

REQUEST FOR PROPOSAL (RFP) Assessing patients and key stakeholders' willingness to pay for new tuberculosis diagnostics to be commercialized in the private sector in low- and middle-income countries

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1. 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, decisionmakers, 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

2. BACKGROUND INFORMATION

Challenges in tuberculosis diagnostics

Tuberculosis (TB) remains a major global health problem owing to its high rates of morbidity and mortality. According to the World Health Organization (WHO) Global TB Report 2021, approximately 10 million individuals contracted TB in 2020; however, because of existing TB programme inefficiencies, and compounded by the effects of the COVID-19 pandemic, 4.1 million individuals with TB went undiagnosed. Reduced access to diagnostics (and subsequent delays in diagnoses and treatment) have also been exacerbated by the COVID-19 pandemic, resulting in an increase in deaths caused by TB (1.3 million deaths in 2020 – levels last seen in 2017).

The limited availability of fit-for-purpose diagnostics has hindered TB case-finding efforts. Case-finding gaps exist due to a combination of under-reporting of individuals diagnosed with TB and underdiagnosis (due to people with TB being unable to access healthcare or not being diagnosed when they do). Specific underserved populations, including children, people living with HIV (PLHIV) and males, continue to be missed – again, this gap has been exacerbated during the COVID-19 pandemic. Existing tools for TB screening and diagnosis are not fit for the purpose of reaching individuals with active TB, while current technology is unable to address geographic variations in "where" and "how" healthcare is accessed.

New product classes

In September 2022, FIND and Unitaid jointly announced a new project funded by Unitaid, DriveDx4TB (Drive Diagnostics for Tuberculosis), to accelerate the introduction of new TB diagnostics that can address barriers to access and improve case detection at the primary healthcare and community levels. DriveDx4TB aims to improve access to TB diagnostics for underserved populations, save lives and reduce the economic impact of TB on individuals and healthcare systems. It will be implemented in four key low- and middle-income countries (LMICs): India, Kenya, South Africa and Viet Nam, over a period of 4 years, from 2022 to 2026.

As part of this work, FIND recently published two Requests for Proposals (RFPs; see <u>here</u> and <u>here</u>) for accelerating the development of three new diagnostic product classes, with the goal of identifying manufacturers that have demonstrated substantial technical and commercial potential to deliver these diagnostic platforms. The three product classes are third-generation lipoarabinomannan (LAM) rapid diagnostic tests (RDTs), point-of-care (PoC) molecular diagnostics (MDx) and near-PoC MDx (with accompanying alternative sampling approaches).

Third-generation LAM RDTs

LAM is a prominent lipoglycan constituent of the cell wall of the bacteria that cause TB; it represents the most promising target antigen for a simple RDT. Individuals co-infected with TB and HIV excrete high levels of LAM in their urine, and a simple LAM RDT has been a gamechanger for TB detection in people living with HIV. Unfortunately, the low analytical sensitivity of the current LAM assays means they are unsuitable for use in other patient populations where urine LAM levels are lower. A highly sensitive LAM assay has the potential to address multiple patient populations beyond people living with HIV and improve decentralized access to TB testing in LMICs.



PoC MDx

In the context of TB, PoC MDx would be capable of detecting TB from a non-sputum sample, with or without a drugresistance profile, enabling testing closer to the patient (decentralized at facility- or community-level). Increased global access to this new class of products will help address the attrition associated with centralized testing models in many countries that have a high burden of TB (e.g. inadequate sample referral pathways and reliance on sputumbased testing), ultimately improving the chances of an individual with undiagnosed TB being identified and reducing the associated catastrophic costs for the patient.

Near-PoC MDx

In contrast with PoC MDx, near-PoC MDx for TB would share similar characteristics with the limited number of molecular WHO-recommended rapid diagnostic tests (mWRDs) currently available at centralized facilities i.e. sputum-based TB testing, capable of simultaneously detecting TB and at least rifampicin-resistance. Increasing the availability of alternative near-PoC MDx platforms in addition to the existing options (e.g. GeneXpert MTB/RIF and Truenat) and specifically reducing costs (upfront and per test), combined with broader drug-resistance profiling or alternative sample types, will enable better adoption by TB control programmes (increasing the proportion of bacteriologically confirmed TB cases) and improve clinical decision-making and treatment outcomes (especially in countries with high rates of drug-resistant TB).

