Frequently Asked Questions

Accelerating the development of new point-of-care (POC) and near POC molecular diagnostics (MDx) for tuberculosis (TB)

(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 for each technology class. It is possible to submit one proposal for the POC MDx technology class and one proposal for the near POC MDx technology class.

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. **Is there a pricing guideline to inform developers' business case and product development?**

With regard to the price paid per TB MDx test, we are currently evaluating responses from several companies. An analysis published by Médecins Sans Frontières (MSF) suggest that a price point of less than US$ 5 per test is achievable. FIND would also like to highlight the publicly available price agreements reached with Cepheid: https://www.finddx.org/pricing/genexpert/. Decisions will not be solely made on price as there could be an opportunity to achieve future price reduction with adequate volumes and cost of goods (COGs) optimization.

8. **Are technologies that fit most of the POC MDx constraints but use sputum samples in scope of the current RFP?**

Solutions considered under the point-of-care molecular diagnostic (POC MDx) technology class should not include sputum only as a sample type under the scope of this RFP. However, they can be submitted to be considered for the near POC technology class.

9. **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.

10. **What information is to be included to describe the "assay design" in the technical assessment matrix and applicant presentation template?**

In the section requesting details to be provided on the "assay design", applicants should describe their current assay in sufficient detail to allow reviewers to assess the performance claims made by the applicant. Applicants are expected to specifically provide any/all information that can be shared regarding how their assay detects TB and determines TB drug resistance, if applicable, to allow for a full and accurate assessment of the submission.

11. **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.

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