



Laboratory Strengthening Response to TB Diagnostic Challenges: Achievements of the Global Laboratory Initiative

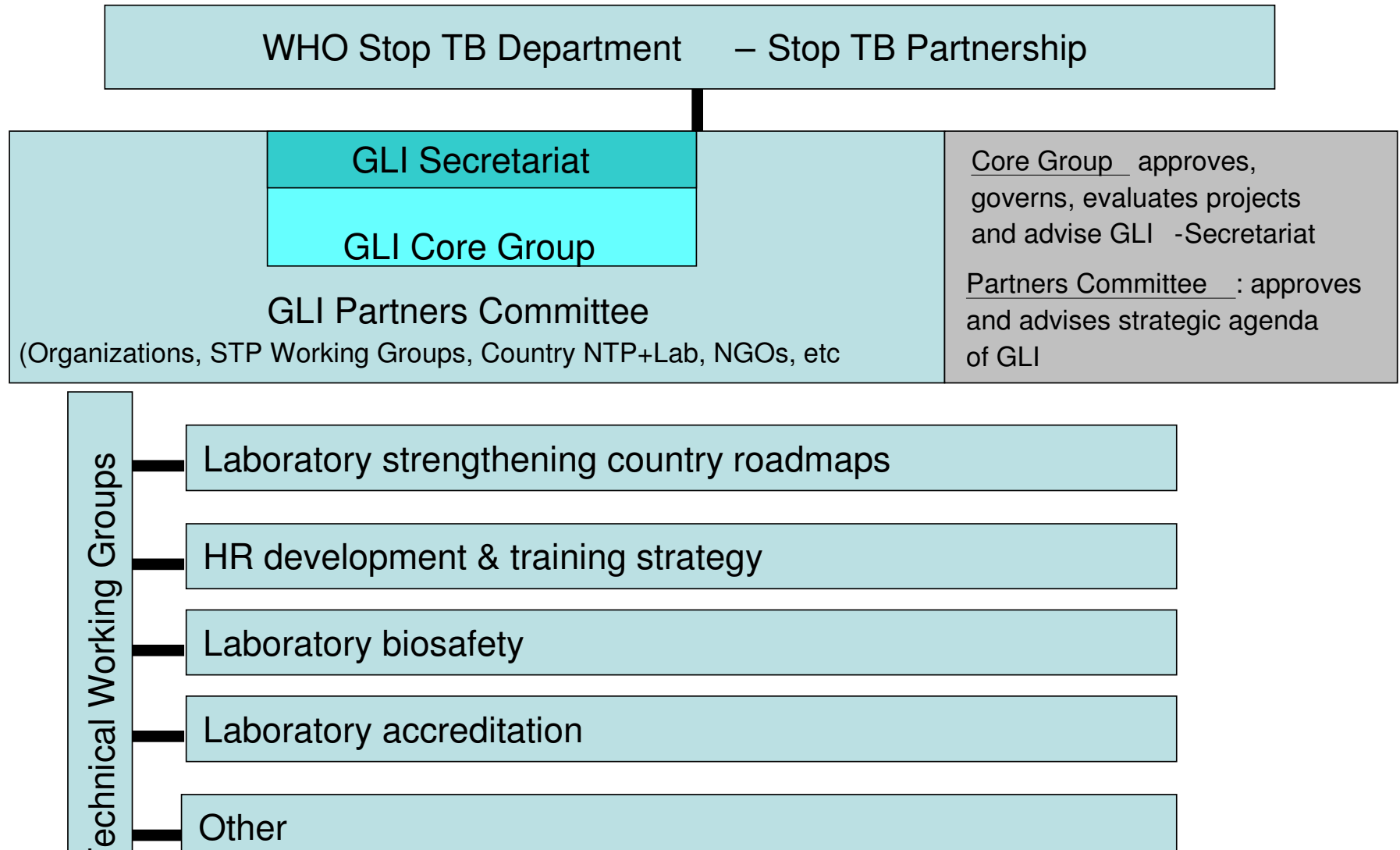
Dr John Ridderhof (CDC)
Chair, Global Laboratory Initiative WG
October 15, 2009
Annecy, France



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)

