New Diagnostics Working Group

Fostering development of new diagnostic tools for TB

Vision

High quality diagnosis of tuberculosis and drug resistance is available for all people in all settings.

Mission

Foster development and evaluation of new diagnostics for tuberculosis by serving as a coordination, communication and advocacy platform for all stakeholders in TB diagnostic research and development.
Supporting the End TB Strategy and the goals of the Global Plan to End TB 2016-2020

- **Objective 1:** Ensure that the critical knowledge enabling the development of new diagnostic tools and solutions is available

- **Objective 2:** Develop a portfolio of new diagnostic tools coupled with a package of accompanying solutions to ensure that results translate into patient treatment

- **Objective 3:** Evaluate the portfolio of new diagnostic tools and solutions, including new detection strategies, approaches for optimized use, and innovative delivery mechanisms

- **Objective 4:** Ensure that fully validated new diagnostic tools and solutions are widely available and appropriately used in endemic countries
A Collaborative initiative to develop a centralized global TB drug resistance database

Global partnership to increase understanding of the genetic basis of resistance by correlating molecular data with results from drug susceptibility testing and, optimally, associated patient outcomes. These data will inform development of new diagnostics, facilitate clinical decision making, and improve surveillance for drug resistance.

Figure 1. ReSeqTB Collaborative Partnership. The partners comprising the collaborative partnership serve as the group responsible for establishing the purpose and scope of the data platform and the initial platform design. Additionally, representatives from each partner serve as the official decision-making body for the effort. A number of potential end users of ReSeqTB are projected and include researchers, clinicians, assay developers, ministries of health, and national tuberculosis programs. The data housed within the platform could be used for many purposes including writing clinical guidelines, developing diagnostic tests, and investigating drug resistance. Abbreviations: CDC, Centers for Disease Control and Prevention; FIND, Foundation for Innovative New Diagnostics; RDST, Rapid Drug Susceptibility Testing Consortium; TB, tuberculosis; WHO, World Health Organization.
ReSeqTB architecture
Who will benefit?

- Patients
- Clinicians
- Diagnostics developers
- Policy makers
- Drugs developers
- Vaccine community
- Scientists
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Pelizza da Volpedo Il quarto stato, Milan Modern Art museum
Task Forces and activities 2016

Use of next-generation sequencing for detection of drug resistance and correlation of specific mutations with *in vitro* MICs

**Coordinator:** Stefan Niemann, Borstel Research Center

**Strategic priority addressed**
Enable timely and effective treatment to reduce mortality and ongoing transmission, and prevent antimicrobial resistance by ensuring universal access to DST, which will require *rapid and simple tests for detection of drug resistance in decentralized settings for existing and future drugs*.

**Objectives**
- Reporting and sharing of data for ReSeqTB and Cryptic projects
- Evaluation of data applicability to DST and use of the findings to support WHO policies for interpretation of drug resistance in low-income countries.
- Forming expert consensus and fostering knowledge for sequencing to become the reference standard for DST for some anti-TB drugs.
Foster development and evaluation of tests for progression of LTBI to active disease

Coordinator: Alberto Matteelli, University of Brescia

Strategic priority addressed
Support the goal of disease elimination by addressing the reservoir of TB infection and efficiently introduce targeted preventive therapy, which will require tests for predicting the risk of progression from latent infection to active TB disease.

Objectives
Enhance the knowledge base and support consensus-building by engaging participation of key experts and stakeholders towards further development and finalization of:
• Target Product Profiles for a test of progression of latent tuberculosis infection
• Study design and protocols for testing the performance of assays targeting latent TB and progression from latent infection to active disease
Task Forces and activities 2016

Build consensus and foster knowledge sharing to enable the identification of suitable biomarkers or biosignatures for TB point-of-care tests

Coordinator: Tobias Broger, FIND

Strategic priority addressed
Reduce the current gap of 3 million cases missed each year and improve TB case detection through the use of accurate tests that are suitable for use in a patient-centered fashion at all levels of healthcare access for all populations, including children and those living with HIV

Objectives

• Synthesize biomarker knowledge to support the identification and aggregation of biomarkers for TB assays with a priority on non-sputum based POCTs for TB diagnosis, and for other potential indications in line with high-priority TPPs

• Convene experts to help inform validation and definition of systems to determine the status and evidence of promising biomarker candidates

• Establish guidelines for researchers and product developers to support the study design, refinement, validation and independent confirmation of new biomarkers

• Support advocacy efforts to promote biomarker data sharing with researchers and developers
NDWG Core Group

Co-Chairs
- Catharina Boehme, FIND / Bill Rodriguez, FIND acting Co-Chair
- Daniela Cirillo, San Raffaele Scientific Institute

Core Group Members (and constituency)
- Martina Casenghi, MSF (NGOs)
- Christopher Gilpin, WHO Global TB Programme (WHO and GLI)
- Philippe Jacon, Cepheid (Industry)
- Stefan Niemann, Borstel Research Center (Academia)

Task Forces and Coordinators
- Build consensus and foster knowledge sharing to enable the identification of suitable biomarkers or biosignatures for TB point-of-care tests
  Tobias Broger, FIND
- Use of next-generation sequencing for detection of drug-resistance and correlation of specific mutations with *in vitro* MICs
  Stefan Niemann, Borstel Research Institute
- Foster development and evaluation of tests for progression of LTBI to active disease
  Alberto Matteelli, University of Brescia

Secretariat  Alessandra Varga, FIND