REQUEST FOR PROPOSAL (RFP)

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

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EXECUTIVE SUMMARY

- FIND, the global alliance for diagnostics, is leading the DriveDx4TB* project to **accelerate the development, validation and launch of new molecular diagnostics for TB detection ("TB MDx")**. In the context of this project, FIND is opening a Request for Proposals (RFP). The short-term areas of focus are:
    - **New TB MDx** products that can be used at the primary healthcare level and within communities using non-sputum samples (**POC MDx**).
    - **New TB MDx** products that can be used at centralized laboratories using sputum (or non-sputum) samples and incorporating drug-susceptibility testing (**near POC MDx**).
- A long-term goal of this RFP is to improve TB case detection in low- and middle-income countries (LMICs) by accelerating the **availability of new TB MDx platforms**, ultimately providing a broader array of **options for decentralized and centralized TB testing**.
- No direct awards will be made to selected applicants. A range of support packages will be provided to successful applicants to accelerate policy recommendations and in-country adoption. This will include participation in a **clinical study to generate the clinical evidence for World Health Organization Global TB Programme (WHO GTB) and Global Fund Expert Review Panel for Diagnostics (ERPD) submissions**.
- Selected applicants are expected to **commit to supplying an affordable product to the public sector in LMICs** if endorsed through the ERPD or WHO policy review process.

***DriveDx4TB** is a Unitaid-funded project aimed at accelerating the introduction of new TB diagnostics to address the current shortcomings and availability of existing tools, ultimately to support TB recovery and elimination efforts. To this end, the project will support manufacturer-independent clinical accuracy studies, cost-effectiveness analyses, and usability studies to develop evidence dossiers for submission to the WHO GTB and ERPD.

BACKGROUND

Tuberculosis (TB) remains a major global health problem owing to its high rates of morbidity and mortality.[1] According to the World Health Organization (WHO) Global TB Report 2021, approximately **10 million individuals contracted TB in 2020**. Reduced access to diagnostics (and subsequent delays in diagnoses and treatment) have been exacerbated by the COVID-19 pandemic, with **4.1 million TB patients undiagnosed** and **1.3 million deaths attributed to TB in 2020** – levels last seen in 2017.[1]

Despite the advent of molecular WHO-recommended rapid diagnostic tests (mWRDs), such as Xpert MTB/RIF Ultra (Cepheid, Sunnyvale, USA) and Truenat MTB/RIF (Molbio Diagnostics, Verna, India), sputum-smear microscopy remains the mainstay of TB testing, and is often the only diagnostic test available.[2] Unsurprisingly, in 2020, **only around 20% of all TB cases identified were diagnosed by mWRDs**[1]. Ultimately, these **existing tools for TB screening and diagnosis are not fit for the purpose** of reaching individuals with active TB in diverse settings. Most of the **currently available TB tests rely on sputum**, a **sample that is both difficult to obtain and to process**; consequently, many of the hundreds of millions of individuals with symptoms suggestive of TB, and almost half of the 10 million individuals estimated to contract TB each year, do not have access to testing. Specific underserved populations, including children, people living with HIV (PLHIV), and males, continue to be missed.[3]

Accelerated diagnostic innovations spurred by the COVID-19 pandemic, particularly the development of swab-based sampling techniques and novel molecular diagnostic (MDx) point-of-care (POC) and near POC platforms, may provide the necessary momentum to introduce alternative TB testing approaches to improve access and close the existing case detection gaps.[4] 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 products in this new class will help address attrition associated with centralized testing models in many countries with a high burden of TB (e.g. inadequate sample referral pathways and reliance on sputum-based testing), ultimately improving the chances of an individual being identified with undiagnosed TB and reducing associated catastrophic costs for the patient. In contrast, **near POC MDx for TB would share similar characteristics to the limited 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 to existing options (e.g. GeneXpert MTB/RIF and Truenat) and specifically reducing costs (upfront and per test), combined with broader drug-resistance profiling, will enable better adoption by 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).

OBJECTIVES AND SCOPE

FIND aims to accelerate the **development, validation and launch of new molecular diagnostics for TB** ("TB MDx") for use in low- and middle-income countries (LMICs). To achieve these goals, FIND seeks TB MDx platforms (either POC MDx or near POC MDx) at Technology Readiness Level 4 (TRL)[5] or higher and that closely meet the key product requirements listed in the "**Technical Assessment**" sheet within the **Assessment Matrix** (see **HOW TO APPLY** below for forms and templates). These product requirements and specifications are largely informed by the WHO "High-priority target product profiles for new tuberculosis diagnostics: report of a consensus meeting, 28-29 April 2014". We encourage all applicants to review these TPPs, particularly "Table A3. Detailed target product profile (TPP) for a rapid sputum-based test for detecting TB at the microscopy-centre level of the health-care system", as well as reviewing the "Update on the use of nucleic acid amplification tests to detect TB and drug-resistant TB: rapid communication, January 2021" to understand the current landscape and performance characteristics of existing TB MDx. Applicants will also be assessed based on their organizational strength and capacity in key areas of product development, quality, manufacturing and commercialization, as well as their commitment to equitable access pricing for LMICs, as listed in the "**Business Assessment**" sheet within the **Assessment Matrix**.