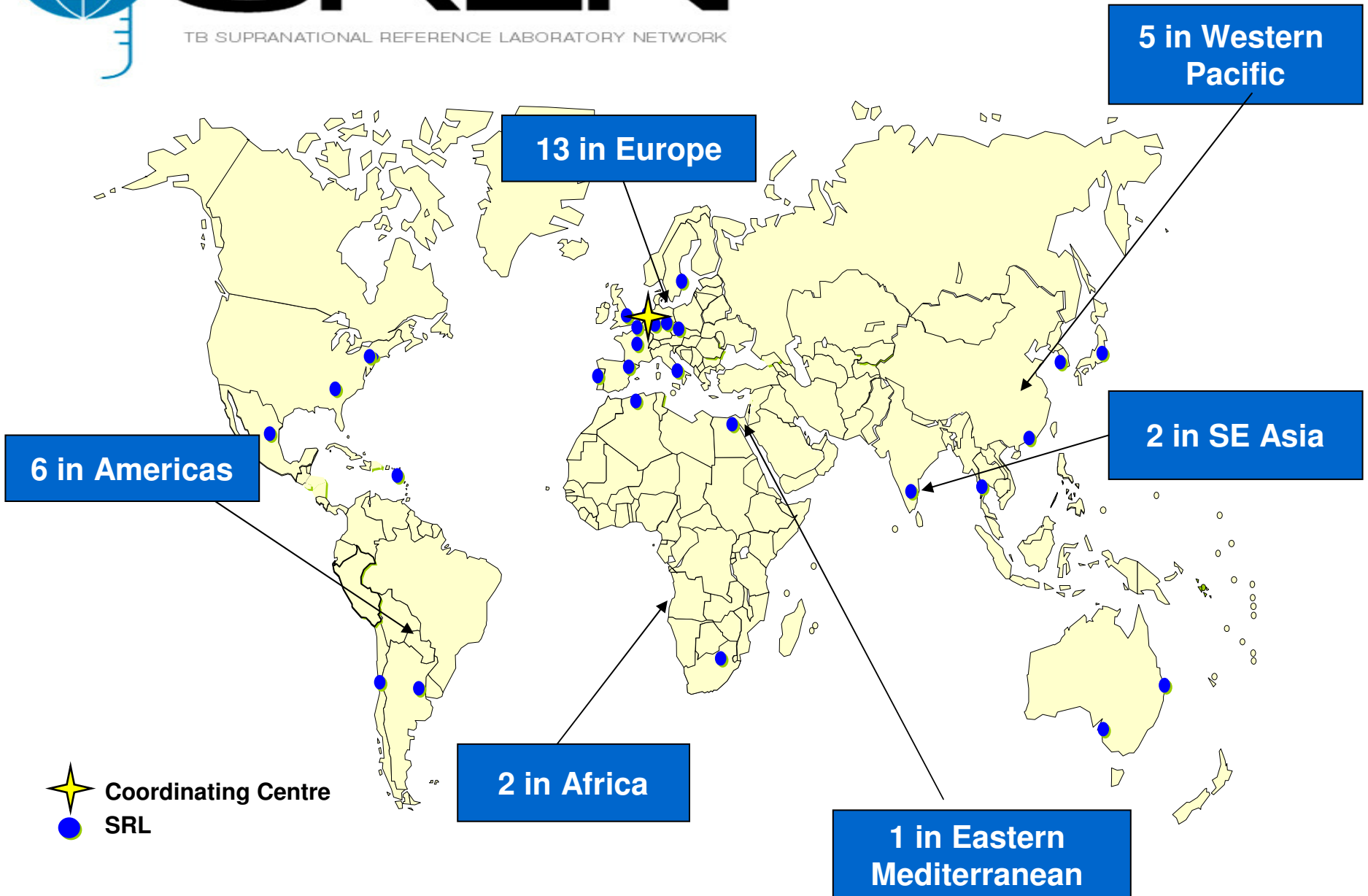
Global Laboratory Initiative – Structure and Governance





