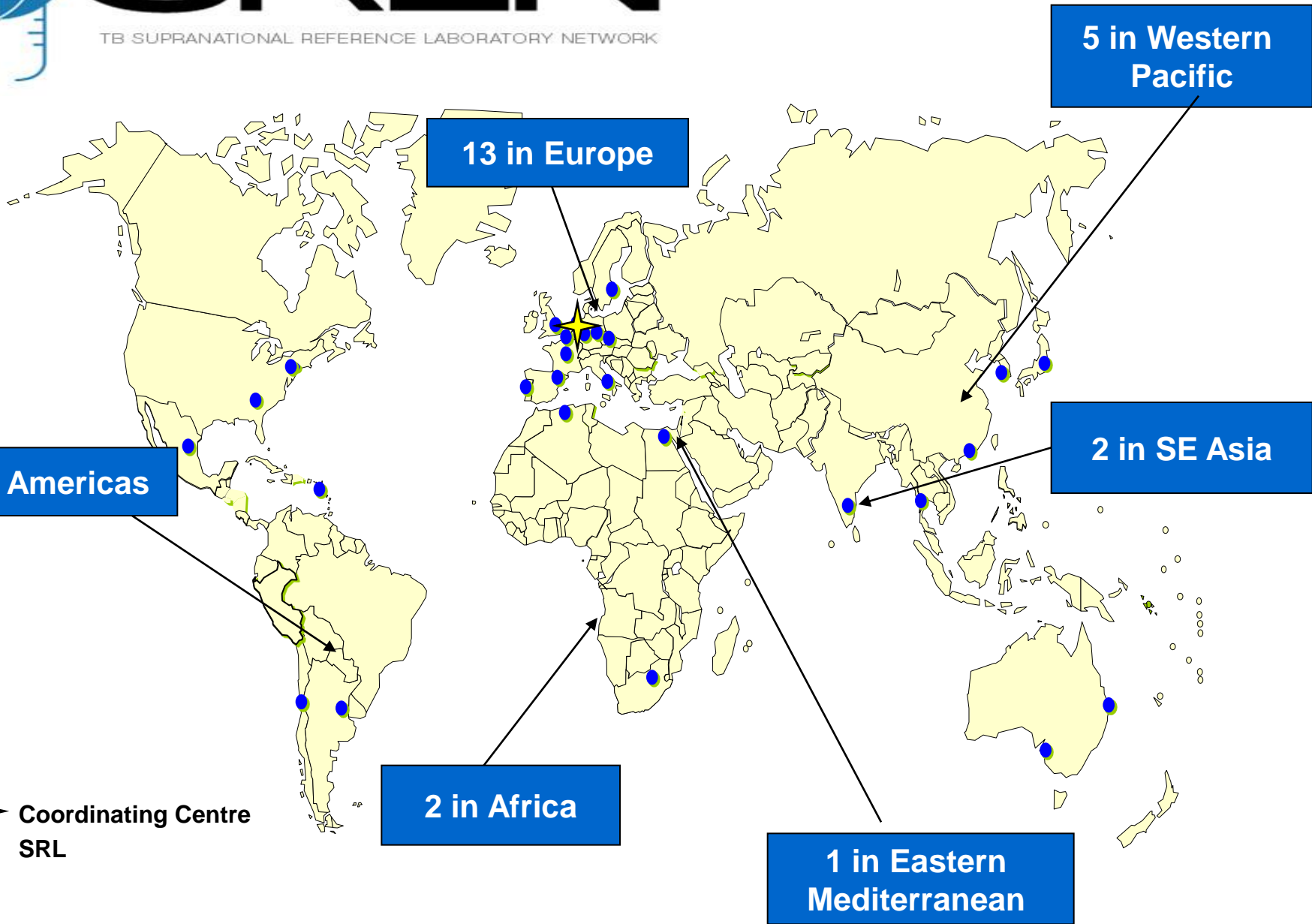
- **Chair Dr Rick O'Brien**
- **WHO Secretariat – Dr Chris Gilpin/Dr Karin Weyer**
- **IUATLD – Dr Armand Van Deun**
- **FIND -**
- **CDC – Dr Tom Shinnick**
- **NTP/NRL – Dr Moses Joloba (Uganda)**
- **NTP/NRL/SRL – Dr Kai Man Kam (China)**
- **NTP/NRL – Dr Satoshi Mitarai (Japan)**
- **NTP/NRL – Dr. Dick van Sooligen (Netherlands)**
- **NTP/NRL – Dr Alice Telles (Brazil)**
- **Dr Rumina Hasan (Pakistan)**
- ***Civil society – Vijay K. Gupta/Tom Otwoma**
- ***PEPFAR – Dr. John Nkengasong**
- ***USAID – Dr. Gavin Macgregor-Skinner**
- **Past Chair-Dr John Ridderhof**
- **Observers**
- **Liaisons with other WGs**