The main focus of this RFP is to identify TB MDx that are:

- **POC MDx technology class**: simple, portable, able to detect TB from a swab or other non-sputum sample, suitable for use in decentralized healthcare facilities in LMICs and specifically at Level 1 and Level 2 facilities or in community-based settings to facilitate timely diagnosis and linkage to care and treatment (see the **"Technical Assessment"** sheet)
- **Near POC MDx technology class**: able to detect TB from a sputum or non-sputum sample with simultaneous detection of drug-resistance (at least rifampicin, but ideally also isoniazid and fluoroquinolones), suitable for use in decentralized or centralized laboratories (see the **"Technical Assessment"** sheet)
- Easy to use and requiring minimal training of staff, reliable, with quick turnaround of results
- Affordable, available, and appropriate for use in LMICs, with a commitment to commercialization strategies (see the **"Business Assessment"** sheet)
- Other considerations: ensure best efforts to limit medical waste and reduce the potential carbon footprint.

The RFP process will assist the DriveDx4TB project in selecting products within the POC MDx or near POC MDx technology classes that can be incorporated into the clinical study; priority will be given to applicants who **demonstrate a high likelihood of achieving product design lock and producing at least 2,000 tests by Q4 2023**.

Subject to contract negotiations, FIND can support successful applicants in their product development with:

- Preclinical testing and manufacturer-independent assessment of performance claims using TB reference panels
- Conducting a manufacturer-independent clinical study in up to four LMICs with a high burden of TB, usability assessment, and cost-effectiveness assessment (at product class level) to generate the evidence package for WHO GTB and Global Fund ERPD submissions
- Mapping of current and future market dynamics (supply and demand factors) to develop commercialization strategies for LMICs
- Providing insights to develop, together with applicants, sustainable commercial models for LMICs by defining internal value propositions and supporting go-to-market planning
- Collaboration with implementation partners and regional manufacturers based in LMICs to improve access

No direct awards will be given to applicants and FIND will not provide any direct financial support for product development, manufacturing scale-up, market access, or post-launch activities, e.g. shipping logistics, procurement, implementation, user training, distributor qualification, or post-market surveillance.

TIMELINES

The expectation is that this RFP process will be concluded by Q1 2023.

FUNDING AWARDS

Funding for the RFP is provided through Unitaid, and we anticipate supporting between four and eight applicants (maximum of eight products) overall within the POC MDx or near POC MDx technology classes, with a minimum of two applicants in each class; **no direct awards will be made to applicants** but a **budget envelope of US$15.9 million** will be utilized by the project to provide **support to selected applicants as described under the OBJECTIVES AND SCOPE.** Contract negotiations will be conducted independently and confidentially for each applicant. Further, it should be noted that this programme can facilitate connections and networking opportunities within a broad ecosystem of partners, working towards support for product procurement, implementation and scale-up.

Applicants may be public or private entities, institutions, or organizations. Applicants may also comprise a group or collaboration of public and/or private entities. A single lead entity shall be designated and shall assume responsibility for the application and for negotiations with FIND. Formal written authorizations from partners will only be required of applicants invited to full contract development. FIND reserves the right to request additional information confirming the validity of specific collaboration agreements, i.e. that specific and appropriate contractual agreements either exist or can be established between partners.

AWARD CONDITIONS

For this RFP, successful applicants are expected to:

- Commit to complete product development activities and achieve product design lock by Q4 2023 (at the latest).
- Commit to supply up to 2,000 tests for manufacturer-independent assessment and for the clinical study by Q4 2023 (at the latest).
- Commit to undertake activities that enable product launch (e.g. local registration, service, and distribution activities) and sufficient production and supply to the public and private sector in LMICs (volumes and details to be negotiated).
- Commit to a pricing model that is transparent and affordable by providing the lowest sustainable pricing to LMICs (i.e. cost of goods sold (COGS)-based pricing).
- Commit to and follow FIND's Global Access Policy and FIND's Code of Conduct and Ethics
- Accept the Terms and Conditions of the Declaration of Undertaking (**Appendix 1**).

SELECTION AND AWARD PROCESS

The deadline for receipt of submissions is 6 October 2022. A commitment to a compressed timescale is required, and we anticipate awards and contract execution within 3 months. The selection process is designed to be objective, independent, and transparent to ensure that the most suitable technologies are supported and any potential conflicts of interest are avoided. Candidates will be evaluated by an internal review panel comprising staff from FIND and by an external review panel comprising FIND and global experts with backgrounds in technical R&D, product launch and implementation. The review panels will use information submitted in the application (see **APPLICATION REQUIREMENTS,** below) as well as publicly available information. The review panels may request additional information or clarifications, if needed, in writing. Applications will be evaluated in stages, as follows (see the **Table** below):

- **Stage 0.** All applicants' eligibility will be verified, and any that are "out of scope" will be excluded. Out of scope applications may include, but are not limited to, platforms with no TB assay in development, technologies not suitable for testing in POC or near POC settings, organizations with no quality management processes in place/under development, and early-stage platforms with little/no feasibility data (at a minimum, a TB MDx should be at TRL 4)[5]. During Stage 0, applications will also be allocated for subsequent assessment to either the POC MDx or near POC MDx technology class, based on the checklist in the sheet titled **"Diagnostic classification"** in the **Assessment Matrix**. Applicants should review **Appendix 1** and verify that they will be eligible to sign at the time of contract execution. An inability to complete the Declaration of Undertaking provided in **Appendix 1** will render the applicant ineligible. (Note that **Appendix 1** is only provided at this time for informational purposes; signing is not requested at the time of application). A long-list of eligible candidates will advance to Stage 1.