SRLN

TB SUPRANATIONAL REFERENCE LABORATORY NETWORK



GLI core group

- **Chair Dr John Ridderhof**
- **WHO Secretariat – Dr Karin Weyer**
- **IUATLD – Dr Armand Van Deun**
- **FIND - Dr Rick O'Brien**
- **CDC – Dr Tom Shinnick**
- **NTP/NRL – Dr Moses Joloba (Uganda)**
- **NTP/NRL/SRL – Dr Kai Man Kam (China)**
- **Observers**
- **Liaisons with other WGs**
- ***Civil society – Vijay K. Gupta**
- ***PEPFAR – Dr. John Nkengasong**
- ***USAID – Dr. Gavin Macgregor-Skinner**
- ***Open solicitation**
- ***Open solicitation**

***New members**

GLI core group members rotating off

THANK YOU

- **IOM – Dr Chris Gilpin**
- **SRL and Euro TB lab task force – Dr Francis Drobnewski (UK)**
- **SRL – Dr Lucia Barrera (Argentina)**
- **Civil society – Case Gordon**

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 strategic priorities

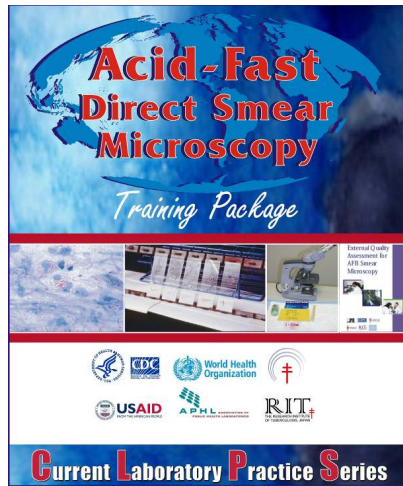
- Accelerating evidence-based **policy development** on diagnostics and laboratory practices
- Promoting a structured framework/**roadmap** for TB laboratory strengthening within the context of national laboratory plans at country level
- Developing a comprehensive set of **tools, norms and standards** 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 Guidance, Tools, Programs



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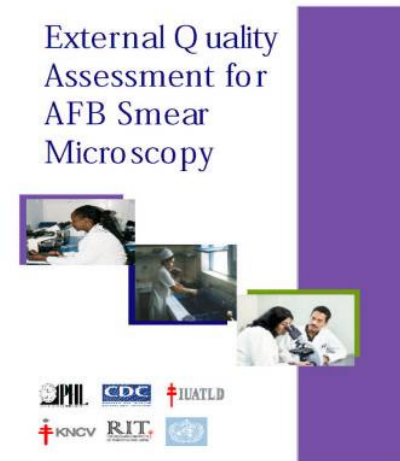
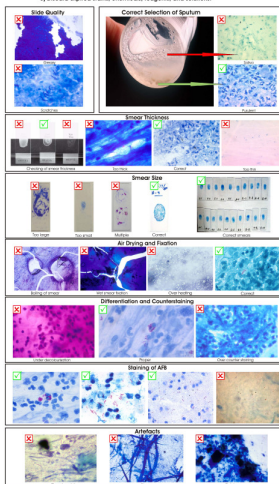
TB SUPRANATIONAL REFERENCE LABORATORY NETWORK

External Q quality Assessment for AFB Smear Microscopy



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.

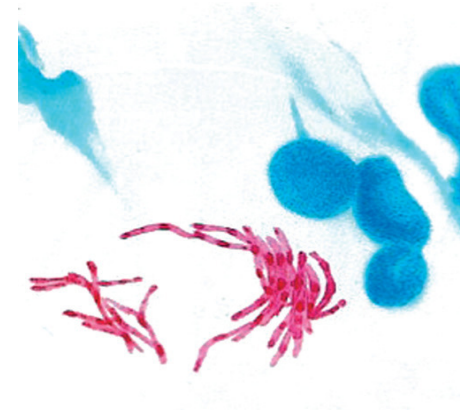


TBCAP Tools Completed

- Standard Operating Procedures (SOPs)
- Management Information System (MIS)
- Logistics/supply management tool
- Culture and DST training ("workshop in a box")
- EQA training ("workshop in a box")

- TBCAP = KNCV, RIT/JATA, IUATLD, WHO, CDC.....

TB CAP Toolbox



Laboratory Tools

Strengthening TB laboratory services **2009**



CONTENTS

This TB CAP Laboratory Toolbox contains five products recently developed to support countries in strengthening their laboratory services:

1. Standard Operating Procedures (SOPs)

Generic instructions on laboratory procedures, including: test methods, operation of equipment, laboratory organization, quality control, safety practices, and record keeping

2. Logistics/Supply Management Tool

Practical information on equipment specifications, recommendations on BSC installation, guidelines on laboratory commodity management, inventory control and algorithms, and spreadsheets for calculating quantities and costs of consumables.