DriveDx4TB

The <u>DriveDx4TB</u> project has four outputs. This RFP is focused on Output 3: Creating a healthy and sustainable market for the introduction of new diagnostics by developing global pricing and equitable access terms for all LMICs; supporting suppliers' go-to-market strategies for the selected target markets; and engaging with multilateral funders and countries to pool demand and negotiate volume-based agreements with suppliers, including access to innovative/trade finance mechanisms and demand-aggregation opportunities where feasible.

3. STATEMENT OF PURPOSE

Understanding how patients and other stakeholders value various aspects of a diagnostics intervention in healthcare is vital to both the design and evaluation of public health programmes. Incorporating these values in decision-making may ultimately result in clinical, licensing, reimbursement and policy decisions that better reflect the preferences of stakeholders, especially patients. Aligning healthcare policy with patient preferences could improve the effectiveness of healthcare interventions by improving adoption of, satisfaction with and adherence to clinical treatments or public health programmes.

In this context, FIND is seeking an individual consultant or consultancy to help understand values and preferences around the various attributes of new classes of diagnostics for TB, as well as the willingness to pay and other pricing requirements, among private sector stakeholders in four LMICs.

4. SCOPE OF WORK

- The condition that is in scope for this work is tuberculosis.
- The three product classes in scope are third-generation LAM RDTs, PoC molecular diagnostics (MDx) and near-PoC MDx (with accompanying alternative sampling approaches).
- Willingness to pay (WTP) as well as values and preferences for each product class are expected to be tested with the following stakeholder groups; these groups are all assumed to exert a large influence on product purchase and procurement decisions:
 - Patients/end-consumers
 - Pharmacists
 - o Clinicians
 - Laboratory staff



• The countries in scope are India¹, Kenya, South Africa and Viet Nam.

A WTP and values/preferences evaluation will be conducted for each of the stakeholder groups mentioned above (the list may vary if justified by the Consultant) in each of the four countries in scope. This WTP evaluation will help FIND determine the optimal price ranges for each of the product classes as well as gain an understanding of the product attributes that drive purchasing and/or procurement decisions.

The key research questions the consultant will be expected to answer are as follows:

- What are the acceptable end-user price ranges (in USD) for each of the three product classes?
- Which product attributes contribute the most to WTP?
- What external factors (unrelated to product) influence WTP the most for each of the three product classes?
- What does the demand-pricing curve look like for each of the product classes?
- What are the expected demand forecast volumes for each of the product classes? How do these volume estimates vary depending on use case scenarios?
- For procurement purposes, how are purchasing decisions taken and what is the purchasing process?

5. METHODOLOGY

FIND does not have a preference regarding the methodology to be used for this analysis but will consider the approach or mix of approaches that seems most appropriate with regards to the specific set of products and types of purchasers that are considered in this project. FIND welcomes new ideas and innovative approaches, such as:

Direct surveys, including but not limited to:

- Expert judgements
- Customer/purchaser surveys: Van Westendorp price sensitivity meter, Gabor-Granger technique, etc.

Indirect surveys, including but not limited to:

- Conjoint analysis
- Discrete choice analysis
- Monadic price testing
- Brand price trade-off (BPTO) analysis

6. PERFORMANCE STANDARDS

Deliverables expected include:

- Deliverable #1: a draft outline of the deliverables, to be agreed upon with FIND
- Deliverable #2: a detailed workplan along with the methodology to be used for the project, to be agreed upon with FIND
- Deliverable #3: a list and contact details of key stakeholders who could potentially be interviewed/surveyed, to be agreed upon with FIND
- Deliverable #4: detailed notes (or transcripts) of all key stakeholder interviews (if applicable)
- Deliverable #5: a detailed report, in Microsoft Word or PowerPoint format (maximum 50 pages/100 slides), answering each of the research questions from the scope of work and detailing all of the findings of the analysis
- Deliverable #6: a finalized report in Microsoft PowerPoint format (maximum 30 slides), synthesizing the findings of the analysis, tailored for external presentations

¹ In India, surveys of patients' and pharmacists' WTP and values and preferences have been conducted and will therefore not be included in this analysis.



