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)

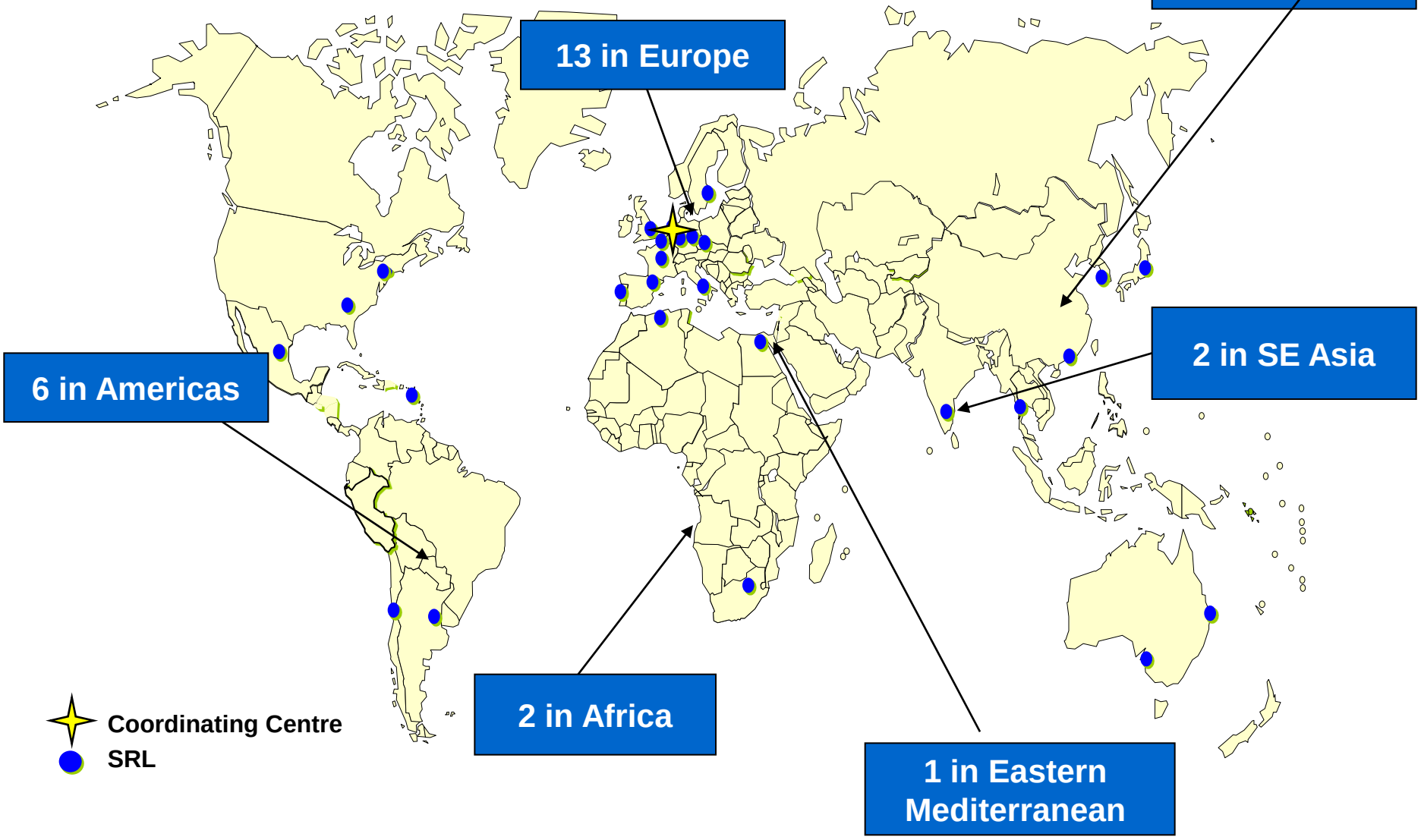
GLI core group

- **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 AliceTelles (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
global laboratory initiative
advancing TB diagnosis

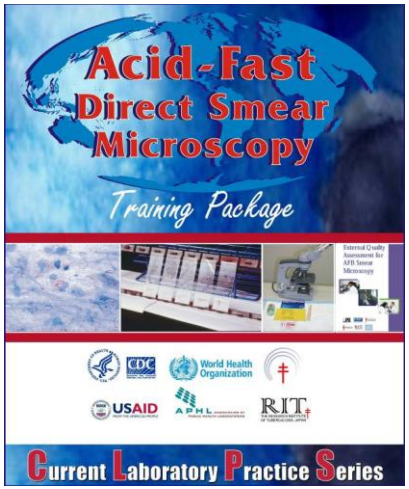
GLI Projects are run on behalf of GLI, and adhere to a collaborative spirit

