

FIND

Diagnosis for all

Request for Proposal (RFP)

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Understanding the TB Diagnostics Market in LMICs

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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, decision-makers, 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-convenor 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

BACKGROUND

Challenges in TB 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 are due to a combination of underreporting 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 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 [here](#) and [here](#)) for accelerating the development of three new product classes, with the goal of identifying manufacturers that have demonstrated significant 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 coinfecting 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 drug-resistance 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 sputum-based 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 DriveDx4TB [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.

In this context, FIND is seeking a consultant with expertise in market research to estimate the current and potential market size for key TB diagnostic tests in the public and private sectors in four project countries (India, Kenya, South Africa and Viet Nam). The final report should provide a general market overview, including but not limited to, total size (volume and value), both current and projected; key players; market shares; distribution channels; and category trends. The report should also include the findings of appropriate primary research activities to assess growth opportunities for new products

(PoC, near-PoC and third-generation LAM). An important aspect of the analysis will be to understand the potential market share and implications for the market of new product entries by third-generation LAM, PoC and near-PoC devices.

KEY RESEARCH QUESTIONS

Topic	Research question
General market information	<ol style="list-style-type: none"> 1. Category. What is the annual total volume of diagnostic tests (number of tests sold) and value (total sales generated from tests sold)? (To be provided in total and by product type) 2. Key players. Who are the key players (manufacturers), and what are their respective market shares (volume and value) and historic growth rates? (Also to be provided by product type) 3. Evolution. How has category volume/value and key players' market share evolved over time (since 2017), and what are the projections for the coming years? (A complete list of diagnostic tests will be the first deliverable for the consultant and the FIND team to agree upon) 4. Sector/channel. What is the breakdown of diagnostic tests' volume and value by sector/channel and by product? (e.g. private, public, online, offline, pharmacies, etc.) 5. Trends. What are the key trends in the diagnostic tests' category? (e.g. new technologies, new distribution channels, new companies, etc.) 6. Markups. For key products, document the relevant markups at different levels in the supply chain (e.g. Ex Works (EXW) price to fully-landed cost) in India, Kenya, South Africa and Viet Nam
Impact of new products on the market	<ol style="list-style-type: none"> 7. New product. What is the potential market share/size for each new product type, assessed by end-user profile and use cases for new TB diagnostic product classes in both public and private sectors in the project countries? 8. Category dynamics. What would be the impact of the launch of new products and technologies on the category volume, value and market share? (e.g. category expansion, contraction, shifting volume and value)
New product insights	<ol style="list-style-type: none"> 9. Category insights. What are the diagnostic's category's key barriers and enablers? (Driving adoption or slowing down adoption) 10. Category cost of goods sold (COGS). What are the pricing structures for key products in the category, based on publicly available literature or benchmarked information (e.g. COGS, gross margins, etc.)

METHODOLOGY

The methodology will be evaluated as part of the overall proposal, and the project is expected to include different types of qualitative and quantitative methods. Creative methodologies rooted in a sound market research approach to derive insights are welcome.

The data will be collected, at a minimum, across three pillars:

1. Existing publicly available literature and data
2. Primary data obtained using appropriate qualitative/quantitative methods

3. Existing proprietary data (e.g. industry, ministries of health (MoH), import/export (e.g. Trade Atlas), international procurement data, manufacturers' procurement data etc.)

It is the responsibility of the market research individual/organization to accurately select and collect the appropriate data.

In the budget, please include detailed information related to the budget required to conduct the primary research (qualitative/quantitative) and/or purchase market reports/raw data.

