

# SUPPORTING, MOBILIZING, AND ACCELERATING RESEARCH FOR TUBERCULOSIS ELIMINATION FAQs



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Accelerating Research for  
Tuberculosis Elimination



## Research Agenda

### **How did SMART4TB develop a research agenda?**

SMART4TB is made possible by the support of the American people through the United States Agency for International Development (USAID) Cooperative Agreement, which means USAID has substantial involvement in the research agenda setting process. The SMART4TB Consortium team proposed studies during the application stage, and through an iterative process Diagnostic, Therapeutic, and Vaccine Preparedness research studies were proposed and approved by USAID with core funds for global benefit. SMART4TB's future research agenda will be defined in close collaboration with USAID missions and will focus on the priorities of the National TB Programs (NTPs), local stakeholders, and mission needs.

### **How often will your research agenda be updated?**

SMART4TB anticipates an annual research agenda setting process. Additional studies and activities will be determined by availability of core and mission funds.

### **How can I propose a research idea or be part of the research agenda setting process?**

SMART4TB will seek feedback on country priorities from mission offices, National TB Programs, and other stakeholders regularly. In Year 1, SMART4TB surveyed potential stakeholders to describe their research priorities; these findings will be reviewed with USAID Headquarters, and in subsequent conversations with Country Mission offices and their partners.

### **How will the process work for confirming country involvement in SMART4TB and allocating funds?**

The decision about country involvement will depend on several factors including the country mission priorities, the NTP priorities, and availability of resources. This process will utilize a bottom-up approach, ensuring local stakeholders have a voice in the decision making process.

### **What are the priority countries for operational research?**

SMART4TB proposes to work in the following 24 USAID priority countries for TB: Afghanistan, Bangladesh, Burma, Cambodia, Democratic Republic of Congo, Ethiopia, India, Indonesia, Kenya, Kyrgyzstan, Malawi, Mozambique, Nigeria, Pakistan, Philippines, South Africa, Tajikistan, Tanzania, Ukraine, Uganda, Uzbekistan, Vietnam, Zambia and Zimbabwe. This is not an all-inclusive list and SMART4TB could potentially work in other countries including the 32 countries that are eligible for Global Fund technical assistance - Angola, Armenia, Azerbaijan, Belarus, Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Côte D'Ivoire, Eswatini, Georgia, Ghana, Guinea, Haiti, Kazakhstan, Lesotho, Liberia, Madagascar, Mali, Moldova, Morocco, Nepal, Niger, Pakistan, Papua New Guinea, Republic of Congo, Rwanda, Senegal, Sierra Leone, Somalia, and South Sudan.

## **What research designs will SMART4TB prioritize to address current and emerging challenges?**

SMART4TB will employ a combination of traditional and creative research designs depending on the technical area. In operational research, SMART4TB will be seeking creative designs that are both meaningful and can answer questions using a variety of designs, such as implementation science interventions, cohort studies, and comparative effectiveness trials.

## **Does SMART4TB have any core funds and if so, how will it identify its priorities?**

SMART4TB's global research agenda is funded by core funds from USAID Headquarters in Washington D.C. with potential investment from USAID missions over the project's lifetime in response to mission research agendas. The project's global priorities were initially identified by USAID in the call for funding but were further elaborated with support from SMART4TB consortium partners.

## **Site Selection**

### **How will study sites be selected?**

Study site selection will be a collaborative process with USAID. All studies have established criteria for participation and SMART4TB will circulate a questionnaire to assess site capacity when a potential site indicates interest. A list of potential sites will be reviewed with USAID/HQ, the USAID missions, NTPs, and other local stakeholders.

### **What are the steps for a non-priority country, or institution from a non-priority country, to become involved in SMART4TB?**

The approach here will depend on the research question, the availability of research sites with capacity to implement studies (e.g., previous experience with implementing TB research activities) and ability to manage USAID supported activities (responding to USAID rules and regulations).

### **What are the site selection criteria for the ADAPT protocol sites?**

Criteria for Potential ADAPT Tier 1 Clinical Trial Sites

- Previous experience conducting high-quality TB diagnostics research.
- Demonstrated capacity to enroll adults (or children, for ADAPT for kids) with presumptive TB at outpatient health centers.
- Quality-assured laboratory with experience doing solid and liquid culture.
- Capacity for onsite molecular testing using GeneXpert platform.
- Reasonable time for ethical and regulatory approvals (< 2-3 months).
- Existing relationship with a SMART4TB consortium member.

