



**EXPAND-TB**  
EXPanding Access to New Diagnostics for TuBerculosis

# EXPAND-TB Program Country Update

*Global consultation of the TB Supranational Reference Laboratory Network  
April, 14<sup>th</sup>-15<sup>th</sup>, 2010*

EXPAND-TB is supported by WHO-GLI, WHO-GDF and FIND under a Grant from UNITAID



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## TARGETS

**Reduce the Dx Gap**

**Service up to 1/3 world population**

**30% MDR-TB estimated prevalence**

**27 countries**

**Funding M\$87 to WHO-GLI, WHO-GDF, FIND**

**Assess and strengthen 101 labs**





## 3 MAIN OBJECTIVES

**Improve control of MDR-TB**

**Improve market dynamics**

**Integrate tools in TB control programmes**



## 3 PROJECT PHASES

### Phase 1: Laboratory Preparedness

- Political commitment --signing MOU- Prerequisite
- Lab assessments
- Infrastructure/biosafety
- Quality Assurance
- SOPs

### Phase 2: Introduction of new diagnostics

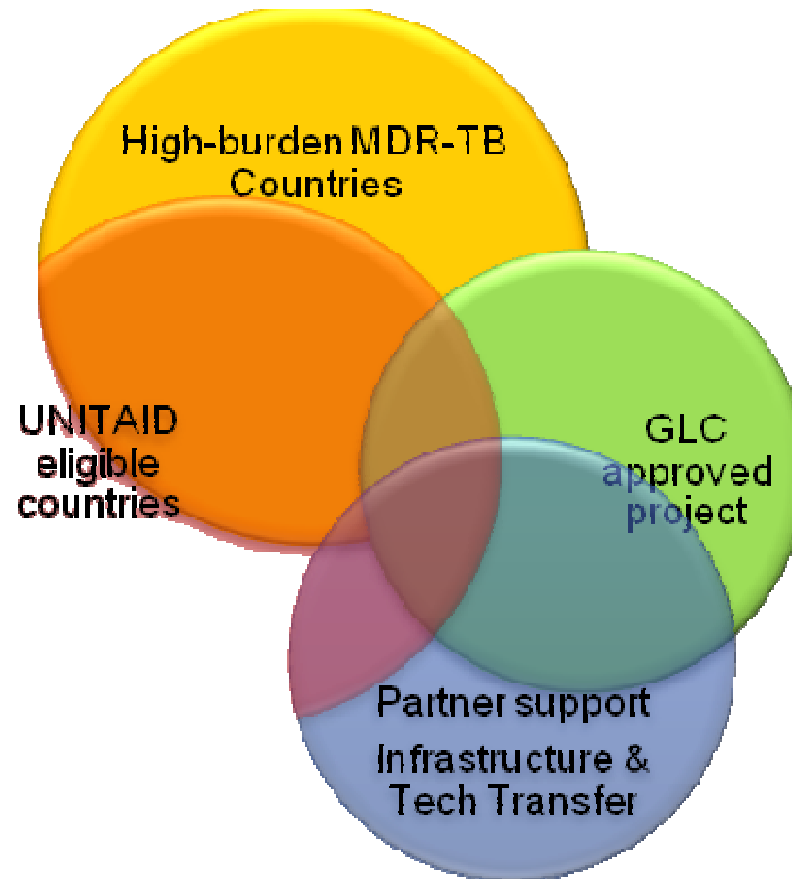
- Procurement of commodities
- Integration of new diagnostics into screening and treatment guidelines (Training, Validation, Knowledge transfer)

### Phase 3: Impact Assessment

- Continued support and oversight of technology transfer
- Impact measured and reported
- Ensuring GLP, IQC and EQA measures

