

FIND SIGNS US\$14.5M GRANT WITH UNITAID TO EVALUATE NEXT-GENERATION SEQUENCING FOR RAPID, AFFORDABLE DIAGNOSIS OF DRUG-RESISTANT TUBERCULOSIS IN RESOURCE-LIMITED SETTINGS

- Project will generate evidence and boost in-country sequencing capacity to support the global adoption of commercial, targeted next-generation sequencing for affordable, scalable and rapid tuberculosis drug-susceptibility testing
- Activities funded by Unitaid will run for 3 years in Brazil, China, Georgia, India and South Africa

Geneva, Switzerland – *4 July 2019* – The Foundation for Innovative New Diagnostics (FIND) announced today that a new US\$14.5 million grant has been signed with <u>Unitaid</u> to evaluate the use of next-generation sequencing (NGS) for diagnosis of drug-resistant tuberculosis (DR-TB) in low- and middle-income countries (LMICs). The grant agreement was signed by FIND CEO Catharina Boehme and Unitaid Executive Director Lelio Marmora, at the Global Health Campus in Geneva, Switzerland.

The project – dubbed Seq&Treat (bringing next-generation TB care to underserved communities) – will start in October 2019. With implementation across Brazil, China, Georgia, India and South Africa over a period of 3 years, it will enable the introduction and global adoption of commercial, targeted NGS solutions for affordable, scalable and rapid TB drug susceptibility testing (DST).

TB is the world's deadliest infectious disease. In 2017 alone, 10 million people fell ill and 1.3 million died from it. Drug-resistant TB continues to be a public health crisis – in 2017, it was estimated that 558,000 people developed TB that was resistant to rifampicin, the most effective first-line drug, and 82% of those people had multidrug-resistant TB. Yet, only 161,000 DR-TB cases were detected and reported. Over a third of the world's DR-TB is found in India and China.¹

The spread of DR-TB is exacerbated by the lack of rapid, accurate diagnostic tests for comprehensive DST. Culture-based DST is the current standard of care, but it is slow and comes with significant biosafety hazards and minimal potential for cost reductions. Targeted NGS has the potential to revolutionize the DST landscape as it can provide faster, safer and more comprehensive results that can inform clinical decision-making for existing, repurposed and new DR-TB treatment regimens.

NGS refers to sequencing technologies that can rapidly process millions of DNA sequences in parallel, to decode the genome of a person or bacterium and find genetic mutations that are associated with drug resistance – which means that a comprehensive drug resistance profile can be effectively identified for accurate diagnosis and management of DR-TB. It is a technique that is already well-established to inform personalized treatment decisions in oncology.

The Seq&Treat project seeks to generate clinical evidence to support World Health Organization (WHO) global guidance for the use of targeted NGS for DR-TB diagnosis, establish a WHO global clinical knowledgebase,

¹ World Health Organization. Global tuberculosis report 2018. <u>https://www.who.int/tb/publications/global_report/en/</u> (accessed 1 July 2019)

evaluate proof-of-principle delivery models for integrating targeted NGS into existing diagnostic work streams, and facilitate inclusion of recommended NGS solutions into global procurement mechanisms and adoption by LMICs.

"The implementation of sequencing for patient care in LMICs has been limited due to perceptions of high cost, technical and workflow complexity, and lack of infrastructure on both supply and demand sides," said Catharina Boehme, CEO of FIND. "This significant investment from Unitaid will enable us to challenge these ideas by demonstrating sustainable and scalable sequencing models in high-burden TB countries."

"New technologies offer a phenomenal pathway to test and treat more people for tuberculosis, including drugresistant TB, while strengthening health systems," said Lelio Marmora, Executive Director of Unitaid.

Seq&Treat will enable rapid diagnosis and comprehensive treatment guidance in the short term, as well as catalyze an eventual decrease in the transmission of DR-TB, and reductions in DR-TB incidence and prevalence.

Seq&Treat is a FIND project, funded by Unitaid, which builds on earlier work on NGS solutions for MDR-TB that was supported by the Bill & Melinda Gates Foundation, the Australian government, and UK aid from the British people.

About FIND

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; and enabling accelerated uptake and access to diagnostics in low- and middle-income countries (LMICs). Since 2003, we have been instrumental in the delivery of 24 new diagnostic tools. Over 50 million FIND-supported products have been provided to 150 LMICs since the start of 2015. A WHO Collaborating Centre, we work with more than 200 academic, industry, governmental, and civil society partners worldwide, on over 70 active projects that cross six priority disease areas. FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control and prevention. For more information, please visit <u>www.finddx.org</u>

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