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## Moving tuberculosis (TB) laboratory capacity strengthening forward: A Global Laboratory Initiative

### Background

Lack of diagnostic capacity is a crucial barrier preventing an effective response to the challenges of TB-HIV and drug-resistant TB, *with less than 5% of the estimated burden of MDR-TB patients currently being detected*. Estimation models and projections based on a variety of epidemiological and programmatic assumptions confirm that an effective response to the diagnostic challenges of TB-HIV and MDR-TB requires urgent and massive scale-up of laboratory services. Stop TB Partnership Working Groups, technical expert bodies, and international research and donor agencies also agree that the critical lack of TB laboratory capacity constitutes a global crisis, requiring a paradigm shift in providing laboratory policy guidance, technical assistance, and knowledge transfer within a global and integrated laboratory network.

In November 2002, the DOTS Expansion Working Group (DEWG) of the Stop TB Partnership established a Subgroup on Laboratory Capacity Strengthening (SLCS), with the secretariat based at the World Health Organization (WHO) in Geneva. The SLCS comprised mainly of the directors of the Supranational Reference Laboratory Network (SRLN), heads of National TB Reference Laboratories (NRLs), technical agencies and Stop TB Partnership members.

In January 2007, the SLCS established a Core Group (CG) of international TB laboratory experts to accelerate activities and set the strategic direction for laboratory capacity strengthening. Over subsequent months, the CG estimated the projected needs in scaling up TB laboratory services and outlined the resource gaps. During this process, consensus evolved among key stakeholders that a Global Laboratory Initiative (GLI) was needed to guide and coordinate the huge effort required, integrating the SLCS and the SRLN and optimizing the network of partners involved in TB laboratory strengthening.

The concept of the GLI was presented to and endorsed by the Stop TB Partnership Coordinating Board in October 2007 and introduced with strong support during the Annual Union Conference on Lung Health in Cape Town in November 2007.

### Gaps and needs

Assuming universal access to TB culture and drug susceptibility testing (DST), as called for by the World Health Assembly in May 2007, current analyses indicate a global need of at least 60 million culture investigations and at least six million DST investigations per year by 2015, in addition to the almost 120 million microscopy investigations needed annually. Given current laboratory capacity to conduct around 10 million culture- and less than one million DST investigations, the huge increase to meet the forecast demands of the Global Plan is evident, estimated to require the following:

- Establishment of at least 5 000 new microscopy laboratories;
- Establishment of at least 2 000 new culture and DST laboratories;
- Training of at least 9 000 new laboratory technicians in smear microscopy;
- Training of at least 23 000 new laboratory technicians skilled in culture and DST;
- At least USD 1 billion in laboratory infrastructure and annual/variable cost.

The associated business model and strategic plan depends on a flexible and responsive approach involving comprehensive resource mapping and multi-sectoral partnerships.

### Global Laboratory Initiative (GLI)

The GLI provides a focus for TB within the framework of a multi-faceted, integrated approach to laboratory capacity strengthening through a network of international partners. The mission of GLI is to serve as a platform of coordination and communication for its members, providing the required infrastructure focused on TB laboratory strengthening, in the areas of:



- Global policy guidance on appropriate laboratory technology and best practices
- Laboratory capacity development
- Interface with other laboratory networks to ensure appropriate integration
- Standardized laboratory quality assurance
- Coordination of technical assistance
- Effective knowledge sharing
- Advocacy and resource mobilization

Organizationally, the GLI is currently a subgroup of the DEWG, one of the seven main working groups of the STP. A proposal to elevate GLI to full Working Group status will be submitted to the Stop TB Partnership Coordinating Board. Functionally, the GLI serves as an independent, technical expert advisory group to WHO, the STP, development agencies and countries. Structurally, the GLI consists of individuals with expertise in multiple disciplines, representing constituencies of stakeholders and/or institutions involved in global and country-level laboratory strengthening.

Similar to other Working Groups, GLI activities are overseen by a Core Group of 10-14 members which acts as a steering committee to guide, evaluate, approve, support and facilitate GLI projects. The GLI is supported by a Secretariat provided by the Stop TB Department at WHO-HQ in Geneva. The Secretariat provides strategic guidance, supports the governance of GLI, facilitates coordination of GLI priority projects, and serves as the focal point for TB laboratory strengthening activities at WHO-HQ. In doing so, the Secretariat works closely with national TB programmes, nongovernmental organizations, technical and funding agencies, WHO offices at country and regional levels, and Working Groups.

### **GLI strategic priorities 2008 - 2010**

***Development of laboratory norms and standards***, including specifications for TB laboratory equipment, standard operating procedures for TB laboratories, policy guidance and technical manuals for first- and second-line drug susceptibility testing, and assessment of evidence for WHO policy recommendations on the use of line probe assays for rapid screening of patients at risk of MDR-TB.

***Acceleration of country laboratory strengthening***, guided by a template/roadmap for country-specific strategic plans on TB laboratory strengthening, being developed under WHO leadership with input from various technical agencies, and country TB Programme and Laboratory Managers. A survey of current laboratory services and most urgent needs in the 22 high burden countries, as well as partner efforts and investment in these countries has been completed by Management Sciences for Health (MSH) and will be used to inform the roadmap process, map available resources and identify resource gaps.

***Prioritization of human resource development and training***, including development of a comprehensive training and retention strategy, and proposals to train a cadre of laboratory consultants from developing countries. Partner organizations with an active interest and involvement include the Association of Public Health Laboratories (APHL), the Netherlands Tuberculosis Foundation (KNCV), the US Centers for Disease Control and Prevention (CDC), the International Union Against Tuberculosis and Lung Disease (Union), MSH and WHO.

***Laboratory accreditation***, involving a task force lead by the International Organization for Migration (IOM) and consisting of international experts and key partners, to develop a consensus strategy and proposal for a voluntary laboratory accreditation programme for national TB reference laboratories and selected country level regional laboratories.

***Laboratory biosafety***, involving an expert consultation under CDC and WHO leadership to achieve consensus on appropriate biosafety standards for laboratories in resource-constrained settings, develop appropriate biosafety manuals, and design a comprehensive training plan and training materials.

***Expansion of the Supranational Reference Laboratory Network***, to fill existing geographical gaps, to enable SRLs to assume broader laboratory strengthening responsibilities and to meet the demand for expanded global drug resistance surveillance capacity.