### **What are the site selection criteria for PRISM-TB?**

Criteria for Potential PRISM-TB Tier 1 Clinical Trial Sites

- SMART4TB used known DR-TB trials, protocol team members' experience, and trials websites (U.S., WHO/Europe, Australian) to search for potential trial sites in the 24 USAID high-priority countries that have experience with DR-TB therapeutic trials (Phase 2-3) or TB trials in pregnancy (see A2. Trials).
- Worksheets are ordered in terms of priority: 1. USAID TB Priority Countries, 2. GFATM Technical Assistance Countries, and 3. Non-USAID, Non-GFATM Countries. All are displayed for consideration given that there are non-priority countries that are high-burden RR-TB countries or have a strong track record in USAID-funded DR-TB trials.
- Priority was given to sites that participated in USAID-funded DR-TB trials (STREAM Stages 1-2, BEAT-Tuberculosis [South Africa], BEAT-TB [India]).
- Experience with operational research or non-therapeutic trials was not considered sufficient as those sites would not be expected to have the laboratory and pharmacy capacity needed to

conduct a therapeutic trial.

- In countries with multiple clinical trial sites, only the highest rated sites by protocol team members or the criteria above were retained.
- Site capacity relating to pregnant persons was also noted but did not limit whether the site was listed.

### **What are the site selection criteria for SMILE-TB?**

Criteria for SMILE-TB Tier 1 Clinical Trial Sites:

- Used known TB trials, team members' experience and searched trials websites (U.S., WHO/Europe, Australian) to identify for trial sites within the 24 USAID high priority countries that have experience with TB therapeutic trials and/or therapeutic trials in children (Phase I-IV).
- Experience with operational research and non-therapeutic (TB diagnostic) trials were not considered sufficient as those sites would not be expected to have the laboratory and pharmacy capacity needed to conduct a therapeutics trial.
- In countries with multiple clinical trial sites (South Africa, Uganda, Kenya, etc.), only the most experienced sites were kept who had performed several pediatric TB trials.
- Site capacity relating to pregnant persons was also noted (as this set of sites may also be used to study HPMZ in pregnant persons) but did not limit whether the site was listed.

## **Regional Collaboratives**

### **How were the proposed regional collaborative hosts selected?**

The regional collaborative hosts were selected based on strategic placement (accessibility to all USAID priority countries), existing and proven capacity, experience in capacity strengthening, and track record in regional and global research efforts, including ongoing, active regional collaborations in TB research and prevention and care activities. The regional collaboratives will assist the consortium with capacity-strengthening activities and work with programs and local institutions to help develop operational research proposals to be considered by SMART4TB.

### **What if I would prefer to collaborate with a different region?**

Regional collaborative hosts are flexible and will work with whichever partners are willing. There will be no formal assignment to a regional collaborative host, and countries can partner or participate in networks with any of the SMART4TB consortium members to optimize their current capacity and resources.

### **How can regional advocacy networks benefit this project?**

SMART4TB's mission includes a focus on policy translation and community engagement, and we have developed strategic activities to ensure rapid translation of research data into practice. We hope to work with existing advocacy networks in high priority countries, who are often those best suited to identify implementation challenges. The Treatment Action Group will be developing community advisory boards to provide community perspectives in research design and implementation, and we also hope to develop capacity for locally led research.

## **Project Implementation**

### **What technical assistance will the project provide in design and implementation?**

SMART4TB will provide training at various levels for partners involved in the project. There will be one-on-one mentoring and support through the Early Stage Investigator program, in-country workshops, and larger training webinars.

### **What are the timelines for SMART4TB? Do they vary by technical areas?**

SMART4TB is a five-year project and timelines for each technical area vary based on USAID

priorities and in-country engagement.

**What approaches will SMART4TB use to engage the community in research and implementation?**

SMART4TB sees community engagement as key to our people-centered mission. SMART4TB will work with USAID country missions, National TB programs, community advisory boards, and consortium partners to ensure community perspectives are considered in research development, implementation, and evidence translation.

**What are the plans for data harmonization and standardization across all the SMART4TB projects?**

SMART4TB has a Biostatistics & Data core staffed by experts who will work with study investigators to develop standard methods for data harmonization. Per USAID requirements, all SMART4TB study data will be publicly available at <https://data.usaid.gov> or on other public websites after primary findings being shared.