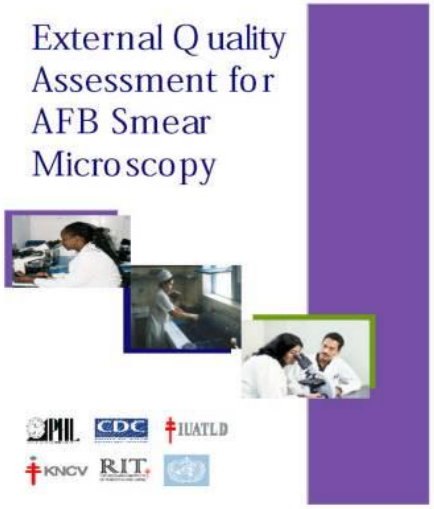
- aligned with strategic agenda and priorities
- complementarity with other projects
- Liaison to GLI-S is established
- project review process established
- adequate partner representation requirements satisfied
- information networks utilized
- …

GLI Partners

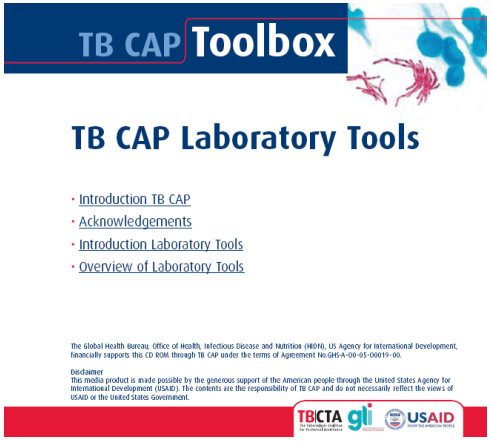
- American Society for Microbiology (ASM)
- Association of Public Health Laboratories (APHL)
- Bill & Melinda Gates Foundation
- Centers for Disease Control and Prevention (CDC)
- CDC Global AIDS Programme (GAP)
- Fondation Merieux
- Foundation for Innovative New Diagnostics (FIND)
- International Union Against TB and Lung Disease
- PEPFAR
- USAID
- KNCV
- Merieux Alliance
- Management Sciences for Health (MSH)
- Medicins 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





SRLN
TB SUPRANATIONAL REFERENCE LABORATORY NETWORK



Recommended interim formats for TB laboratory recording and reporting

gli global laboratory initiative advancing TB diagnosis

TBCTA The Tuberculosis Coalition for Technical Assistance

USAID FROM THE AMERICAN PEOPLE

gli global laboratory initiative advancing TB diagnosis

TBCAP Tools

« home

Overview of Laboratory Tools

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

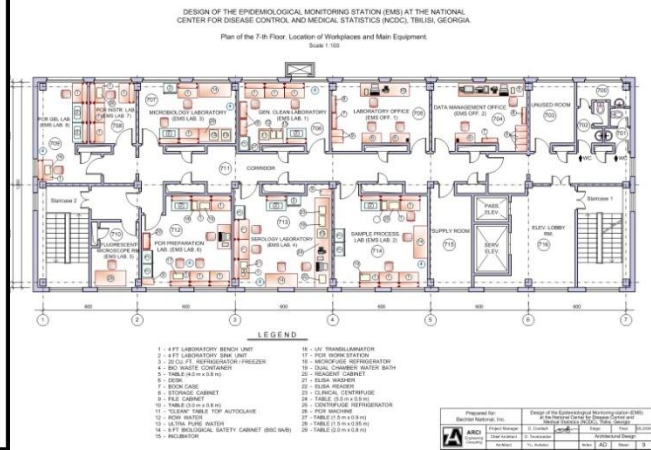
EXPAND-TB
EXPanding Access to New Diagnostics for TuBerculosis