3. External Quality Assurance package (EQA)

Covering main areas of AFB-microscopy EQA: rechecking, panels and supervision; fluorescence; review of different AFB-microscopy techniques; AFB-microscopy training package.

Management Information System (MIS)

Tools for reporting and monitoring of AFB-smears and supplies. Promotes also correct analysis, rechecking EQA important parameters, and culture internal quality control.

5. Culture & DST Package

12 modules on topics such as: bio-safety, C/DST, use and maintenance of equipment, R&R, and QM.

For more information please visit our website www.tbcta.org



TBCAP Tools In Process

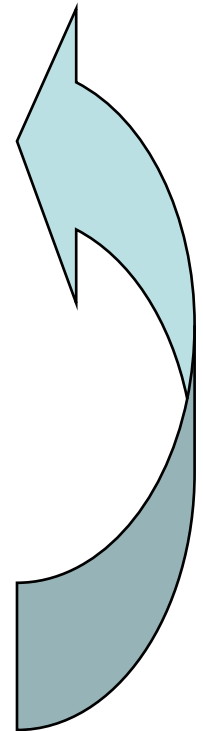
- Guidelines to purchase Lab Products (equipment specifications)
- Develop a country roadmap for laboratory strengthening
- Develop training and a manual on biosafety for laboratories

TBCAP = KNVCV, RIT/JATA, IUATLD, WHO, CDC.....

Roadmaps for TB Laboratory Strengthening

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

Strategic Laboratory Plan



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

Available at: <http://www.who.int/tb/dots/laboratory/policy/en/print.html>

- In process:
 - LED microscopy as alternative for both fluorescence and conventional light microscopy (pending STAG endorsement)
 - Selected non-commercial culture and DST methods not alternatives for gold standards, but may provide interim solution (pending STAG endorsement)



- Accelerated uptake of new MDR-TB diagnostics in 27 countries, 2009 - 2013
- State-of-the-art commodities (instruments, tests, reagents) funded by UNICEF
- 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')