- **Stage 1.** This first evaluation will down-select the long-list of candidates to a short-list of approximately 10 candidates. The internal review panel will evaluate long-listed candidates based on their submitted application materials (see **APPLICATION REQUIREMENTS**). Specifically, candidates will be evaluated on:
    - Existing product specifications, scored in the sheet titled **"Technical Assessment"** in the **Assessment Matrix.**
    - Organizational criteria, scored in the sheet titled **"Business Assessment"** in the **Assessment Matrix.**
    - **Applicant Presentation,** which details specific topics described in the **APPLICATION REQUIREMENTS**.

  The internal review panel will then score each candidate's alignment with the goals of the RFP (see the sheet titled **"Alignment Criteria"** in the **Assessment Matrix**). The **Applicant's Total Score** will then be calculated as a weighted sum of the scores from the Technical Assessment, Business Assessment, and Alignment Criteria:

$$\boldsymbol{Applicant's\ Total\ Score}= \\ (Technical\ Assessment) \text{ x } 0.25 + \\ (Business\ Assessment) \text{ x } 0.25 + \\ (Alignment\ Criteria) \text{ x } 0.50$$

  Short-listed candidates will be selected during a consensus call with reviewers and will advance to Stage 2.

- **Stage 2.** This second evaluation will down-select short-listed candidates to a list of finalists. Candidates will be evaluated using:
    - **Follow-up Live Presentation** (by teleconference): short-listed candidates will be invited to give a follow-up presentation to address a set of structured questions that will be provided to applicants in advance.
    - **Applicant Presentation**, which details specific topics described in the **APPLICATION REQUIREMENTS**.
    - Scores from the Technical Assessment and Business Assessment (completed in Stage 1) will also be provided to the external review panel.

  The external review panel will score each candidate's alignment with the goals of the RFP (see the sheet titled **"Alignment Criteria" in the Assessment Matrix**). *This scoring will be conducted independently of the candidate's score in the Alignment Criteria from the internal review panel during Stage 1.* Lastly, the **Applicant's Total Score** will be calculated.
- Finalists will be selected during a consensus call with reviewers and, following approval by Unitaid, will advance to contract negotiations. The final awards and contract execution are expected to be completed by Q1 2023. Note: applicants not selected will be notified; however, reasons for their non-selection will not be provided.
- **Due diligence**: Given the tight timelines for this RFP, due diligence (DD) to verify applicants' submissions and claims will proceed in parallel with contract negotiations. The DD process may include an inspection or audit of the manufacturers' facilities (site visits and/or phone/video conferencing), as well as requests for additional information including access to technical and quality documentation. Access to the above documentation would be covered under a separate confidentiality and disclosure agreement (CDA). Any such inspection would be conducted during regular business hours and upon reasonable advanced notice; any related costs would be pre-agreed and covered by FIND and will be subject to the terms and conditions of the mutual CDA. Should the DD reveal any unresolvable inconsistencies with this RFP and/or donor requirements and restrictions, applicant exclusion at this late stage is still possible. FIND may outsource the DD process to an independent third party, according to FIND procedures.

Stage 0	Stage 1	Stage 2
Initial screening of all applicants to obtain a set of long- listed candidates *Allocation to the POC MDx or near POC MDx technology class*	*First evaluation to down-select long-listed candidates to short-listed candidates (up to 10)*	*Second evaluation to down-select short-listed candidates to a list of finalists (4-8 overall, minimum of 2 in each technology class)*
• Verification that the contents of the application are in-scope. Applicants that are out of scope will be excluded. • Verification of applicant eligibility. Applicants that are not eligible will be excluded. • Candidates allocated to either the POC MDx or near POC MDx technology class based on the checklist in the "Diagnostic classification" sheet within the Assessment Matrix.	• Evaluation of long-listed candidates will be performed by an internal review panel. • Candidates will be evaluated based on: 1. Score on the "Technical Assessment" within the Assessment Matrix (scoring completed based on diagnostic classification completed in Stage 0) 2. Score on the "Business Assessment" within the Assessment Matrix 3. Applicant Presentation • The internal review panel will score the candidate's overall alignment with the goals of the RFP (see the sheet titled "Alignment Criteria" within the Assessment Matrix).	• Evaluation of short-listed candidates will be performed by an external review panel. • Candidates will be evaluated based on: 1. Scores on the "Technical Assessment" and "Business Assessment" completed in Stage 1. 2. Applicant Presentation 3. Follow-up questions and Live Presentation • The external review panel will score the candidate's overall alignment with the goals of the RFP (see the sheet titled "Alignment Criteria" within the Assessment Matrix).

