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Media Contact: Rekha Radhakrishnan, <u>rradhak5@jh.edu</u>

ENROLLMENT BEGINS FOR STUDY EVALUATING ACCURACY OF POINT-OF-CARE TUBERCULOSIS DIAGNOSTIC TESTS

The ADAPT study will collaborate with global partners in this space as part of the largest-ever coordinated effort to further TB diagnostic development

BALTIMORE, November 7, 2023 — The USAID-funded Supporting, Mobilizing, and Accelerating Research for Tuberculosis Elimination (SMART4TB) award is excited to announce enrollment of study participants in Nigeria, Zambia and the Philippines in the Assessing Diagnostics at Point-of Care for Tuberculosis (ADAPT) study. This study seeks to identify and assess promising novel point-of-care TB tests that do not rely on sputum. The study will generate evidence to inform World Health Organization (WHO) review and ultimately, uptake of new, effective diagnostic tests in TB high-burden countries.

"Better diagnostics that work where patients seek care are key to finding the 3.1 million people with TB who go undiagnosed each year," said Adithya Cattamanchi, chief, Division of Pulmonary Diseases and Critical Care Medicine at University of California, Irvine. "Our goal with this study is to evaluate tests that are easier on patients and that could produce fast, reliable results in diverse healthcare settings."

Partnering with the U.S. National Institute of Allergy and Infectious Diseases-funded The Rapid Research in Diagnostics Development for TB Network (R2D2 TB Network), Feasibility of Novel Diagnostics for TB (FEND-TB), FIND and Unitaid-funded DriveDx4TB, ADAPT will first rigorously evaluate the performance of Tongue Swab Xpert Ultra and Truenat MTB Plus, two WHO-endorsed rapid molecular tests for TB to determine whether they are an effective alternative method for diagnosing TB. SMART4TB is partnering with the Zankli Research Centre at Bingham University in Nigeria, De La Salle Medical and Health Sciences Institute (DLSMHSI) in the Philippines and Centre for Infectious Disease Research in Zambia (CIDRZ). Across these sites, the study will enroll 900 participants who present to health clinics with a cough for two or more weeks and/or have TB risk factors plus a positive World Health Organization (WHO)-recommended TB screening test, including key populations such as close contacts of people with TB, adolescents, and people living with HIV.

"The difference a tongue swab test could make for patients—particularly young people and people living with HIV, who struggle to produce sputum—cannot be underestimated, influencing everything from their likelihood of getting tested to moving them more rapidly towards treatment options," said John Bimba, director of the Zankli Research Centre.

"We need diagnostics tests that are user friendly. Healthcare settings for TB can vary widely and one of the goals with any new test is how well our staff is able to repeatedly conduct it. We will be looking at that closely with both tests," said Charles Yu, former vice chancellor for research



services and a professor at the College of Medicine of the De La Salle Medical Health and Sciences Institute.

"Rapid, low-cost and accurate tests can play a major role in ending TB in Zambia. We are looking forward to seeing the results and hope this study plays a role in transforming TB care globally," said Monde Muyoteta, program director for TB at the Centre for Infectious Disease Research in Zambia.

The researchers expect to have initial results from the study to share in March 2024.

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The SMART4TB Consortium brings together experts in TB tools development, implementation science, capacity strengthening, civil society engagement, and policy translation. Led by <u>Johns Hopkins University</u>, consortium members include <u>Elizabeth Glaser Pediatric AIDS Foundation</u>, <u>KNCV Tuberculosis Foundation</u>, <u>Treatment Action Group</u>, and <u>University of California</u>, <u>San Francisco</u>.

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