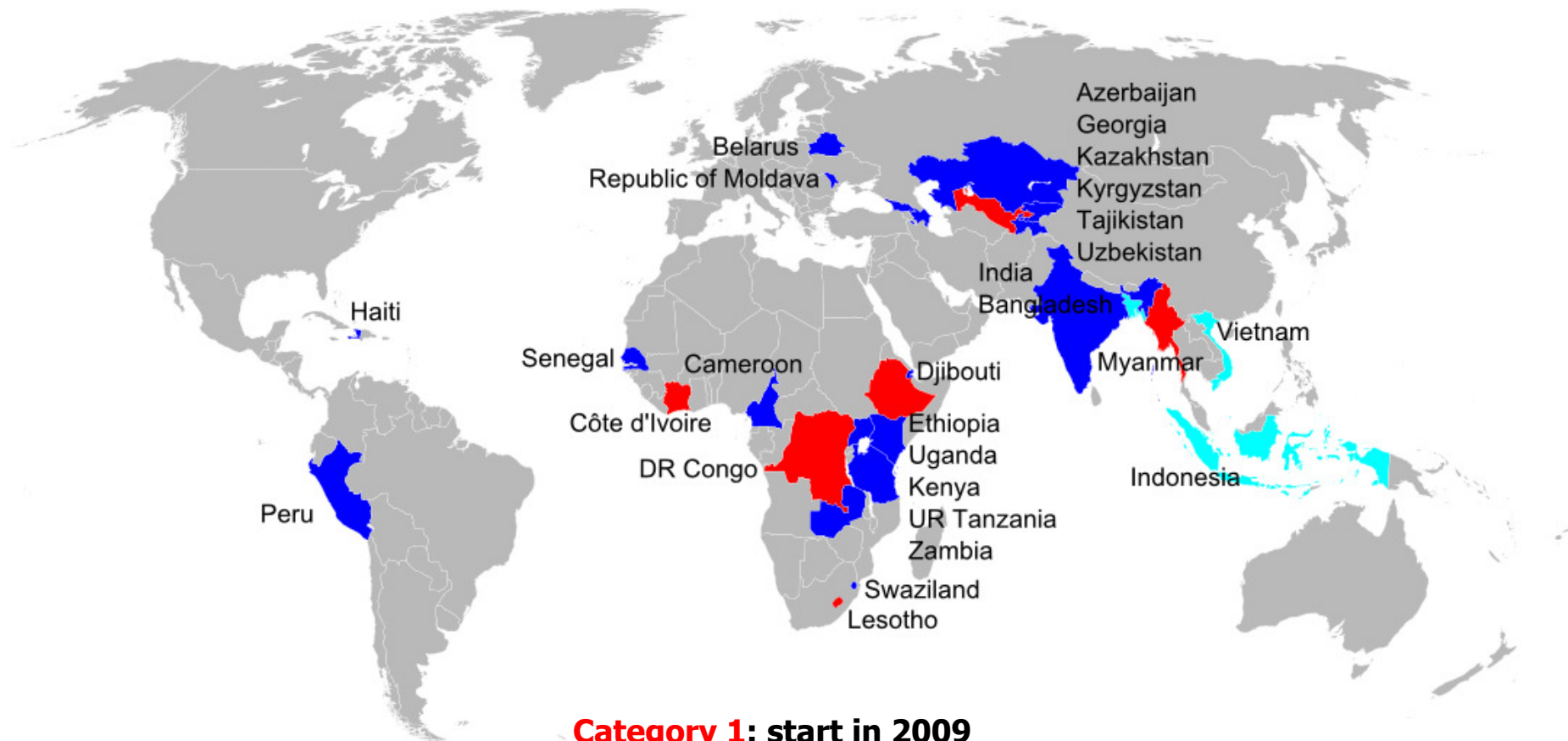


EXPAND-TB

EXPanding Access to New Diagnostics for TuBerculosis



Recipient countries



Category 1: start in 2009

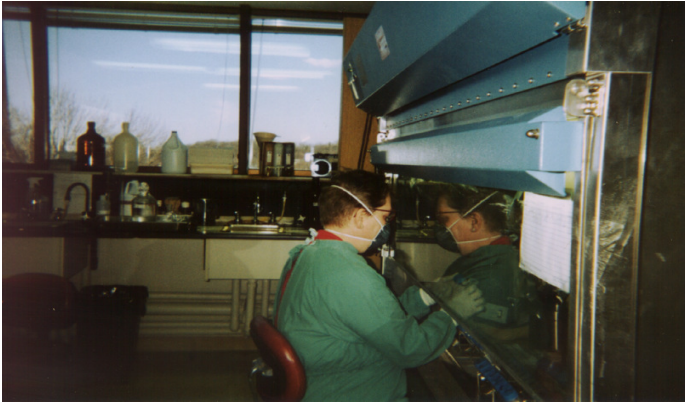
Category 2: start in 2010

Category 3: start in 2011

Background

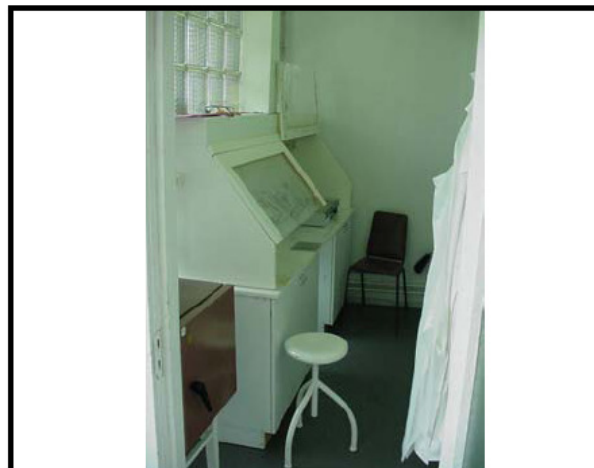


- Initial project
 - UNITAID Board approval: April 2008,
 - Project Agreement signed: December 2008
 - 16 countries; ~74,000 patients
 - Time frame: 2009 – 2011
- Expansion project
 - UNITAID Board approval: May 2009
 - Project Agreement expected: December 2009
 - 11 additional countries; ~56,000 additional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