• Deliverable #7: a market-sizing model, with inputs (assumptions) and outputs (visualizations) clearly shown, including the market-sizing methodology, in Microsoft Excel format

7. APPLICATION GUIDELINES

Candidates interested in responding to this RFP should submit a proposal, in Microsoft Word or PowerPoint format, that includes the following information:

- **Organizational profile:** a short overview of your organization and a brief outline of services/products provided (consulting, market research, off-the-shelf data, reports, etc.)
- **Experience:** relevant experience, including a list of relevant projects you have worked on in the past (with a description and the duration of each assignment, along with the size of the team involved). Ideally, short case studies should also be included.
- **Methodology:** a description of the technical approach(es) that will be used to conduct the WTP analysis, e.g. the use of interviews, surveys or other tools/techniques. FIND welcomes new ideas and innovative approaches.
- **Proposed scope of work and a work plan:** the work plan should explain the plan for implementing the main activities/tasks of the assignment, their content and duration, phasing and interrelationships, milestones (including interim deliverables), and tentative delivery dates for the reports. The proposed work plan should be consistent with the technical approach and methodology.
- **Deliverables:** a list of the final documents (including reports) to be delivered as the final output(s) should be included. The work plan should be consistent with the requirements laid out in this document but can deviate if relevant and/or justified.
- **Budget:** a financial proposal for this project, with a full breakdown (in USD) of staff cost components/level of effort (for staff) and/or of 8-hour days, with daily rates required per deliverable (for consultants) and any other direct costs (please refer to the budget template provided in Appendix A). In the budget estimate, please include any additional expenses expected to be incurred related to market research.
- **Proposed team:** short biographies of key staff involved in the work, along with their roles and responsibilities; include short CVs of key personnel proposed as team members.
- Networks and partnerships in the four countries in scope: provide details of local teams, partners and/or other stakeholders that are to be involved in the completion of this work. In case of the involvement of subcontractors, describe the roles and expertise of each organization/individual chosen to participate on this project as a subcontractor.
- Contact details.

8. AWARD CONDITIONS

Applicants/Bidders that are selected for final awards are required to:

- Be legally permitted to perform work in the country where the contract will be performed
- Commit to and follow the FIND Global Access Policy and the FIND Code of Conduct and Ethics
- Accept the Terms and Conditions of a Declaration of Undertaking for Unitaid (Appendix B)

9. HOW TO APPLY

Proposals are to be submitted by 22 March 2023 at 18:00 CET. The successful applicant(s) will be notified by 31 March 2023 at the latest if their proposal has been accepted. The work should begin on 21 April 2023 and be completed by 21 July 2023. Please send submissions and any questions to <u>Market.Intelligence@finddx.org</u>.



10. EVALUATION AND AWARD PROCESS

The evaluation process is designed to be objective, independent and transparent, to ensure that the most suitable proposals are identified. All proposals will be evaluated by an internal review panel comprising members of the Access and Technology & Development teams within FIND.

Proposals will be evaluated against the following criteria:

- The quality of the financial proposal as well as the transparency and breakdown of all financial elements included in the final quote. Candidates should provide as much information as possible to explain their proposed budget.
- Proposed scope of work, indicating the candidates' understanding of the scope of work and the extent to which the proposed activities match the objectives, scope of work, deliverables, timelines and budget listed in this RFP.
- Market research expertise, i.e. candidates' experience and expertise in the various market research approaches listed in this RFP and experience in performing similar market assessments; executing specific market intelligence deliverables (disease management/policy landscape analysis, funding landscape analysis, procurement and distribution landscape analysis, market landscape and marketsizing analysis); and conducting primary and secondary market research, e.g. through key opinion leader (KOL) interviews, surveys, focus groups, etc.
- Experience conducting market assessments in LMICs and in the diagnostics field.
- The "quality" of the proposed team, i.e., composition, experience, that will work on the RFP. Candidates are required to present the members of the team, detailing how their background and experience are relevant, and they must submit complete CVs of the proposed team members.
- Networks or physical location(s) of the candidates in the countries in scope, i.e. access to networks of relevant stakeholders in the key countries.