***New members**



SRLN

TB SUPRANATIONAL REFERENCE LABORATORY NETWORK



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

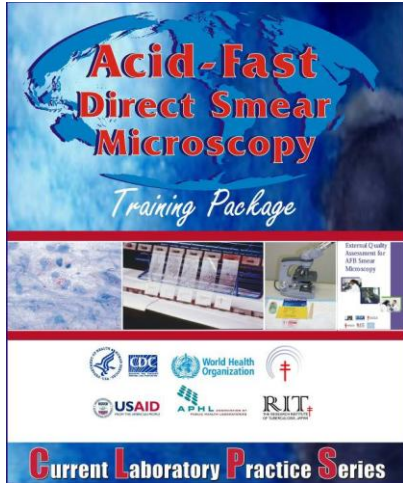
GLI Projects are run on behalf of GLI, and adhere to a collaborative spirit

- aligned with strategic agenda and priorities
- complementarity with other projects
- Liaison to GLI-S is established
- project review process established
- adequate partner representation requirements satisfied
- information networks utilized
- ...

GLI Partners

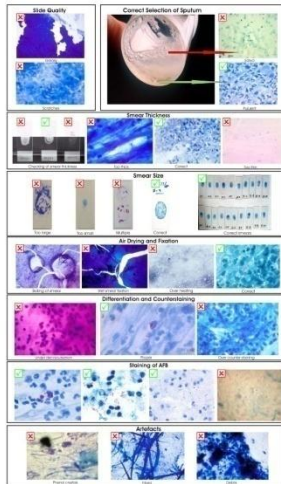
- American Society for Microbiology (ASM)
- Association of Public Health Laboratories (APHL)
- Bill & Melinda Gates Foundation
- Centers for Disease Control and Prevention (CDC)
- CDC Global AIDS Programme (GAP)
- Fondation Merieux
- Foundation for Innovative New Diagnostics (FIND)
- International Union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

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](#)

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TBCAP Tools

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Overview of Laboratory Tools

1. Standard Operating Procedures (SOPs)

[Introduction](#)

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

[Introduction](#)

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3. External Quality Assurance Package

[Introduction](#)

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4. Management Information System

[Introduction](#)

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5. Culture & DST Package

[Introduction](#)

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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-tuberculous 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