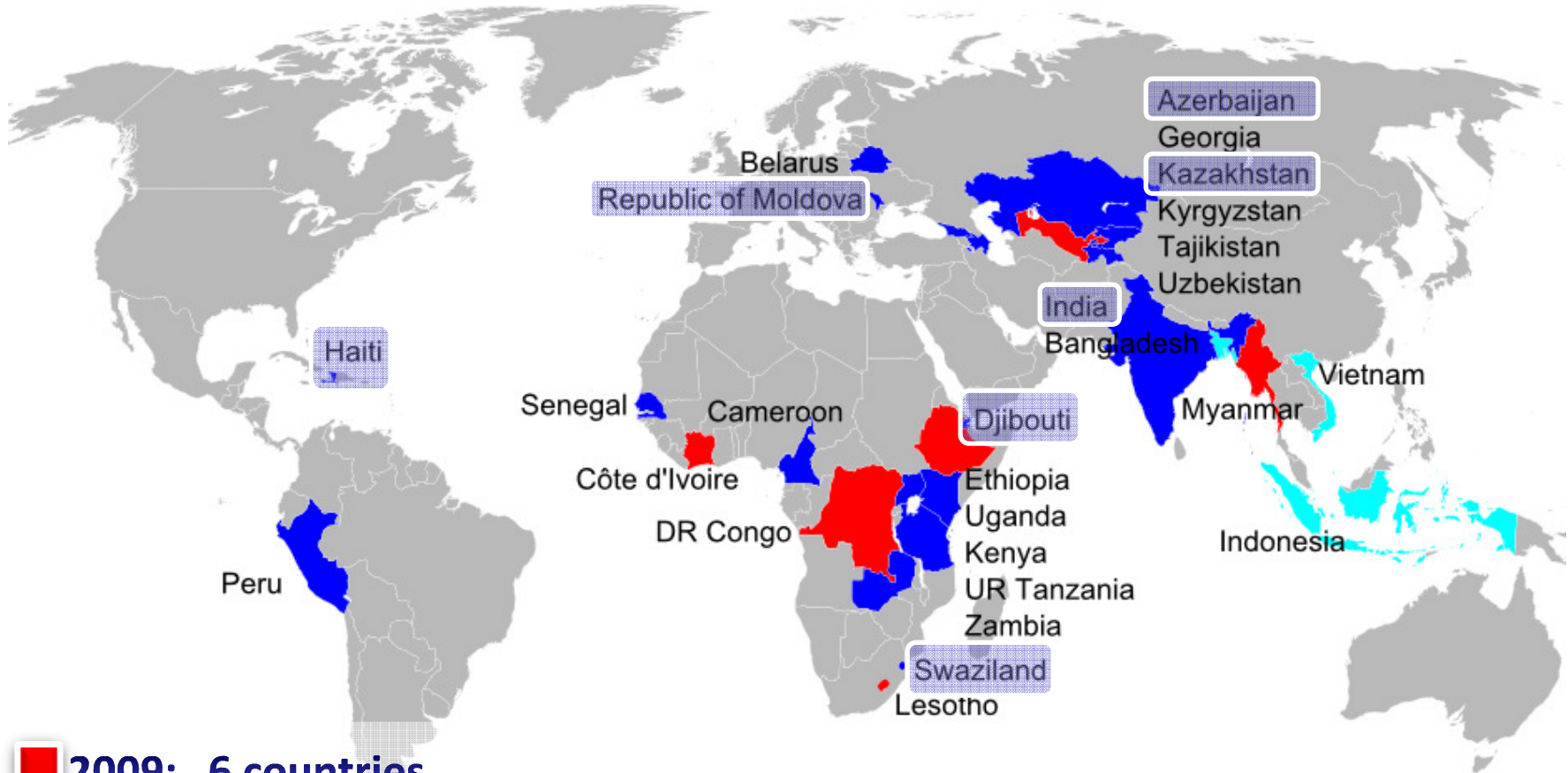


## SELECTION OF COUNTRIES





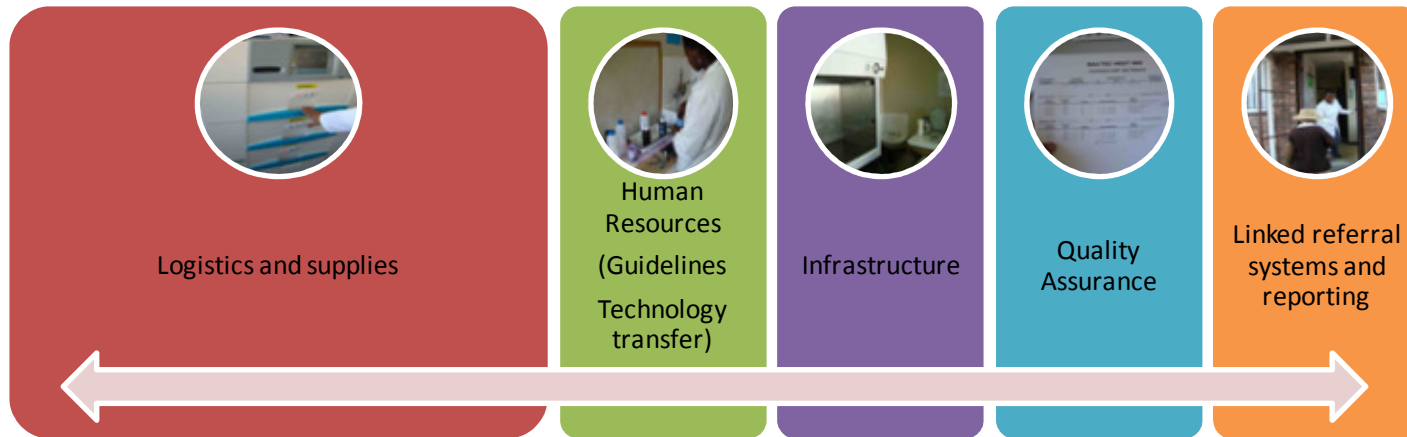
# WORLDWIDE COMMITMENT



- 2009: 6 countries
- 2010: 18 countries including India (43 labs)
- 2011: 3 countries



# A UNIQUE PARTNERSHIP MODEL



Funding for essential instruments, reagents, supplies



- Policies, norms international standards
- Participate in lab assessments
- Provide long-term, on-site monitoring
- Develop indicators and tools for M&E

**Global Laboratory Initiative**

- Negotiate with partners to ensure lowest prices
- Ensure customer support in place
- Share know-how from product development process
- Provide long-term, on-site mentoring for technology transfer



- Coordinate and manage procurement and delivery
- With FIND, engage industry to ensure affordability and sustained price decreases
- Collaborate with WHO pre-qualification to include diagnostics

**Global Drug Facility**





## WHAT IS INCLUDED IN THE PROJECT?

- **Initial and continuous assessment** of TB laboratories and TB labs networks
- **Procurement:**
  - Equipment for liquid culture/speciation and line probe assay
  - Reagents and consumables for project length
- **Training:**
  - Quality assurance and data management
  - Liquid culture and LPA
  - Biosafety and waste management
- **Follow-up** of the laboratories
- **Overall project management**



## WHAT IS NOT INCLUDED IN THE PROJECT

- **Premises for culture:**

- Need for a negative pressure room
  - Need for a strong biosafety level

- **Premises for molecular biology**

- 3 different rooms are required for such analysis

- **Equipment:**

- Non-specific equipment is not included in the project, which needs to be covered by other financial sources