APPLICATION REQUIREMENTS

Applications should include the following:

1. **Applicant Presentation**
    - Applicants shall provide a slide deck of **no more than 25 slides** that must include the following information and must use the provided PowerPoint template (see **HOW TO APPLY** for templates and forms):
        - Overview of the TB MDx technology, including a workflow diagram for each specimen type that shows each step with details and the duration from sample collection to result. Please describe the technology features that enable the high sensitivity of the test.
        - Current performance of the TB MDx: evidence of the assay's performance, including but not limited to any existing feasibility studies, verification and/or validation studies demonstrating performance (published or internal) with contrived or clinical samples, as well as cross-reactivity (including *in silico* analyses, as applicable) and stability studies.
        - Alignment with Product Requirements. Provide evidence to support performance claims, particularly for requirements assigned a weight of "3" in the sheet titled **"Technical Assessment"** in the **Assessment Matrix**.
        - Roadmap, including the current stage of development and proposed activities to meet the design requirements and timeline for design lock, where the existing specification does not meet either the Optimal or Acceptable specification (in the sheet titled **"Technical Assessment"** in the **Assessment Matrix**).
        - Description and timeline of activities proposed under the DriveDx4TB award. Please also include any other support required to meet product requirements and/or pricing and supply in LMICs (not included in **FUNDING AWARDS**).
        - Proposed pricing model: describe a COGS-based pricing model and expected business model. Include the pricing structure, indicating the expected cost of manufacture, markup, royalties, expected distributor margin, and budget for service and maintenance.
        - Commercialization plan for select LMICs (including service and distribution plans, if applicable). Indicate where additional funding or assistance, beyond this award, may be required from FIND or global partners.
        - Demonstration of any commitments to access pricing for LMICs (for example, access pricing structures for other products).

- Organizational strength: evidence of institutional commitment and/or track record of the organization or key personnel with experience in respiratory pathogens, in vitro diagnostics (IVD), and/or LMIC markets.

2. **Assessment Matrix**
   - Applicants are to complete the noted columns of the provided **Assessment Matrix** spreadsheet (see **HOW TO APPLY** for templates and forms), specifically:
     - Technical Assessment
       - Please describe the TB MDx's existing Design Specifications (column G), and provide supporting evidence and/or data (column H) to support the claims made in column G.
       - Reviewers will only score one of the Technical Assessment sheets according to the allocation to the POC MDx or near POC MDx technology class at Stage 0. If in doubt, please include the information in both Technical Assessment sheets.
       - If the Existing Specification does not fall within the Acceptable or Optimal Specifications, please use the Applicant Presentation to briefly describe the plan or expected activities required to modify the existing specification into a proposed acceptable specification.
     - Business Assessment
       - Please provide evidence and supporting information (column C) regarding each of the criteria. Applicant responses to be supported by/verifiable through corporate documentation and due diligence.
3. **Supporting Documents**
   - Aside from the two forms listed above, the only additional documents allowed for submission are registration/regulatory certificates; quality management system (QMS)/ISO certificates or evidence of submissions in process; instructions for use/product inserts for existing or relevant products, if available; and curricula vitae (CVs) of relevant team members and management.
   - There will not be any public opening of awards, or separate technical and financial bidding documents.

HOW TO APPLY

Applications should be submitted via FIND's Technology Scouting Submission Webform. Please select **"Tuberculosis"** as the "Disease Area" and "**RFP: DriveDx4TB TB MDx"** as the "Disease Area Subtype", and proceed with the online submission. Templates for the **Applicant Presentation** and **Assessment Matrix** can be downloaded from the submission portal. Please upload your completed **Applicant Presentation** and **Assessment Matrix,** along with any supporting documents, by **6 October 2022**.

QUESTIONS & FURTHER INFORMATION

Please email any questions to: ua_mdx@finddx.org. Questions will be accepted and responded to promptly until 26 September 2022. Submitted questions (and corresponding answers) will be publicly available on the FIND website from 27 September 2022. All applicants are invited to attend a webinar on 20 September 2022. The webinar will present the RFP's scope, content and process; furthermore, it will address any questions submitted (to date) to the email address given above. Attendance is encouraged to obtain clarification and further information. A recording of the webinar will be posted online for those unable to attend.

CONFIDENTIALITY

All information supplied to the applicant by FIND, including the RFP and all other documents relating to the RFP process, must be treated as confidential, and not disclosed to any third party unless the information is already in the public domain or is required to be disclosed and vice versa. FIND considers any application and supporting documents received under the RFP as confidential. If required, FIND can sign a CDA with interested applicants prior to proposal submission. FIND shall not disclose the proposal to third parties without the prior written agreement of the proposal submitter. All members of the review panel will also be under confidentiality obligations and shall 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.

CONTRACTUAL TERMS AND CONDITIONS

FIND will use a commercial-level contractual mechanism where the standard Terms and Conditions address the requirements and access conditions for supplying a product for public health particularly in LMICs, as set forth under **Appendix 2**.