DELIVERABLES

No.	Title and description	Format	Timeframe
1	Outline of proposed and agreed upon methodology/approach	Word	Within 1 week of signing the contract; review at the kick-off meeting
2	List of all data sources	Excel, with linked files provided	Ongoing access; final list at project closure
3	Draft outline of the final report, slide deck and database to be provided for FIND to review	Word, PowerPoint, Excel	Within 3 weeks of signing the contract; at the kick-off meeting
4	Market size scenario model	Excel	Signing of the contract +3 months
5	Training/handover session on the model used, to include clearly defined inputs, outputs, methodology and assumptions	PowerPoint/TBD	Signing of the contract +3 months
6	Database of raw, cleaned market data relating to TB diagnostics	Excel, PowerPoint, TBD	Signing of the contract +3 months
7	Draft final market report	Word	Signing of the contract +3.5 months
7a	Draft final market report executive summary (including tables, graphs, and charts that address the key market research questions)	Word, maximum 10 pages; PowerPoint, maximum 20 slides	Signing of the contract +3.5 months
8	Final market report	Word and PowerPoint	Signing of the contract +4 months
8a	Final market report executive summary	Word, maximum 10 pages; PowerPoint, maximum 20 slides	Signing of the contract +4 months

REQUIREMENTS FOR PROPOSAL PREPARATION

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

- Organizational profile
- Areas of expertise
- Services provided (consulting, market research, off-the-shelf data and reports, etc.)
- Experience, including a list of relevant projects you have worked on
- Proposed scope of work and a work plan
- Methodology
- Budget (please refer to the budget template provided in Appendix A)
- Proposed timelines
- Proposed team (including CVs of team members)
- Networks and partnerships in high-priority LMICs
- Case studies
- Client references
- Contact details (in case FIND needs to follow-up regarding the proposal)

EVALUATION AND AWARD PROCESS

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

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.
- The proposed scope of the work, indicating candidates' understanding of the scope of work and the extent to which proposed activities match the activities listed in this RFP.
- Market research expertise, i.e. candidates' experience and expertise in the various market research topics listed in this RFP and their experience in performing similar market assessments; executing specific market intelligence deliverables (e.g. disease management/policy landscape analysis, funding landscape analysis, procurement and distribution landscape analysis, market landscape and market sizing analysis); and conducting secondary and primary market research (through key opinion leader (KOL) interviews, surveys, focus groups, etc.)
- Experience in conducting market assessments in LMICs and in the diagnostics field.
- Proposed team: the "quality" (i.e. composition, experience) of the team that will work on the RFP. Candidates must describe the team members, detailing their background and experience; complete CVs for all proposed team members must also be submitted.
- Networks or physical locations of candidates in the countries of scope, e.g. access to networks of relevant stakeholders in LMICs/specific project countries.

With regards to the evaluation of proposals, each criterion is equally weighted, except for the criterion "Quality of the financial proposal" (weight x2).

Proposals are to be submitted at Market.Intelligence@finddx.org by **15 February 2023, 18:00 CET**.

Where FIND judges multiple applications to be complementary to one another, FIND reserves the right to suggest a partnership within the RFP process.

CONFIDENTIALITY

FIND considers any proposal received under the RFP as 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. Review of proposals will be carried out by an internal FIND team all of whom are under confidentiality and are 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.

APPENDIX A: BUDGET TEMPLATE FOR APPLICANTS

Applicants should use the provided template in responding to this RFP. If applicants choose to prepare the grant budget using a different currency, the budget should be converted using a 6-monthly average rate from a trusted source (e.g. Central Bank or Oanda).

NAME OF THE APPLICANT :						
TITLE OF THE PROJECT :						
PROJECT FUNDER:	FIND (Unitaid)					
PROJECT TERM:	dd/mm/yyyy					
BUDGET ASSUMPTION, CALCULATION AND VALUES						
STAFF						
Position	Location	Mesurement Unit	Unit Cost	Number of Units	Total requested (USD)	Comments and Justifications
			\$ -	0.00	\$ -	
			\$ -	0.00	\$ -	
Fringe benefits, if any					0%	\$ -
Total staff costs (USD)					\$ -	
CONSULTANTS						
Budget line	Location	Mesurement Unit	Unit Cost	Number of Units	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)					\$ -	
OTHER PROJECT EXPENSES						
Budget line		Unit Cost	Unit Type	# of Units	Total requested (USD)	Comments and Justifications
					\$ -	
					\$ -	
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 and comply with Unitaid financial guidelines, which will be communicated by FIND.