FIND and Unitaid kick off new US$15.9 million grant to improve tuberculosis diagnosis in primary care and community settings with two calls for partners

- **DriveDx4TB (the Drive Diagnostics for Tuberculosis project) will accelerate the introduction of new TB diagnostics that can address barriers to access and improve case detection at primary healthcare and community levels**
- **The project will run for 4 years across South Africa, India, Kenya, and Viet Nam, generating evidence to inform policy recommendations for three technology classes that have advanced significantly as a result of investments made in testing for COVID-19**
- **Innovators, developers, and manufacturers are now invited to respond to requests for proposals to accelerate the development of third-generation LAM tests, point-of-care (POC), and near-POC molecular diagnostics for TB**

GENEVA, SWITZERLAND – 6 September 2022. FIND, the global alliance for diagnostics, and Unitaid announced today that a new US$15.9 million grant has been signed to accelerate the introduction of new TB diagnostics that can address barriers to access and improve case detection at primary healthcare and community levels. Two requests for proposals (RFPs) have been launched to kick off the project.

Dubbed DriveDx4TB (Drive Diagnostics for Tuberculosis), the project aims to improve access to underserved populations, saving lives and reducing the economic impact of TB on individuals and healthcare systems. It will be implemented in South Africa, India, Kenya, and Viet Nam (countries in which FIND has regional hub offices), over a period of 4 years.

TB is among the world's deadliest infectious diseases and remains a major global health problem owing to high rates of illness and death. In 2020, an estimated 10 million people fell ill with TB worldwide, over 4 million of whom went undiagnosed. Of the estimated 1.5 million people who died from TB that year, 1.3 million were HIV negative. Underserved populations, including children and people living with HIV, continue to be undiagnosed. Already-stretched TB programme efforts have been greatly impacted by the COVID-19 pandemic, and access to diagnostics remains significantly reduced in high-burden countries, delaying initiation of life-saving treatment.

Low- and middle-income countries (LMICs) bear the greatest burden of TB. Current TB tests are not generally fit-for-purpose for use in LMIC primary healthcare centres, where patients often first seek care, or within communities where an early diagnosis is challenging to perform. This diagnostic gap has hindered TB case-finding efforts and highlighted the need to invest in development of new tools.

The DriveDx4TB project aims to address this issue by generating evidence to inform policy recommendations for three technology classes that have advanced significantly as a result of investments made in testing for COVID-19. FIND will conduct in-country, manufacturer-independent clinical accuracy studies, cost-effectiveness analyses, and usability studies to develop robust evidence that can be submitted to the World Health Organization (WHO) Global Tuberculosis Programme and Expert Review Panel for Diagnostics. Innovators, developers and manufacturers interested in taking part in the project are invited to respond to the RFPs that launched today:

First, for **third-generation lipoaribomannan (LAM) tests**, which can identify TB in urine samples using a "rapid test" format (similar to a COVID-19 Ag RDT) that can be conducted anywhere. Traditional TB tests rely on hard-to-provide sputum samples, which people with HIV and children particularly struggle with, whereas urine samples are readily available from all populations. The RFP for evaluation of third-generation LAM tests is available here.

Second, for **point-of-care (POC) molecular diagnostics** designed to bring the accuracy of gold-standard laboratory tests into community settings, for example using battery-powered, portable equipment. Third, for **near-POC molecular tests**, which bridge the gap between laboratory and community health services. New sampling approaches for molecular diagnosis are also being explored, such as tongue swabs. The RFP for evaluaton of POC and near-POC molecular tests is available here.

Community and civil society organizations are vital to the success of DriveDx4TB and an expression of interest for engagement and collaboration in the project will be issued in the coming weeks.

Philippe Duneton, Executive Director of Unitaid, said: "Business as usual will not bring an end to the TB epidemic. Unitaid is committed to bringing innovation to the TB response so the highest quality, best adapted tools and strategies can reach more people with life-saving care. This latest investment builds on Unitaid's longstanding efforts to close the gap in TB, with more than a quarter of a billion dollars in current funding aimed at improving TB prevention, diagnosis, and treatment."

Bill Rodriguez, CEO of FIND, said: "TB is one of the deadliest infectious diseases in the world – second only to COVID-19 in recent years – yet we can test for it, treat it, and cure it. Millions of people die from TB simply because they cannot get a diagnosis. Compounding the problem, COVID has made people hesitant to visit a health facility, leaving TB to spread unchecked faster than ever across households and communities. Providing better tests that can help communities test for TB locally, stop its spread, and ensure people can access treatment is the highest priority to tackle the TB burden. This investment from Unitaid will enable us to work with developers and communities to bridge the TB diagnosis gap so that lives can be saved."

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About FIND

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world. We connect countries and communities, funders, decision-makers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems. We are working to save 1 million lives through accessible, quality diagnosis, and save US$1 billion in healthcare costs to patients and health systems. We are co-convener of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, and a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation. For more information, please visit www.finddx.org

About Unitaid

Unitaid is a global health agency engaged in finding innovative solutions to prevent, diagnose, and treat diseases more quickly, cheaply, and effectively, in low- and middle-income countries. Its work includes funding initiatives to address major diseases such as HIV, malaria, and tuberculosis, as well as HIV co-infections and co-morbidities including advanced HIV disease, cervical cancer and hepatitis C, and cross-cutting areas, such as fever management. Unitaid is now applying its expertise to address challenges in advancing new therapies and diagnostics for the COVID-19 pandemic, serving as a key member of the Access to COVID-19 Tools (ACT) Accelerator, co-leading with Wellcome the therapeutics pillar and participating in the diagnostics pillar. Unitaid is hosted by the World Health Organization. For more information, please visit www.unitaid.org

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