COMPLAINTS

Applicants who consider that actions or decisions taken during the RFP result in an unfair dis/advantage may file a related complaint. Such a complaint should be addressed in writing to FIND (ua_mdx@finddx.org), detailing the grounds for the complaint and referring to the applicable provisions in the RFP or other applicable regulations. The complainant may also use FIND's Ethics Hotline as a channel to anonymously raise complaints. FIND shall acknowledge the complaint within three (3) days of receipt and respond with results of the complaint handling process within ten (10) working days thereafter.

REFERENCES

- 1. World Health Organization. Global tuberculosis report 2021. Geneva: World Health Organization, 2021.
- 2. Nathavitharana RR, Garcia-Basteiro AL, Ruhwald M, et al. Reimagining the status quo: How close are we to rapid sputum-free tuberculosis diagnostics for all? *EBioMedicine* 2022;78:103939. doi: 10.1016/j.ebiom.2022.103939 [published Online First: 2022/03/28]
- 3. Chikovore J, Pai M, Horton KC, et al. Missing men with tuberculosis: the need to address structural influences and implement targeted and multidimensional interventions. *BMJ Glob Health* 2020;5(5) doi: 10.1136/bmjgh-2019-002255 [published Online First: 2020/05/07]
- 4. Ruhwald M, Carmona S, Pai M. Learning from COVID-19 to reimagine tuberculosis diagnosis. *Lancet Microbe* 2021;2(5):e169-e70. doi: 10.1016/s2666-5247(21)00057-4 [published Online First: 2021/03/30]
- 5. Seven T. Biomedical DoD Technology Readiness Levels (TRLs): Medical Devices [Available from: https://tier7.us/biomedical-dod-trls-medical-devices/ accessed 29 June 2022.

Appendix 1: Declaration of Undertaking

Accelerating the development of new point-of-care (POC) and near POC molecular diagnostics for TB (the "**Contract**")

1. We hereby certify that neither we nor any of our board members or legal representatives nor any other member of our Consortium (or Collaboration, as applicable), including Subcontractors under the Contract, are in any of the following situations:
    1.1. being bankrupt, wound up or ceasing our activities, having our activities administered by courts, having entered receivership, reorganization or being in any analogous situation;
    1.2. convicted by a final judgement or a final administrative decision or subject to financial sanctions by the United Nations, the European Union or Switzerland for involvement in a criminal organization, money laundering, terrorist-related offences, child labour or trafficking in human beings; this criterion of exclusion is also applicable to legal Persons, whose majority of shares are held or factually controlled by natural or legal Persons who themselves are subject to such convictions or sanctions;
    1.3. having been convicted by a final court decision or a final administrative decision by a court of the European Union or the national authorities in Switzerland for Sanctionable Practice in connection with a Tender Process or the performance of a Contract or for an irregularity affecting a country's financial interests *(in the event of such a conviction, the Applicant or Bidder shall attach to this Declaration of Undertaking supporting information showing that this conviction is not relevant in the context of this Contract and that adequate compliance measures have been taken in response)*;
    1.4. having been subject, within the past five years to a contract termination fully settled against us for significant or persistent failure to comply with our contractual obligations during such Contract performance, unless this termination was challenged, and dispute resolution is still pending or has not confirmed a full settlement against us;
    1.5. not having fulfilled applicable fiscal obligations regarding payments of taxes either in the country where we are constituted or in Switzerland;
    1.6. being subject to an exclusion decision of the World Bank or any other multilateral development bank and being listed on the website http://www.worldbank.org/debarr or respectively on the relevant list of any other multilateral development bank *(in the event of such exclusion, the Applicant or Bidder shall attach to this Declaration of Undertaking supporting information showing that this exclusion is not relevant in the context of this Contract and that adequate compliance measures have been taken in reaction)*; or
    1.7. being guilty of misrepresentation in supplying the information required as a condition to participation in this Request for Proposals (RFP).
2. We hereby certify that neither we, nor any of the members of our Consortium (or Collaboration, as applicable) or any of our Subcontractors under the Contract are in any of the following situations of conflict of interest:
    2.1. having a business or family relationship with FIND's staff involved in the RFP or the supervision of the resulting Contract, unless the stemming conflict of interest has been brought to FIND's the attention and resolved to its satisfaction;
    2.2. being controlled by or controlling another Applicant or Bidder, or being under common control with another Applicant or Bidder, or receiving from or granting subsidies directly or indirectly to another Applicant or Bidder, having the same legal representative as another Applicant or Bidder, maintaining direct or indirect contact with another Applicant or Bidder which allows us to have or give access to information contained in the respective Applications or Offers, influencing them or influencing the decisions of FIND;
    2.3. being engaged in a Consulting Services activity, which, by its nature, may be in conflict with the assignments that we would carry out for FIND;
    2.4. in the case of procurement of Works, Plant or Goods:
        i. having prepared or having been associated with a Person who prepared specifications, drawings, calculations and other documentation to be used in the Tender Process of this Contract;
        ii. having been recruited (or being proposed to be recruited) ourselves or any of our affiliates, to carry out works supervision or inspection for this Contract.
3. If we are a state-owned entity, and compete in a Tender Process, we certify that we have legal and financial autonomy and that we operate under commercial laws and regulations.
4. We undertake to bring to the attention of FIND, any change in the situation with regard to points 1 to 3 above.
5. In the context of the RFP and performance of the corresponding Contract:
    5.1. neither we nor any of the members of our Consortium (or Collaboration, as applicable), nor any of our Subcontractors under the Contract, have engaged or will engage in any sanctionable practice during the