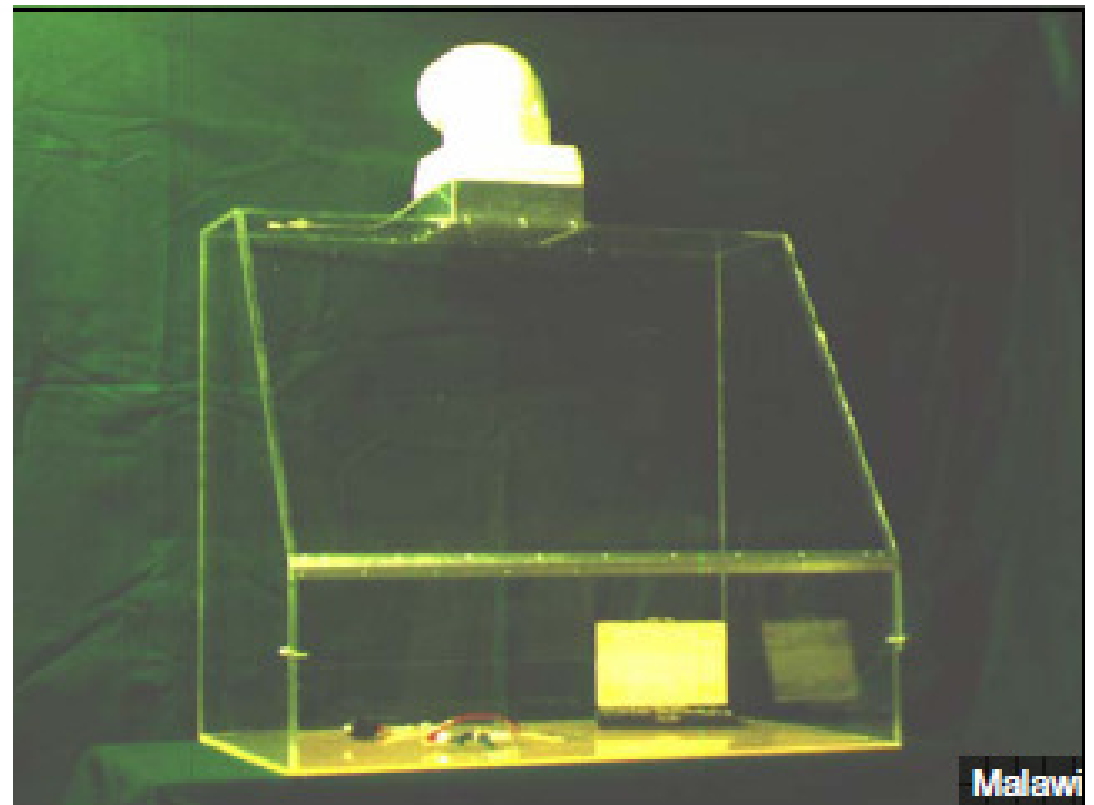
Biosafety Initiatives

- CDC/WHO Technical consultation, Atlanta, Sept 08
- Guidance on process, design principles and ventilation for laboratory construction and renovation (funding proposal)
- Recommendations and guidance for simple “Ventilated Workstations” for smear microscopy
- Guidance and training on TB laboratory biosafety (TBCAP)