- ➔ Extra partnerships need to be established



## IN-COUNTRY PARTNERS

<b>Ethiopia</b>	<b>Lesotho</b>	<b>Côte D'Ivoire</b>	<b>Uzbekistan</b>	<b>Myanmar</b>	<b>Haïti</b>
<ul style="list-style-type: none"><li>• MOH, PEPFAR-CDC, GAP/ILB, JHU &amp; ICAP</li></ul>	<ul style="list-style-type: none"><li>• MOH, PIH, PEPFAR/CDC, WHO, URC, GF, BD, SAMRC</li></ul>	<ul style="list-style-type: none"><li>• MOH, PNLT, IPCI; CAT Adjame, CeDReS, ASM, PEPFAR, EGPAF</li></ul>	<ul style="list-style-type: none"><li>• MOH, WHO, KfW (EPOS), GF, USAID, Euros Lab strengthening task force</li></ul>	<ul style="list-style-type: none"><li>• MOH, WHO, NTPL, AKK. JAICA, PSI, MSF, UNION</li></ul>	<ul style="list-style-type: none"><li>• MOH, NTP, WHO, NPHL, NRLM, GHESKIO, Fondation Mérieux, CDC-PEPFAR, ASM, Cornell University</li></ul>



## FIRST EXPTB INTERNATIONAL TRAINING WS

### 11 trainees (India, Myanmar, Vietnam & Thailand)

10 day training with Exptb, CDC/GAP & NTRL Bangkok.

Train young TB personnel to perform and interpret quality assured liquid culture/DST/species ID

Using a standardized training curriculum

Extensive hands-on practice sessions

Several topics concerning quality assured laboratory practices (GLP, QA, QC measures)

Laboratory sessions for technical proficiency.

Basics of biosafety and adequate BSL3 laboratory layout

Sputum processing

PCR and DNA hybridization/management of spills

Pre and Post KAP (knowledge, attitude and practice) evaluation showed a significant increase.

Comment: "This training increased my understanding, basic knowledge and grasp of laboratory practices. The lectures were informative and our hands-on exercises will help us to organize things more efficiently in our home laboratory."