RFP process and, in the case of being awarded a Contract, will not engage in any sanctionable practice during the performance of the Contract;

5.2. neither we nor any of the members of our Consortium (or Collaboration, as applicable) or any of our Subcontractors under the Contract shall acquire or supply any equipment nor operate in any sectors under an embargo of the United Nations, the European Union or Switzerland; and

5.3. we commit ourselves to complying with and ensuring that our Subcontractors and major suppliers under the Contract comply with international environmental and labour standards, consistent with laws and regulations applicable in the country of implementation of the Contract and the fundamental conventions of the International Labour Organization (ILO) and international environmental treaties. Moreover, we shall implement environmental and social risks mitigation measures when specified in the relevant environmental and social management plans or other similar documents provided by FIND and, in any case, implement measures to prevent sexual exploitation and abuse and gender-based violence.

In the case of being awarded a Contract, we, as well as all members of our Consortium (or Collaboration, as applicable) partners and Subcontractors under the Contract, will (i) upon request, provide information relating to the RFP application and the performance of the Contract, and (ii) permit FIND or an appointed auditor, and in the case of financing by the European Union also to European institutions having competence under European Union laws, to inspect the respective accounts, records and documents, to permit on the spot checks and to ensure access to sites and the respective project.

6. In the case of being awarded a Contract, we, as well as all our Consortium (or Collaboration, as applicable) partners and Subcontractors under the Contract, undertake to preserve the above-mentioned records and documents in accordance with applicable laws, but in any case, for at least six years from the date of fulfillment or termination of the Contract. Our financial transactions and financial statements shall be subject to auditing procedures in accordance with applicable laws. Furthermore, we accept that all data (including personal data) generated in connection with the preparation and implementation of the RFP and the performance of the Contract are stored and processed by FIND, according to the applicable law and in compliance with the EU GDPR.

Name: _____ In the capacity of: _____

Duly empowered to sign in the name and on behalf of: _____

Signature: Dated:

Appendix 2: Example Contractual Terms and Conditions

A list of certain key terms and conditions to be addressed in any contractual agreement executed by FIND for investment and support of successful project applications to the RFP. The below language is given for guidance purposes only.

Final language to be agreed between the parties ("XYZ" and FIND) to each agreement denoted by [●].

1. SOME KEY DEFINITIONS

Affordable Price	shall have the meaning ascribed to it under the Article [●]
Commercially Reasonable Efforts	means the level of diligence, effort and resources required to carry out a particular task or obligation in an active and sustained manner consistent with the general practices that a company (or an organization) within the medical device industry and similarly situated to XYZ (or FIND, as applicable) applies in the exercise of its reasonable business discretion relating to other similar products which are of similar market potential and at a similar stage in the product life, and taking into account the specificities of this Agreement, including Global Access terms;
Cost Analysis	means the Product cost information that XYZ shall provide under the format described in Schedule [●];
Manufacturing Cost of Goods Sold (COGS)	means all of the direct costs such as labor, material and allocated overhead costs in a Product *manufacture* as detailed in Schedule [●], and excluding sales and marketing costs (S&M) as well as selling, general, and administrative expenses (SG&A);
Ex Works (EXW)	means the defined Incoterm under INCOTERMS 2020 and based on COGS;
Eligible Purchasers	means purchasers within the Public Health Sector or Private Health Sector for final use in the Territory;
Global Access	means the principles according to which diagnostic products shall be available, affordable and appropriate for use in Territory, as further set forth in FIND's Global Access Policy available at www.finddx.org/policies, as amended from time to time;
Intellectual Property (IP)	means any patents, rights to inventions, copyright and related rights, moral rights, trademarks, trade names and domain names, rights in get-up, rights in goodwill or to sue for passing off, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which may now or in the future subsist in any part of the world. Such IPR may be encompassed in part or in whole under the deliverables and/or Product;

Instrument Unit	means the specific instrument and accessories used to run a specimen that has been collected and processed with a Test Unit, and to display the result.
Know-how	means all technical and other information which is not in the public domain (other than a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, relating to but not including Foreground Intellectual Property or Intellectual Property, as previously defined in this Agreement;
LMICs	means those countries defined by the World Bank as having "low-income economies", "lower middle-income economies" or "upper middle-income economies", and may be amended from time to time;
Manufacturer of Record	means the named legal entity legally responsible for placing a Product on the market as recognized by the appropriate in country regulatory authority. For the purposes of this Agreement the Manufacturer of Record shall be the Third Party which is the recipient of the Technology Transfer.
Priority countries	means the list of countries as set forth under the Article [●];
Product	means the TB MDx and the materials provided with the Product as explicitly listed in the associated instructions for use, and all subsequent versions, and subsequent assays to be mutually agreed and documented as an amendment to this Agreement;
Private Health Sector	means any non-governmental institute which operates on a for-profit basis but which may have access to preferential access conditions to a Product such as set out under Global Access, and as determined on a case-by-case basis by FIND;
Public Health Sector	means (i) any government in the Territory, including any government ministry of health, department or agency, or any local or regional governmental body, authority or entity, and (ii) any officially recognized, not-for-profit organization including private not-for-profit organizations, or funds, that pursue activities to relieve suffering, promote the interests of the poor, provide basic social services, or undertake community development, including, but not limited to, the World Health Organization (and other UN organizations), ICRC, UNICEF, Save the Children Fund, Médecins Sans Frontières, Unitaid, PEPFAR, the Global Fund, FIND or its authorised designee, and other funding organizations;
Stringent Regulatory Authority (SRA)	defined by WHO here: https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs, and may be updated from time to time;
Technology Transfer	means those activities required to successfully transfer and validate such transfer of required manufacturing processes, procedures, and Know-how, to a Manufacturer of Record;
Technology Licence (Licence)	means the licence to use XYZ IP and Know-how required to commercialise a Product, and as further set out under the Article [●];