With regards to the evaluation, each criterion will have the same weight except for the criterion "the quality of the financial proposal", which has twice the weight of each of the other criteria.

Where FIND judges more than one application to be complementary, FIND reserves the right to suggest a partnership within the RFP process.

11. CONFIDENTIALITY

FIND considers any proposal received under the RFP to be confidential. If required, FIND can sign a confidentiality disclosure agreement (CDA) with interested Applicants/Bidders prior to proposal submission. FIND will not disclose the proposal to third parties without the prior written agreement of the proposal submitter. The review of proposals will be carried out by an internal FIND team, all of whom are under confidentiality agreements and will be recused if found to have a potential conflict of interest (which they are obliged to disclose). Any specific questions concerning confidentiality should be addressed to the FIND team.

12. QUESTIONS AND COMMUNICATIONS PROTOCOL

Please email any questions to: <u>Market.Intelligence@finddx.org</u>. Questions will be accepted and promptly responded to until 10 March 2023, at 18:00 CET.



APPENDIX A: BUDGET TEMPLATE

Applicants should use the provided budget template in responding to this RFP. If applicants choose to prepare the budget using a currency other than USD, the budget should be converted to USD using a 6-monthly average rate from a trusted source, e.g. a central bank or OANDA.

NAME OF THE APPLICANT :							
TITLE OF THE PROJECT :							
PROJECT FUNDER:	FIND (Unitaid)						
PROJECT TERM:	dd/mm/yyyy						
BUDGET ASSUMPTION, CALCULATION	N AND VALUES						
STAFF							
Position	Location	Mesurement Unit	Unit Cost			Total requested (USD)	Comments and Justifications
			\$	-	0.00		
			\$	-	0.00		
Fringe benefits, if any		0%					
Total staff costs (USD)						\$ -	
CONSULTANTS			1				
Budget line	Location	Mesurement Unit	Unit Cost			Total requested (USD)	Comments and Justifications
			\$	-	0.00		
			\$	-	0.00	\$-	
Total consultant costs (USD)						\$-	
TRAVEL RELATED							
Budget line		Mesurement Unit	Unit Cost		Number of Units	Total requested (USD)	Comments and Justifications
						\$-	
						\$ -	
Total consultant costs (USD)			\$ -				
SUPPLIES AND EQUIPMENT	,						
Budget line		Mesurement Unit	Unit Cost		Number of Units	Total requested (USD)	Comments and Justifications
						\$ -	
						\$ -	
Total consultant costs (USD)			1			\$ -	
OTHER PROJECT EXPENSES	1						
Budget line		Unit Cost	t	Unit Type	# of Units	Total requested (USD)	Comments and Justifications
0						\$ -	
						\$ -	
		- 1	1			T	1
TOTAL PROJECT COSTS		\$ -					
TOTAL PROJECT COSTS	- -						

All expenses included in the budget must be necessary, incremental and reasonably costed. In addition, all expenses incurred must be (i) exclusively incurred for the benefit of the project; (ii) properly approved and documented in accordance with the applicant's existing organizational and financial policies, with its applicable accounting framework, as well as with local laws and regulations; and (iii) identifiable in the applicant's accounting system and verifiable. The selected applicant will adhere to and comply with Unitaid financial guidelines, which will be communicated by FIND.

APPENDIX B: DECLARATION OF UNDERTAKING FOR UNITAID

This DOU is a statement containing all the legal requirements that are mandatory and must be included in all projects supported with Unitaid funding.

By attaching this DOU as an exhibit to the Agreement, the Contractor agrees (i) to comply with all the requirements below and (ii) that DOU shall be made an integral part of the Agreement.

