

SUPPORTING, MOBILIZING, AND ACCELERATING RESEARCH FOR TUBERCULOSIS ELIMINATION



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Supporting, Mobilizing, and
Accelerating Research for
Tuberculosis Elimination



SMART4TB

The Supporting, Mobilizing, and Accelerating Research for Tuberculosis Elimination (SMART4TB) Consortium brings together experts in TB tools development, implementation science, capacity strengthening, civil society engagement, and policy guidance, with a plan to collaborate to transform TB control in the next five years. SMART4TB's strategy involves targeted research in collaboration with local partners in priority countries, strengthening capacity for conducting future research by country partners, and ensuring that the knowledge derived from research studies is translated into policy and practice at the global, national, and local level. The consortium, led by Johns Hopkins University (JHU), includes the University of California, San Francisco (UCSF), KNCV Tuberculosis Foundation (KNCV), the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), the Treatment Action Group (TAG) and regional collaboratives strategically based at research institutions in high-burden countries.

Technical Area 1: Diagnostics

The largest gaps in TB cascades of care are in identifying individuals with TB infection, disease, and drug resistance. Current tools for detecting TB infection and disease, as well as for monitoring treatment response and cure, are grossly inadequate. For TB infection, traditional skin tests are non-specific, blood-based assays requiring advanced laboratory infrastructure, and both perform poorly for predicting the risk of developing active TB. For TB disease, current molecular tests are expensive, have suboptimal operational characteristics to reach peripheral settings, and are reliant on sputum which is challenging to collect in key populations (e.g., children, sub-clinical disease, PLHIV). Resistance testing using semi-automated molecular tests is limited to a few drugs, and while sequencing solutions are improving, further simplification is needed for integration into routine clinical care. Tools to monitor response to therapy are currently limited to sputum-based tools with long turn-around-times (culture) or low sensitivity and specificity (smear). SMART4TB has identified Technical Area 1 as a priority objective, to identify new tools and approaches that meet requirements specified in high priority target product profiles, and to evaluate their implementation and impact on case detection and treatment in programmatic settings.

Diagnostics Objectives

In Year 1, SMART4TB will leverage high-quality TB diagnostics research sites and existing protocols to rapidly initiate evaluations that will enable World Health Organization (WHO) review of promising novel tests through the following technical objectives:

- Identify, help advance, and select novel diagnostics for field evaluations;
- Evaluate the usability and performance of non-sputum-based point-of-care (POC) TB diagnostic tests among adults to facilitate WHO policy review; and
- Evaluate the usability and performance of non-sputum based POC TB triage and diagnostic tests among children to facilitate WHO policy review.

Diagnosics Activities

Technology Scouting: The goal of this activity is to identify the most promising technologies ready for evaluation in diagnostic accuracy trials. SMART4TB will coordinate ongoing technology scouting activities across existing studies and initiatives and integrate input from USAID, USAID country missions, SMART4TB Regional Collaboratives, and our investigator network. The goal is to identify promising platforms/tests for co-development and to select assays that are ready for multi-center field evaluations.

Evaluation of TB Point of Care Diagnostics in Adults: SMART4TB will evaluate the diagnostic accuracy, yield, and acceptability of novel POC TB diagnostics in adults with presumptive TB. Our approach will be to expand the countries included in existing consortia (R2D2 TB Network, FEND, DriveDx4TB) by supporting additional study sites to drive faster WHO review and enhance potential for market uptake. We will work with existing consortia to finalize a standardized protocol for TB diagnostic accuracy trials in adults, implement the protocol at selected sites, and work with USAID country missions and SMART4TB regional collaboratives to identify additional counties and sites for accuracy trials and implementation research.

Evaluation of TB Point of Care Diagnostics in Children: SMART4TB will evaluate the diagnostic accuracy, yield, and acceptability/usability of novel POC TB diagnostics in children with presumptive TB. Our approach will be to leverage two sites supported by R2D2 and to support activities at one new site in Year 1 to initiate an evaluation of promising tests among children, SMART4TB will explore expanding to additional sites in Year 2. We will adapt protocols from ongoing pediatric TB diagnostic studies to finalize a standardized protocol and implement the protocol at selected sites.