Frequently Asked Questions

Accelerating the development of new diagnostics for tuberculosis (TB): rapid detection tests for TB (third-generation LAM tests)

(Last updated: 22 September 2022)

1. **How can I access the recording after the webinar?**

The link to the recording of the webinar session is available on the FIND calls for partners webpage, just under the request for proposals (RFP) link.

2. **What is the funding range for each awardee under the DriveDx4TB project?**

There will be no direct funding awards provided to applicants through the DriveDx4TB project. The budget envelope of US$ 15.9M will be used by FIND to fund activities that will indirectly support successful applicants in developing evidence dossiers for submission to the World Health Organization (WHO) Global TB Programme (GTB) and Expert Review Panel for Diagnostics (ERPD) and preparing for in-country implementation in low- and middle-income countries (LMICs). The specific supported activities are described in the RFP document under the section OBJECTIVES AND SCOPE.

3. **Can organizations apply as a consortium?**

Yes, partnerships/consortia are accepted but a single lead entity shall be designated and shall assume responsibility for the application and for contract negotiations with FIND. Please refer to the section FUNDING AWARDS in the RFP document for more information.

4. **Is the RFP open for submissions from international applicants?**

We welcome submissions from international applicants and there is no restriction on the origin of applicants, except where an international embargo or sanction by the United Nations, the European Union or the Government of Switzerland applies. Please review the Declaration of Undertaking provided in Appendix 1 of the RFP document for further information.

5. **Is it possible to submit more than one proposal?**

A maximum of one proposal can be submitted per organization.

6. **Should I apply to FEND-TB or DriveDx4TB?**

FIND has launched multiple calls for proposals to support companies developing new TB diagnostics:

- The **NIH-funded Initiative for Feasibility of Novel Diagnostics for TB in Endemic Countries (FEND-TB)** led by Rutgers University and FIND invites developers of TB diagnostics to submit proposals for **evaluation of early-stage TB diagnostics** and novel testing strategies. The FEND-TB initiative provides access to adaptable and open trial protocols, with the aim to conduct clinical studies, laboratory evaluations of prototype assays, and economic analysis, along with transmission modelling.
- The **Unitaid-funded DriveDx4TB project** led by FIND invites developers of TB diagnostics to submit proposals for products at a more advanced stage of development. **Developers must be able to**

commit to complete product development activities and supply tests that are the final "locked" product design for clinical evaluation by Q4 2023. The DriveDx4TB project provides access to manufacturer-independent clinical studies, cost-effectiveness analyses, usability studies, and market intelligence and market shaping activities to support successful applicants in developing evidence dossiers for submission to the WHO GTB and ERPD, and preparing for in-country implementation in LMICs.

- Applicants may submit proposals to both the FEND-TB and DriveDx4TB projects, simultaneously. Diagnostics that advance through FEND-TB to design locked products could naturally progress into the DriveDx4TB project.

7. **Our technology does not require an instrument. How should we complete the sections of the Technical Assessment matrix related to the instrument?**

Please indicate that no instrument is required and therefore the specific criterion is not applicable, and the maximum score will be given as per the scoring guidelines.

8. **What information is to be included under "Description and timeline of activities under the DriveDx4TB project" in the Applicant Presentation template (slide 6)?**

In this section, applicants should describe how their own planned activities will complement the activities supported under the DriveDx4TB project to accelerate their product development, validation, and launch in LMICs.

9. **Please clarify the terminology "third-generation LAM assay"?**

The first-generation urine lipoaribomannan (LAM) assay, Determine TB LAM test from Abbott (Alere), has been recommended by the WHO for diagnosis of tuberculosis in people living with HIV (PLHIV) despite low sensitivity. A "second-generation urine LAM assay" refers broadly to a class of technology that would achieve a higher sensitivity in PLHIV. The scope of the RFP is to address multiple patient populations beyond PLHIV, therefore a "third-generation urine LAM assay" should achieve detection of lower levels of LAM regardless of a patient's HIV status.

10. **Are aerosol-based technologies in scope of the current RFP?**

We do not consider aerosol-based technologies to be in scope of the current RFP, as we are not currently able to support TB aerosol product development with the provision of appropriate sample panels as required for the assessment of technology performance claims prior to clinical studies. We continue to follow the work in the TB aerosol space and potential opportunities, although not in the scope of this RFP. Please note that you may consider applying for the Rutgers-FIND initiative for feasibility of novel diagnostics for TB in endemic countries (FEND-TB). The link to the FEND-TB call for proposals is also available on the FIND calls for partners webpage.

11. **Please provide a list of suitable cross-reactive pathogens or pathogen proteins and potentially interfering substances to add to the urine for testing?**

Urine is a complex biological matrix, and it is well known that the physical and chemical composition of the urine vary drastically across individuals, depending on several factors including diet, health condition, medication, and hydration status. Typically, in an immunoassay, the components from the matrix might interfere with the analyte. However, Broger et.al., (https://doi.org/10.1371/journal.pone.0215443) have

shown that there is no evidence of inhibitor protein in urine, and the matrix effects do not appear to be a significant factor when detecting LAM in urine. Therefore, addition of any interfering substance to the complex urine matrix might not be necessary. Moreover, cross-reactivity to non-tuberculous mycobacteria and other actinobacteria in urine depends on the antibody and/or of LAM epitopes detected by the specific antibodies.

12. How can developers request access to LAM antibodies from the FIND biobank?

Please reach out directly to ua_lam@finddx.org.

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