EXPAND-TB

EXPanding Access to New Diagnostics for TuBerculosis



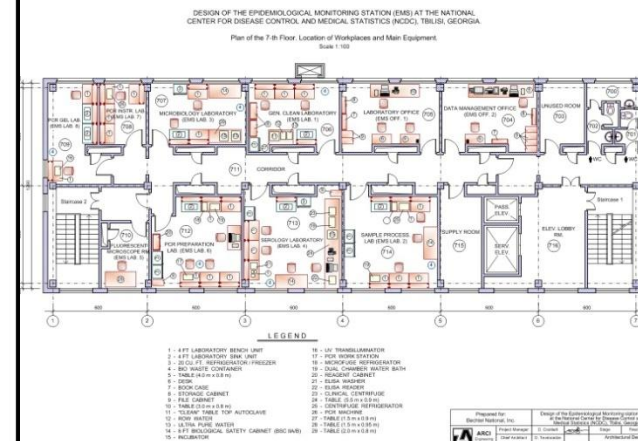
Background

- 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



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



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**

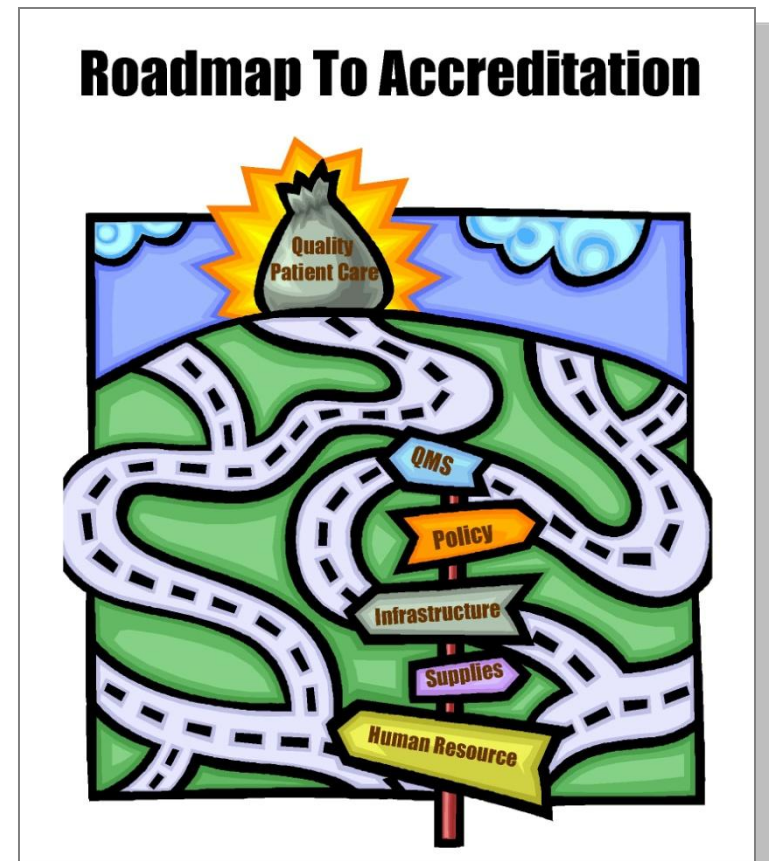
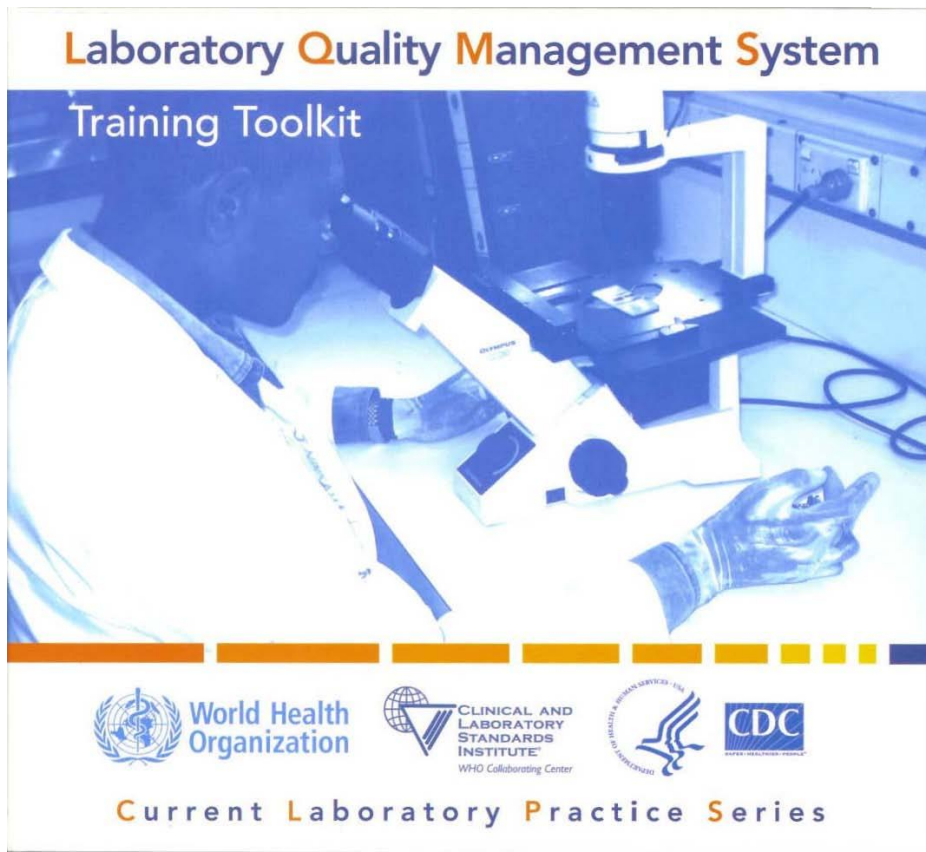
Produced with the collaboration of:

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

GLI Accreditation Process/Proposals

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

WHO AFRO Stepwise Accreditation Program



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.**

TB laboratories under the supervision of National TB Reference Laboratories in Tier 1 Countries

| Country | Smear Microscopy | | | Culture | | DST | |
|---------------------------|------------------|------------------|----------|---------|-------------|-----|--------------|
| | No. | per 100,000 popn | % in EQA | No. | per 5M popn | No. | per 10M popn |
| <i>Routine Dx Min Req</i> | | 1 | | | 1 | | 1 |
| Afghanistan | 545 | 1.9 | 72 | 1 | 0.2 | 0 | 0 |
| Bangladesh | 753 | 0.5 | 100 | 4 | 0.1 | 2 | 0.1 |
| Brazil | 4,044 | 2.1 | 45 | 232 | 0.6 | 38 | 2.0 |
| Cambodia | 205 | 1.4 | 93 | 5 | 1.7 | 1 | 0.7 |
| DR Congo | 1,545 | 2.4 | 85 | 1 | 0.1 | 1 | 0.2 |
| Ethiopia | 1,000 | 1.2 | 0 | 6 | 0.4 | 6 | 0.7 |
| India | 13,000 | 1.1 | 93 | 17 | 0.1 | 17 | 0.1 |
| Indonesia | 4,855 | 2.1 | 100 | 41 | 0.9 | 11 | 0.5 |
| Kenya | 930 | 2.4 | 4 | 5 | 0.6 | 1 | 0.3 |
| Mozambique | 252 | 1.2 | 100 | 3 | 0.7 | 1 | 0.5 |
| Nigeria | 1,138 | 0.8 | 44 | 9 | 0.3 | 9 | 0.6 |
| Pakistan | 1,131 | 0.7 | 32 | 5 | 0.1 | 1 | 0.1 |

Source: WHO Global Tuberculosis Report 2009

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|---------------------------|------------------|-------------------------|-----------|--------------|------------------------|------------|------------------------|
| | No. | per 100,000 popn | % in EQA | No. | per 5M popn | No. | per 10M popn |
| <i>Routine Dx Min Req</i> | | 1 | | | 1 | | 1 |
| Philippines | 2,374 | 2.6 | 100 | 3 | 0.2 | 3 | 0.3 |
| Russia | 4,048 | 2.9 | 0 | 965 | 34 | 280 | 20 |
| South Africa | 249 | 0.5 | 97 | 18 | 1.8 | 10 | 2.0 |
| Tanzania | 717 | 1.7 | 0 | 3 | 0.4 | 1 | 0.2 |
| Uganda | 741 | 2.3 | 100 | 4 | 0.6 | 2 | 0.6 |
| Ukraine | - | - | 0 | - | - | - | - |
| Zambia | 158 | 1.3 | 13 | 3 | 1.2 | 3 | 2.5 |
| Zimbabwe | 180 | 1.3 | 0 | 1 | 0.4 | 1 | 0.7 |
| USAID Tier 1 Total | 37,865 | Yes=15 (75%) | 66 | 1,326 | Yes=4 (20%) | 388 | Yes=4 (20%) |

Source: WHO Global Tuberculosis Report 2009

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)

Acknowledgements



- **STB/THD Laboratory Strengthening Team**

- Karin Weyer (Lead)
- Chris Gilpin
- Jean de Dieu Iragena
- Faud Mirazayev
- Mien Patthey
- Kalpana Singh

- **GLI Core Group**

- Rick O'Brien (Chair)
- Kai Man Kam
- John Ridderhof
- Tom Shinnick
- Armand van Deun
- Maria Alice Telles
- Satoshi Mitarai
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