This DOU shall be applicable to any and all Projects, Activities conducted under the Agreement that are funded by Unitaid.



Background

Unitaid, a global health initiative hosted and administered by World Health Organization ("WHO") has elected to fund a project, "_____", also known as ____.

"Unitaid Grant Agreement" or "Grant Agreement", means the agreement between FIND and Unitaid signed on _____, entitled, "_____", also known as _____.

Contractor means XYZ

Requirements

 <u>Audits, Review, Operational and Programmatic Evaluations</u>: FIND and/or Unitaid and/or parties designated by FIND and/or Unitaid, may conduct or commission operational or programmatic evaluations of any or all of Contractor's activities, documents or records relating to this Project (the "Ad-hoc Audit") at any time during the lifetime of this Agreement and for a period of three (3) years following submission of the Final Report or equivalent end of Project review. Such reviews, operational or programmatic evaluations shall be conducted during regular business hours and upon reasonable notice to Contractor. The costs of such Ad-hoc Audits will be covered by FIND and/or Unitaid.

2. Access granted to Unitaid:

- 2.1 Unitaid shall have access to documents and information provided by Contractor to FIND under the Agreement, but in any case, FIND shall ensure that Unitaid shall treat such documents as confidential, unless otherwise agreed between the Parties. Furthermore, Contractor shall ensure availability of all data generated, which shall be treated as Confidential Information under Clause XX of this Agreement.
- 2.2 For clarification purposes, Contractor hereby acknowledges and agrees that FIND will have the right to share any Contractor's Confidential Information with its co-funding partner Unitaid, and therefore Contractor acknowledges that Unitaid will be granted access to, and will obtain any documents and information provided by Contractor to FIND under the Agreement (so long as FIND ensures that Unitaid shall agree to maintain the confidentiality of that information on terms similar to those of the Agreement).
- 2.3 Contractor agrees and acknowledges that FIND will share any of the results generated by the Project with Unitaid, or at Unitaid's request, WHO, for feedback prior making any external communication in relation to such results, including, without limitation, through publication of scientific journal articles, presentations to international conferences, press releases and public statements. FIND will share the results with Unitaid and/or WHO (as applicable) as soon as reasonably possible prior to such external communication and will consider any feedback provided by Unitaid and/or WHO in good faith.
- 3 <u>Financial terms and conditions</u>: In addition to the general financial terms and conditions set forth in the Agreement, the Contractor agrees to adhere to the conditions of Unitaid Financial Guidelines as



set forth under the Unitaid site at <u>https://unitaid.org/assets/Financial-guidelines-for-Unitaid-Grantees.pdf</u>, as applicable.

4 <u>Acknowledgments</u>. For any Project funded through Unitaid, in addition to the acknowledgment of each Party's contribution in any publication, and/or presentations that disclose information developed or conceived under this Agreement, the Parties shall make a statement to acknowledge the financial support provided by Unitaid, such statement to be read as follows:

"Support for this Project was provided through funding from Unitaid through The Foundation for Innovative New Diagnostics. The views expressed by the authors do not necessarily reflect the views of the funding agency."

- 5 Publications & Use of name:
 - 5.1 Any documents publicized should adequately represent both Parties by name, trademark or other identifier as approved by appropriate representatives of the Parties, and will acknowledge the contribution of Unitaid as co-funder.
 - 5.2 Contractor hereby agrees that Clause XXX of the Agreement related to the use of name shall be applicable to WHO/Unitaid.
- 6 <u>Indemnification</u> Contractor agrees and acknowledges that the Indemnification clause set forth in the Agreement shall be applicable by extension to WHO/Unitaid for any and all claims and liabilities (including legal fees and costs) arising or resulting from such any Activities carried out by Contractor, its employees, authorized agents, and subcontractors.
- 7 <u>Termination:</u> In addition to the termination rights set forth in Section XXX of the Agreement, in the event the Unitaid Grant Agreement is terminated, FIND may terminate the Agreement by giving Contractor thirty (30) days' written notice of termination in writing.