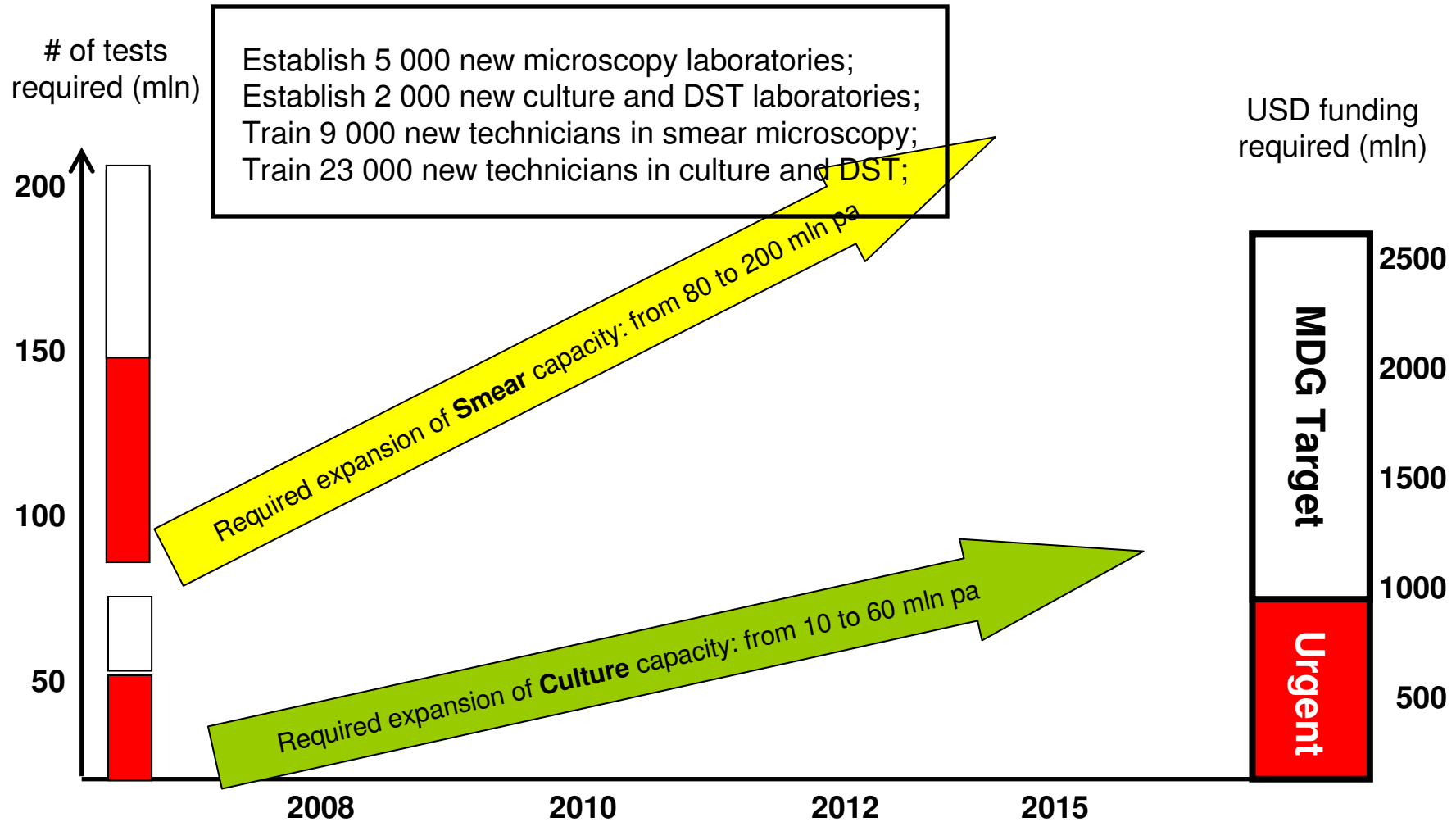
Expert Consultation: Developing Specifications for TB Smear Preparation “Ventilated Workstations”

APHL/CDC/USAID/WHO
September 15-16, Atlanta, USA



Global Laboratory Capacity Gap

To reach MDG targets, a global capacity need of **120 million smears**, **60 million cultures** and **6 million DST investigations** must be met by 2015, requiring at least **6.1 billion USD** by 2015



Paris 2008--GLI Challenges

- Majority of donor resources focused at country level
- There is no forum or structure to promote collaborations
GLI, OGAC Lab WG, WHO HIV Collaborative, Polio, IDSR, etc.
- Address and promote TB technical needs and contribute to integrated systems
- Shortage of full time laboratory scientists in partner organizations to contribute to GLI---dependent on part-time volunteers
- WHO GLI office is 3 technical staff

Laboratory Quality Management System

Training Toolkit



World Health
Organization



CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE®
WHO Collaborating Center



Current Laboratory Practice Series

WHO AFRO launch Stepwise Accreditation Program

“Strengthening Laboratory Management to Accelerate National Laboratory Service Capacity Building Towards Accreditation in the African Region”