Target Product Profile (TPP)	means the desired 'profile' or characteristics of a target product that is aimed at a particular disease or diseases, including intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics, and as specifically referenced under the Article [●] to this Agreement;
Territory	means all LMICs;
Test Unit	means the specific assay and all required ancillary reagents and other consumables to run a single test on a single human specimen.

2. QUALITY REQUIREMENTS

Quality Management Systems ("QMS"). XYZ shall ensure compliance at all times with the following;

a) Ensure an appropriate QMS covering *in vitro* diagnostic products, is in place and compliant with SRA and/or WHO Pre-qualification ("PQ") requirements; and
b) Ensure any Product obtains and maintains appropriate SRA and/or WHO PQ authorization or approval, as appropriate, for the duration of this Agreement or its market availability in LMICs, whichever is longest.

3. ADDITIONAL THIRD PARTIES. XYZ may use Third Parties as subcontractors in the performance of its activities undertaken in connection with this Agreement, provided; a) FIND is informed and agrees in advance in writing to such subcontractor, and b) XYZ must obtain each subcontractor's written agreement to comply with all the applicable terms and conditions of this Agreement. In addition, FIND may require reviewing the relevant Articles of any agreement between XYZ and the Third Party in question, solely to ensure compliance with this Article [●]. For the sake of clarity any activity and/or obligation assigned to a Third Party under this Article [●] of this Agreement shall be considered nonetheless as being assigned to XYZ and XYZ shall be wholly held accountable for the fulfilment of such activity/obligation and any failure by the Third Party to execute their obligations shall be considered the full and direct responsibility of XYZ.

4. GLOBAL ACCESS AND GENERAL PRODUCT SUPPLY CONDITIONS

General. Each Party recognizes their requirements, in accordance with FIND's Global Access Policy, to ensure that any Product arising from the Agreement will be made on an accessible and affordable basis to people living in LMICs. XYZ's access requirements include committing to provide access to the Product on an affordable basis, obtaining the required in-country registrations as agreed with FIND, and to deliver local service and support. In addition, the Parties subscribe to the concept and implementation of Global Access as set out under the FIND policy at www.finddx.org/policies whereby, subject to the terms and conditions of this Agreement, specified results and data generated pursuant to this Agreement shall be made broadly and publicly available to any and all entities including any Public Sector bodies, as well as for-profit and not-for-profit organizations, and research centres working in healthcare in, or for, resource-limited settings.

Eligible Purchasers and Affordable Price. XYZ agrees to the following;

a. In particular, with respect to pricing, under the TPP, the Affordable Price shall be determined as an EXW price, currently as a target of US$ per Test Unit/Instrument Unit, which may include consumables used for sample preparation or instrument (if required);

   XYZ will ensure that it or its manufacturing and/or commercial partners sell the Product to Eligible Purchasers at a price that does not exceed the Affordable Price, which is equal to the EXW price.

   The Affordable Price does not include (i) freight and insurance charges to the country destination from the XYZ site of shipment; nor (ii) import duties into the final destination country. Regarding the freight

charges, XYZ shall negotiate directly with the purchaser a mutually agreed cost, retaining at all times the requirement to minimise such a cost, in accordance with Global Access requirements.

XYZ shall use Commercially Reasonable Efforts to ensure that any margin charged for local distribution of the Product to Eligible Purchasers in the Territory will not exceed [●]% of the Affordable Price.

In the case of the Product not meeting the Affordable Price criteria at (E.g. launch or 1 year post launch in the target markets), even under a COGS plus scenario, XYZ commits to work with FIND on a cost-reduction plan, considering among other factors, current market conditions, Cost Analysis (Schedule [●]), supplier input costs, internal allocation of costs, and if applicable in the context of the distributor, any unjustifiable mark-ups, as well as Product performance and other attributes of alternative products. XYZ commits to working with FIND to document the various price points along the supply chain to more accurately reflect price points along the supply chain. Furthermore, the applicant shall ensure a clear manufacturing volume vs cost reduction plan is in place and made available to FIND. Such a cost assessment shall be carried out at least 6 months prior to LMIC launch, and repeated 18 months after, or at a reasonable time point agreed between the Parties.

b. Other Countries. Notwithstanding the above, XYZ shall make its commercial best efforts to ensure sufficient supply of products to LMICs which are not Priority Countries.