Background

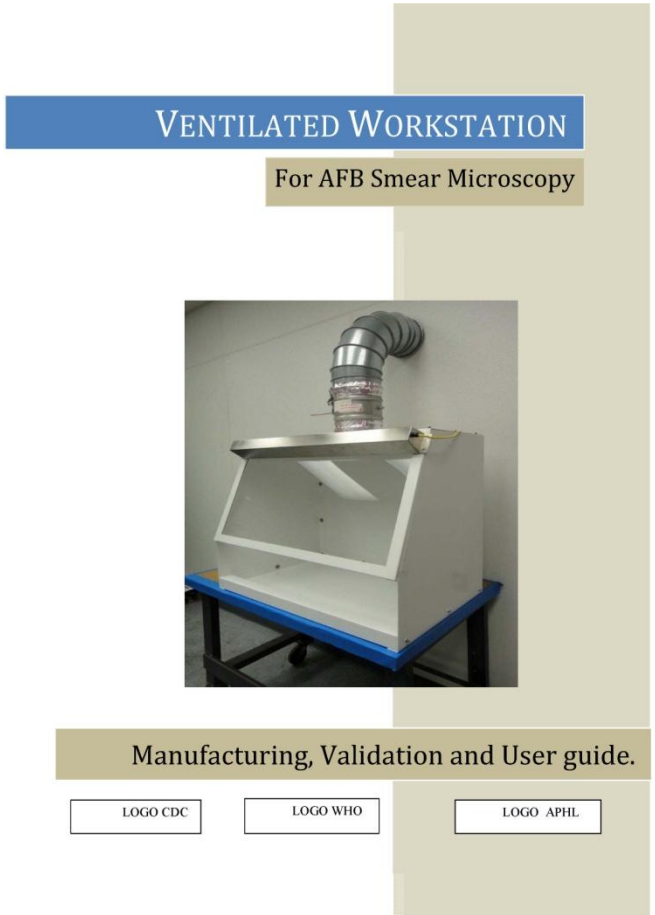
- Initial project
  - UNITAID Board approval: April 2008,
  - Project Agreement signed: December 2008
  - 16 countries; ~74,000 patients
  - Time frame: 2009 – 2011
- Expansion project
  - UNITAID Board approval: May 2009
  - Project Agreement expected: December 2009
  - 11 additional countries; ~56,000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



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

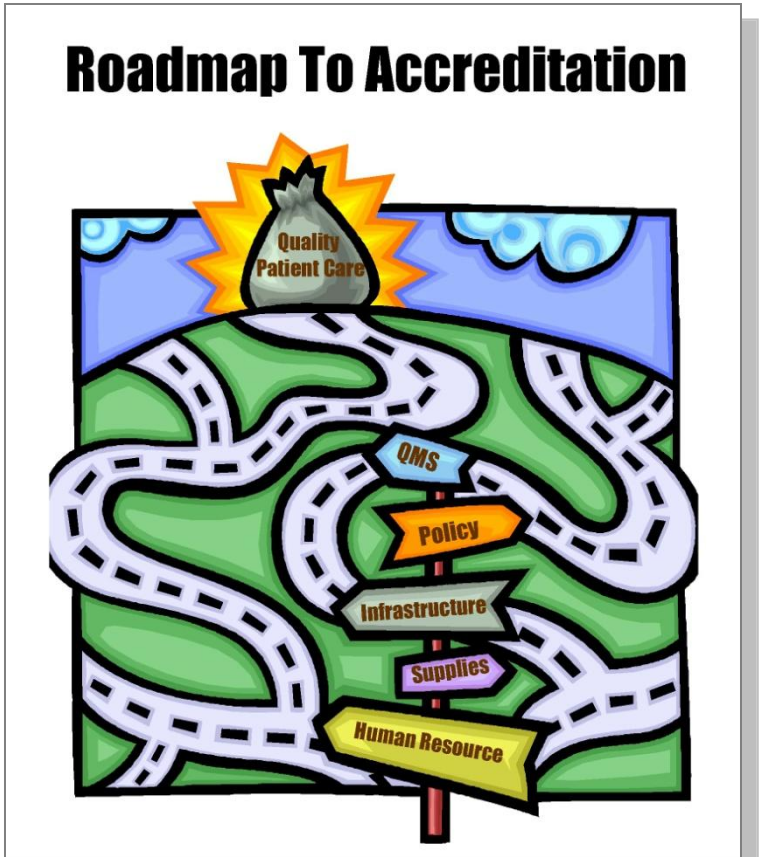
Produced with the collaboration of:

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	
2008 WHO data	**No.**	**per 100,000 popn**	**% in EQA**	**No.**	**per 5M popn**	**No.**	**per 10M popn**
Routine Dx Min Req		*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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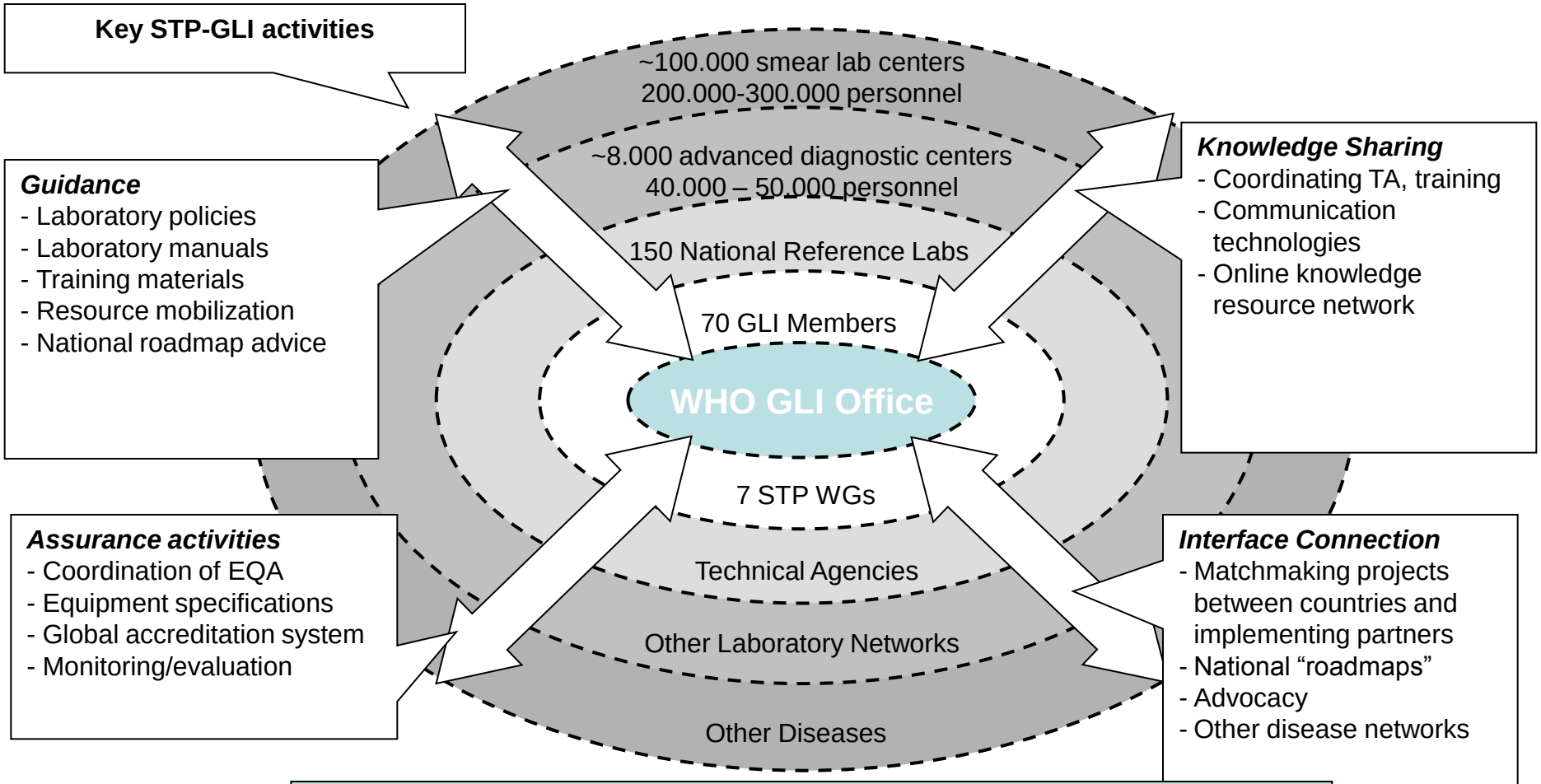
Routine Dx Min Req		*1*			*1*		*1*
Philippines	2,374	2.6	100	3	0.2	3	0.3
Russia	4,048	2.9	0	965	34	280	20
South Africa	249	0.5	97	18	1.8	10	2.0
Tanzania	717	1.7	0	3	0.4	1	0.2
Uganda	741	2.3	100	4	0.6	2	0.6
Ukraine	-	-	0	-	-	-	-
Zambia	158	1.3	13	3	1.2	3	2.5
Zimbabwe	180	1.3	0	1	0.4	1	0.7
USAID Tier 1 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



Acknowledgements

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  - 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
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