July 22 -24, 2009
Kigali, Rwanda

Roadmap To Accreditation



Harmonization of Global Support for Laboratory Strengthening

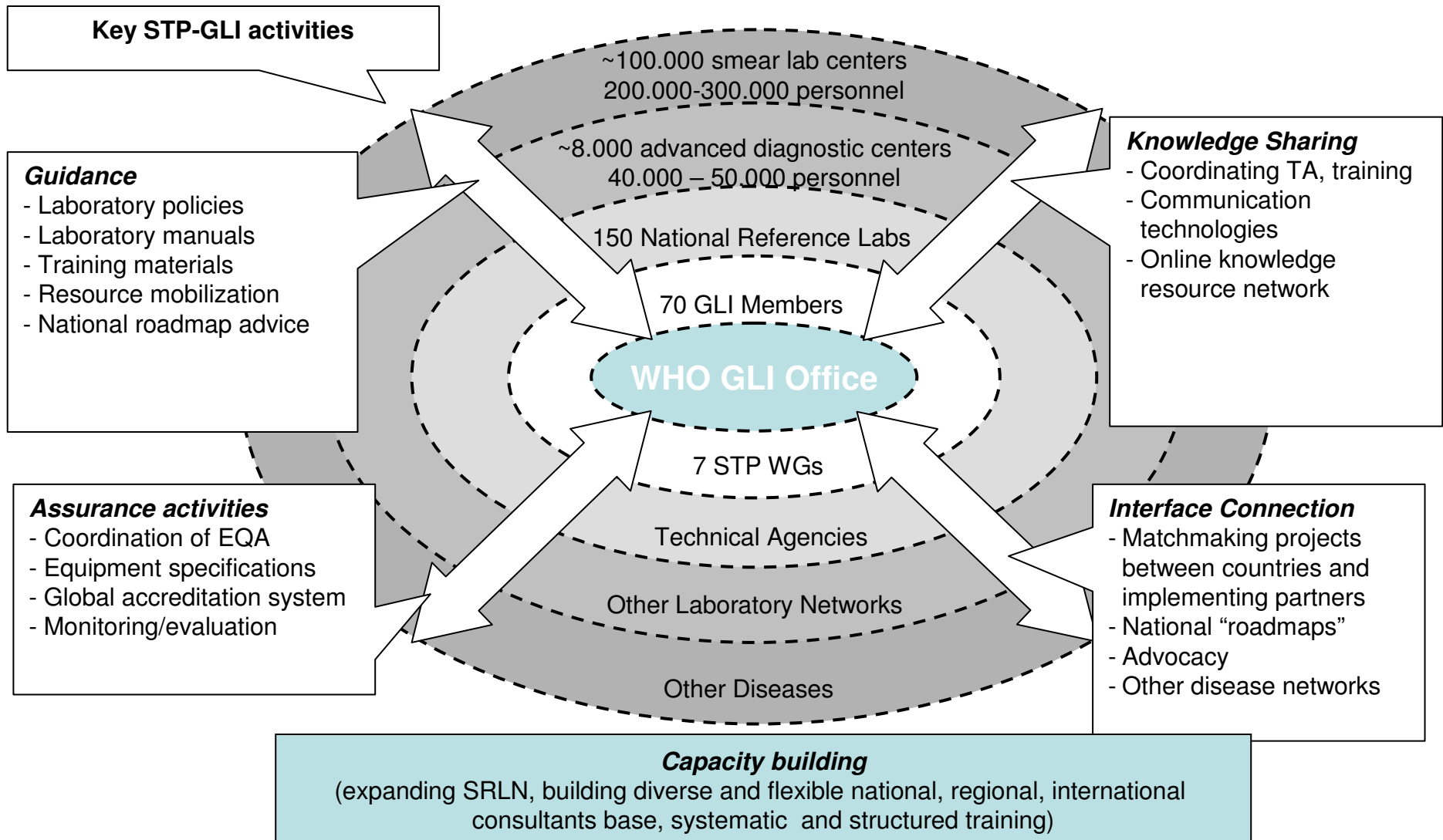
October 28-30, 2009

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.

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



Acknowledgements



- **STB/THD Laboratory Strengthening Team**

- Paul Nunn (THD Coordinator)
- Kalpana Singh
- Veronique Vincent
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- Karin Weyer

- **GLI Core Group**

- Lucia Barrera
- Francis Drobniowski
- Chris Gilpin
- Case Gordon
- Moses Joloba
- Kai Man Kam
- John Ridderhof (Chair)
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The findings and conclusions in this report are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention

