Expression of interest (EOI) – Point-of-care (POC) molecular diagnostics for TB

Globally, tuberculosis (TB) is responsible for more deaths than any other infectious disease. New diagnostics are urgently needed to screen the hundreds of millions of individuals with symptoms suggestive of TB and to deliver an accurate diagnosis for the 10 million individuals who fall ill with TB each year. The COVID-19 pandemic has accelerated innovations in swabs and other sampling tools, while new, rapid molecular diagnostic platforms suitable for use at the point-of-care (POC) are in development. POC molecular platforms can be repurposed for TB detection, e.g. from swabs; it is anticipated that this will help to overcome the barriers impeding the delivery of quality diagnostics in settings where patients seek care.

As part of a large, Unitaid-funded grant¹ that has been proposed, FIND will accelerate the development, evaluation, and market launch of POC molecular diagnostic platforms for the detection of TB. With this call for EOIs, we seek to identify agile developers/manufacturers to collaborate on a co-development and trialling programme for TB detection assays, ultimately aiming for regulatory approval and global policy with the World Health Organization (WHO).

Potential benefits of participating

Following this call for EOIs, we intend to publish a request for proposals¹ and enter partnerships, through which selected developers/manufacturers will receive support in one or more of the following areas:

- Technical and co-development support to meet critical design specifications (e.g. development of a TB-specific assay for an existing multi-pathogen platform)
- Feasibility assessment against a reference panel and verification of key claims in relevant clinical settings
- Manufacturer-independent clinical trialling to meet WHO policy and prequalification requirements, including financial, logistical and operational support
- Map current and future market dynamics (supply and demand factors) to develop product commercialization strategies in low- and middle-income countries (LMICs)
- Collaboration with major procurers to establish market access terms

FIND will accept submissions from manufacturers for products with the following characteristics:

- A design-locked TB assay ready for trialling by Q4 2023
- Portable molecular platforms that can be operated with basic infrastructure and training
- POC platforms (simple, capable of detecting TB from a swab or other non-sputum sample) and near-POC platforms (molecular TB detection assays with simultaneous drug-resistance detection; at least rifampicin, but ideally also isoniazid and fluoroquinolones)
- Affordable and suitable for use in low- and middle-income countries (LMICs) settings
- Designed with best efforts to limit medical waste and reduce any potential carbon footprint

How to apply

FIND welcomes interest and participation from any molecular diagnostic developers/manufacturers with late-stage products able to obtain a TB diagnosis using POC or near-POC platforms.

Responses to this EOI should be submitted via email to UA_MDx@finddx.org. Please complete the attached application checklist and send any relevant additional supporting materials.

The deadline to respond to the EOI is 11:59PM CET, 8th April 2022.

If you have any questions, please contact: UA_MDx@finddx.org

¹ Grant under negotiation with Unitaid and subject to funding approval by Unitaid