Priority Countries and Volume Commitments. In general, the Parties agree that the Eligible Purchasers should be the main focus for Product supply and have the right to the Global Access terms set out under this Article [●]. In addition, the following countries shall be considered as the "Priority Countries" [●].

Technology Licence Agreement – *in the case of a Technology Transfer, if applicable*

XYZ shall enter into a Technology Licence Agreement with ABC, based on the following terms, comprising the following key Definitions and "flow through" obligations:

a. **Field** shall mean the detection of Tuberculosis in humans, or as mutually further agreed with respect to other infectious disease agents by the Parties.
b. **Territory** shall include all LMICs as defined by the World Bank, as amended from time to time.
c. **Global Access** key terms regarding the Affordable Price and other key access terms to be an obligation under the Licence.
d. **Scope of the Licence**: XYZ to be granted, a non-exclusive, non-sublicensable (only to Affiliates), royalty-free, fully paid up and perpetual licence under the ABC IP to develop, make, or have made, use, offer for sale, sell, have sold, export or import the Product anywhere in the world for the purpose of its use in the Field and in the Territory. As per Article [●], the Field definition may be extended by mutual agreement of the Parties.
e. **Background IP**: Such Licence shall include the right to use any pre-existing (Background) ABC IP at zero (or minimal) royalty rates as long as it is required for the commercialisation of the Product.
f. **Technology Transfer**: Such Licence shall include appropriate technology transfer obligations under which XYZ and the Manufacturer of Record shall develop a mutually agreed plan of activities and deliverables to ensure such successful Technology Transfer (the **"Transfer Plan"**) in order to ensure that the Manufacturer of Record will be able to produce and commercialize the Product. The Transfer Plan shall be agreed within [●] weeks of the Effective Date.

As the principal funding partner under this Agreement, FIND reserves the right to participate in the licence negotiations between XYZ and ABC. The final Licence Agreement will fully reflect and incorporate the terms for such Licence as set out in this Agreement. XYZ will provide to FIND copies of such final Licence Agreement prior to execution, for FIND's review and comments and final acceptance, and a final copy of the fully executed agreement for its records.

5. INDEMNIFICATION

XYZ will be responsible for the manner in which all activities performed under or as a result of this Agreement are carried out and will indemnify and hold harmless FIND for any and all claims and liabilities (including legal fees and costs) arising or resulting from such activities carried out by XYZ, its employees, authorized agents, and subcontractors.

6. COMPLIANCE WITH FIND POLICIES

Code of Conduct and Ethics: FIND has established a Code of Conduct and Ethics (the "Code") as set forth under the FIND site at https://www.finddx.org/policies. By executing this Agreement, XYZ acknowledges it has read and understood the contents of the Code, has informed the appropriate personnel of the Code's existence and agrees to abide with the Code terms and conditions, or warrants that it has its own code of conduct which is substantially equivalent and that such own code of conduct is currently applied to XYZ.

Anti-Terrorism: XYZ will not participate, directly or indirectly, in support of activities (a) related to terrorism; (b) with persons or entities that appear on the United Nations Security Council Consolidated List; or the sanctions list of donor countries including the UK, The Netherlands, Germany, USA, Canada and Australia; (c) with countries or territories against which the U.N. maintains comprehensive sanctions, under applicable law unless specifically approved by FIND in writing, at FIND's sole discretion.

Anti-Corruption & Anti-Bribery: XYZ will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision by FIND, including by assisting any party to secure an improper advantage.

Political Activity & Advocacy: XYZ may not use funds to influence the outcome of any election for public office in any country, or to carry on any voter registration drive.

Child Safeguarding: XYZ is committed to comply with all relevant local law on child rights and welfare in order to provide what is in 'best interest of the child' including employment law that apply to children and shall not use any funds under this Agreement to support the contrary.

Specific warranty regarding tobacco and arms. XYZ has, and currently has not had during the past four (4) years, any relations or linkages, with the tobacco or arms industry, or any subsidiary of a tobacco or arms company or commercial entity involved with the manufacture, sale, or distribution of tobacco/arms or tobacco/arms products, including, but not limited to, financial interests, controlling interests, or commercial relations resulting in licensing agreements, programmes, initiatives, research, or projects funded by the tobacco/arms industry, jointly administered with tobacco/arms-affiliated entities, or done for the tobacco/arms industry.

7. GOVERNING LAW AND DISPUTE RESOLUTION

This Agreement shall be governed by and construed in accordance with the laws of Switzerland.

The Parties hereto undertake to settle any dispute concerning the validity, interpretation, and/or performance of this Agreement in an amicable manner. To the extent practical, the Parties shall continue to work under the Agreement pending the final outcome of any dispute. If the Parties fail to resolve such dispute, controversy or difference through good faith negotiations, any dispute, shall be submitted to mediation in accordance with the WIPO Mediation Rules, in effect at such date. The place of mediation shall be Geneva, Switzerland. The language to be used in the mediation shall be English. If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within sixty (60) days of the appointment of the mediator, it shall, upon the filing of a Request for Arbitration by either Party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules in effect at that date.