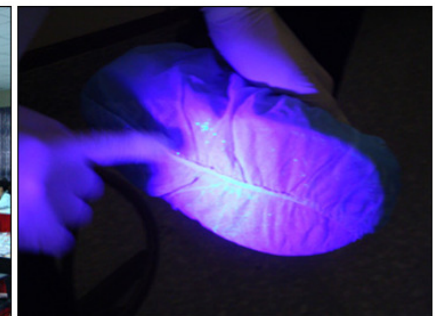
Reading, identification and reporting - [More photos](#)



Activities: PCR - [More photos](#)



Laboratory layout exercise



Spill drill - [More photos](#)



## PRE-QUALIFICATION PROCESS

### Model for electing suppliers through EXPAND-TB

To enlarge the pool of quality manufacturers to further reduce the diagnostics price through a comprehensive competitive bidding process.

#### Procedure requirements are:

- 9001 and 13485 ISO certification
- Registration by strict regulatory authorities (e.g. FDA, CE ...)
- Equivalency to the gold standard diagnostics used for approval by WHO

#### To demonstrate equivalency:

At least two SNRLs will compare the new tests according to the product specifications of the gold standard (STAG-TB endorsed)

The SNRL will finally submit the results through WHO for expert evaluation

Equivalent diagnostics will be selected in the next GDF public tendering





# PROGRESS AT A GLANCE

2009

- Kazakhstan
- Azerbaïdjan
- Swaziland
- DR Congo
- Haïti
- Côte d'Ivoire
- Myanmar
- India



2010

- Cameroon
- Moldova
- Georgia
- Belarus
- Uzbekistan, regional
- Lesotho, regional
- Ethiopia, regional
- Tajikistan
- Kyrgyzstan
- Senegal
- Peru
- Zambia
- Uganda
- Tanzania
- Kenya



# LESOTHO

## A Model for Scale UP

**1 reference lab:** QEII hospital

**1 regional lab:** Mafeteng government hospital

**1- 2006-2008:** FIND, PIH and WHO renovated the NRL and reinforced microscopy services, streamlined culture and DST and introduced modern TB diagnostic methods.

**2-2007:** Established BSL3, solid culture and DST and an EQA for smear microscopy within 4 months.

**3-Liquid culture and DST** were introduced a month later.

**4-2008:** A year later, introduced LPA for the rapid detection of MDR-TB

**6- 2009:** the National TB/HIV Strategic Plan for 2008 – 2012 was finalized

2009 FIND conducted retraining for laboratory technicians at the NRL

Validation of new TB diagnostics algorithm presented

1 regional laboratory is currently being renovated, and biosafety facilities are being installed

**7- Have started enrollment** under ExpTB

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### Experience establishing tuberculosis laboratory capacity in a developing country setting

C. N. Paramasivan,\* E. Lee,\* K. Kao,<sup>1</sup> M. Mareka,<sup>1</sup> G. Kubendiran,<sup>2</sup> T. A. Kumar,<sup>3</sup> S. Keshavjee,<sup>5</sup> H. Satti,<sup>6</sup> G. Alabi,<sup>6</sup> M. Raviglione,<sup>6</sup> G. Roscigno\*

\*Foundation for Innovative New Diagnostics (FIND), Geneva, Switzerland; <sup>1</sup>Ministry of Health, Maseru; <sup>2</sup>FIND, Maseru; <sup>3</sup>Partners In Health, Maseru, Lesotho; <sup>4</sup>Stop TB, World Health Organization, Geneva, Switzerland

#### SUMMARY

**OBJECTIVE:** To describe the experience of strengthening laboratory diagnosis of tuberculosis (TB) in a resource-limited country with high TB-HIV (human immunodeficiency virus) and multidrug-resistant TB (MDR-TB) prevalence.

**METHODS:** In the Kingdom of Lesotho, which is confronted with high levels of TB, MDR-TB and HIV prevalence, between 2006 and 2008 a coalition of the Foundation for Innovative New Diagnostics, Partners In Health and the World Health Organization renovated the National TB Reference Laboratory and reinforced microscopy services, streamlined conventional culture and drug susceptibility testing (DST) and introduced modern TB diagnostic methods.

**FINDINGS:** It was feasible to establish a biosafety level three facility for solid culture and DST and an external quality assessment programme for smear microscopy within 4 months, all in 2007. Liquid culture and DST

were introduced a month later. Preliminary results were comparable to those found in laboratories in industrialised countries. A year later, line-probe assay for the rapid detection of MDR-TB was introduced.

