USAID FROM THE AMERICAN PEOPLE

Supporting, Mobilizing, and Accelerating Research for Tuberculosis Elimination

SMART4TB Consortium

# *ADAPT Study*
# *Assessing Diagnostics At Point-of-care for Tuberculosis*

## BACKGROUND

Diagnosis is the entry point to TB care, yet the largest gap in the tuberculosis care cascade is in identifying individuals with TB disease. Some 4 million TB cases per year go undiagnosed, and thus untreated, leaving people with TB sick and at risk of death and allowing more opportunity for the disease to spread. To close this gap, TB diagnostics are needed that work at or closer to the point-of-care and use samples other than sputum, which can be difficult for some people to produce.

## STUDY GOAL

To rigorously and efficiently evaluate, via a study platform, the diagnostic accuracy, yield, and acceptability of novel TB diagnostics to inform World Health Organization review. ADAPT will first evaluate the diagnostic accuracy of tongue swab samples on Xpert Ultra and Truenat MTB Plus. New promising tests ready for evaluation will be added to ADAPT over time.

## STUDY LEADERS

ADAPT is led by **Adithya Cattamanchi** at the University of California, Irvine and **Claudia Denkinger** at University of Heidelberg in partnership with Johns Hopkins University, University of California, San Francisco, KNCV Tuberculosis Foundation, the Elizabeth Glaser Pediatric AIDS Foundation, and Treatment Action Group.

## STUDY POPULATION

People older than 12 years who have presumptive TB based on symptoms (cough longer than 2 weeks) or TB risk factors (HIV, self-reported close contact with someone with TB, history of mining work) plus a positive TB screening test.

## STUDY LOCATIONS

Nigeria, Philippines, Zambia

## STUDY DESIGN (ClinicalTrials.gov NCT05941052)

ADAPT is a study platform, enrolling approximately 1,300 people annually, designed to efficiently assess accuracy and acceptability of promising new diagnostics in large-scale validation studies, in settings of intended use, ADAPT will compare novel tests' diagnostic accuracy with the reference standard to determine if they meet World Health Organization (WHO) **target product profile requirements**. ADAPT will also examine, using validated measurement tools, the usability and acceptability of these diagnostics through direct observations and surveys of health care workers involved in sample collection and TB testing.

Current tests being evaluated in ADAPT include Xpert MTB/RIF Ultra (Cepheid, USA) and Truenat MTB Ultima (Molbio Diagnostics, India) on tongue swab samples. Both are **polymerase chain reaction** (PCR) tests, already endorsed by the WHO for detecting TB (and some forms of drug resistance) via sputum. Primary outcomes are sensitivity and specificity as compared to a **microbiological reference standard** (sputum culture).

As novel diagnostics come through the development pathway, and are design-locked and ready for evaluation, ADAPT will add them into its standardized protocol for evaluation.

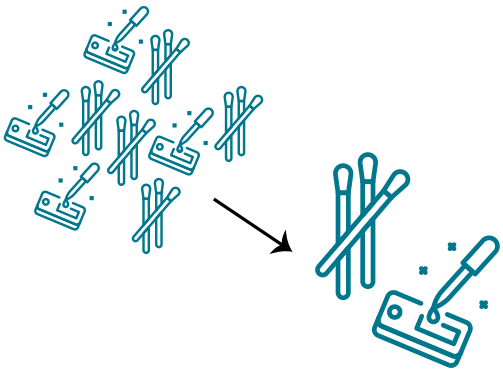
**Target Product Profile Requirements** are the ideal characteristics of a product designed for a specific disease.

**Polymerase Chain Reaction test** is a type of test that copies DNA to look for diseases, in this case to identify TB bacteria

**Microbiological Reference Standard** is defined by a positive culture for TB on sputum samples.

.

## HOW ADAPT WORKS



**Selecting promising novel diagnostic tests for evaluation**

**Evaluating most promising diagnostic tests for accuracy in adults**

**Evaluating diagnostic tests for ease of use in healthcare setting**

## ABOUT SMART4TB

This report is made possible by the support of the American people through the United States Agency for International Development (USAID). The contents are the sole responsibility of SMART4TB and do not necessarily reflect the views of USAID or the United States Government or consortium collaborators or members.

**If you have any questions, please contact us at: smart4tbinfo@jh.edu**