**DISCUSSION:** Through strong political commitment and collaboration, it is possible to rapidly establish quality assured TB diagnostic capacity, including current methods, in a resource-limited setting. Case detection and management for TB and MDR-TB have been greatly enhanced. From a low baseline, TB culture throughput in the laboratory increased ten-fold and has been sustained. This experience has served as a catalyst to translate policy into practice with new diagnostic technologies. It supports global policy setting to enhance and modernise laboratory work in developing countries.

**KEY WORDS:** TB laboratory capacity; liquid culture; line-probe assay; MDR-TB; low-income country







# ETHIOPIA

## 8 sites supported:

**2 central labs:** EHNRI (NRL), St Peters Hospital and **6 regional labs:** Mekelle, Bahir Dar, Jimma, Awasa, Adama (Nazret), Harrar

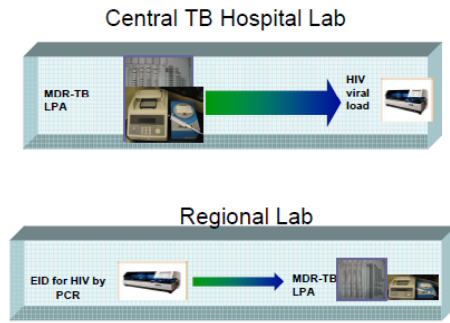
FIND involved since 2007 with full time consultant

Integrated HIV viral load testing with Line Probe Assay at central and regional locations

Refresher training in 2 central labs

Technical proficiency validated (sputum processing, SC, LC, LPA)

Negative Air Pressure and equipment installed at 6 regional labs, training planned



Inauguration March 2009





## INDIA, UNITAID & GF

### 40 sites to be supported:

4 national reference lab , 27 intermediate reference state laboratory, 9 medical colleges

Joint project involving UNITAID (EXPTB) and GF (CTD-MoH)

In 2008, Collaboration Agreement Gol and FIND to demonstrate introduction Liquid Culture/LIPA/Species ID

In 2010 FIND's role as a sub-recipient for India's GFr9:  
 -support of human resources in data management and lab support  
 -technical assistance and on-site training support for technology uptake.

Signing of Expand-TB MoU and start of activities April 2010





# UZBEKISTAN

**2 sites supported:**

**1 reference lab** in Tashkent and **1 regional lab** in Samarkand

Have started enrollment under ExpTB

Samarkand regional lab re-equipped by KfW, negative air pressure to be implemented by Exptb

Pilot drug resistance surveillance being finalized

A regional assessment visit is planned May 2010.





# COTE D'IVOIRE

## 3 sites in Abidjan:

**1 central lab, IPCI, and 2 regional labs, CeDReS, CAT-Adjame** handles 60% of all TB patients

Buildings under construction/renovation, BSL3 to be functional in Q2, 2010

In-country training is being coordinated by ASM/Exptb

- Training packages have been translated to French
- Liquid culture training will take place in Q2,2010 when negative pressure in BSL3 is fully functional
- LPA training just conducted by Exptb





# MYANMAR

**2 sites**

**1 central lab, in Yangon and 1 regional lab in Mandalay**

Equipment for 2 BSL3s shipped, installation completed

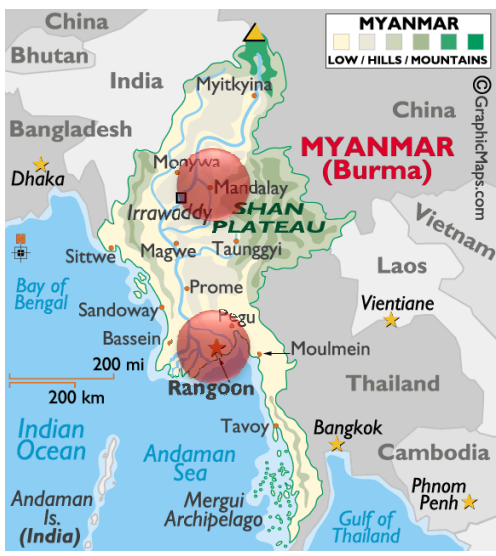
WHO country office acts as recipient of goods

MOH, Government of Myanmar in charge of customs clearance & shipping to sites

Exptb consultant coordinating all activities

Government of Myanmar has refurbished the lab areas

5 Lab techs underwent 2-week training in Bangkok







# THANK YOU

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