

## Enabling regional supply of diagnostic tests in LMICs

### Request for Proposals 1: RDTs made in Africa, for Africa

#### BACKGROUND

The COVID-19 pandemic highlighted significant inequitable access to health technologies. A key factor behind this inequity was the concentration of manufacturing capacity in certain geographic regions. In diagnostics, manufacturing has historically been highly centralized among a small number of companies primarily based in Asia, North America, and Europe. This situation still pertains today. While these manufacturing facilities have realized important economies of scale among other benefits, the lack of a more distributed spread of regional facilities has meant that many countries have been solely dependent on a limited set of global suppliers and manufacturers. Centralization exacerbates fragility during global crises and outbreaks, as regional import/export restrictions can impact many manufacturing sites. This disproportionately affects low- and middle-income countries (LMICs) that lack sufficient production capacity to meet local demand, and there is no possibility to compete with higher-income countries (HICs) for limited supply, resulting in inequities in access. Not only has this resulted in a lack of resilience in many health systems, but it has also meant that the health needs unique to LMICs are frequently underserved.

**FIND and Unitaid are committed to supporting distributed, sustainable diagnostic manufacturing,** through expanding and strengthening regional markets, and acknowledge that efforts are required at all steps of the value chain. Several longstanding barriers hinder regional diagnostics production and supply in LMICs, ranging from financing, supply chain, regulatory, policy, and procurement challenges. FIND and Unitaid have engaged with manufacturers and stakeholders to define these barriers and to jointly identify potential solutions.

While progress has been made in different geographies to coordinate the supply and quality of diagnostics, the gap in access to diagnostics during the COVID-19 pandemic was especially acute in **the African region**. While the African region is among the largest consumers of rapid diagnostic tests (RDTs), the vast majority are imported from outside the continent. Many efforts have been made to strengthen the capacity for manufacturing on the continent through initiatives lead by Africa CDC, the African Society for Laboratory Medicine, and other key African institutions. Therefore, in the frame of this regional manufacturing initiative, **this RFP is being launched to build on these efforts and focuses on supporting African Regional RDT Suppliers.**<sup>1</sup>

Robust regional RDT markets will take time to develop, yet many African countries, pan-African and regional institutions and other partners and donors are launching efforts to accelerate their development. Specifically, Africa CDC have launched the **Africa Collaborative Initiative to Advance Diagnostics (AFCAD)** a strategic partnership with African Society for Laboratory Medicine, Institut de Recherche, de Surveillance Epidémiologique et de Formation, WHO-AFRO, Clinton Health Access Initiative, African Field Epidemiology Network and Unitaid to promote local manufacturing of diagnostics, map, identify and build capacity of diagnostic centre of excellence (the Africa Biobanking

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<sup>1</sup> For purposes of this RFP, "African Regional RDT Suppliers" are companies based in one of the AU member states that currently (or plan to) manufacture and commercialize RDTs. See more specific details in the eligibility section below.

Network), facilitate harmonization of regulatory processes and requirements, and global market negotiation [NB: with respect to regulation, there is also an intention to develop high-quality regulatory reviews in the region].

Additionally, WHO, PEPFAR, The Global Fund and Unitaid have launched various initiatives that support the acceleration of quality-assured HIV rapid diagnostic tests (RDTs) and HIV self-tests (HIVST) manufacturing in Africa:

- **Procurement:** PEPFAR and the Global Fund are the largest procurers of HIV RDTs and HIVST. While most of the tests bought are for use in Africa, exceptionally few are sourced from African manufacturers. In order to catalyse a shift in the market, in December 2022, [PEPFAR announced](#) that it targets procuring 15 million HIV tests produced by African manufacturers in 2025.
- **Accelerated review:** In August 2023, the Global Fund, Unitaid, and PEPFAR, supported by WHO, launched a [Pilot Expert Review Panel](#) (ERPD) to accelerate access to HIV professional use and self-testing RDTs manufactured in Africa.

Building on these and many other initiatives, **this RFP targets African Regional RDT Suppliers and specifically<sup>2</sup> companies with a current (or planned) sustainable business model** encompassing several functions in the RDT supply value chain: **manufacturing, marketing, and sales**. African Regional RDT Suppliers must be **responsive to regional demand, including high-quality, affordable RDTs produced at relevant scale**.

## OBJECTIVE

The long-term vision for this initiative is **to enable African Regional RDT suppliers to meet regional demand** for quality assured, affordable RDTs, in a **financially sustainable** manner, thereby contributing to the development of robust regional diagnostics markets and supporting Universal Health Coverage and Pandemic Preparedness. We aim to strengthen the complete RDT value chain in Africa, either through backward integration support or strategic partnerships within the continent.

The specific objective of this RFP is to support RDT manufacturers based in Africa with manufacturing and commercialization (e.g. development/manufacturing/capacity expansion/quality assurance/market entry) of at least 2 high performing quality assured cost-competitive (total cost of ownership) RDTs for integration into national programmes on the continent.

## SCOPE

We seek proposals from African Regional RDT Suppliers, specifically enterprises with **current or planned** operations spanning the value chain for RDT supply, including product development, manufacturing (from raw materials to finished product), and marketing of quality assured affordable RDTs. African Regional RDT Suppliers must have a viable, financially sustainable business plan anchored in meeting

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<sup>2</sup> Note: this RFP is one component of a broader initiative to enable the regional supply of diagnostics tests in LMICs. To identify potential future investments, FIND and Unitaid are launching end of October 2023, in parallel to this RFP, an Expression of Interest (EOI) for companies not eligible to this RFP but interested in advancing the regional supply of diagnostics in LMICs.

regional RDT demand. Their RDT portfolio should address local markets, including disease needs, at a relevant manufacturing scale. RDTs must be affordable, high-performing, and produced in a quality-assured manner. Companies not currently directly performing end-to-end RDT manufacturing are expected to have plans to develop these capabilities in-house by 2030 for at least one of the RDTs in their portfolio.

In the near term, suppliers must demonstrate an ability to manufacture (at least assembly of semi-finished products), market, and sell at least one quality assured regionally relevant RDT, at scale, to the local public sector or donor-funded procurement mechanisms by year-end 2025. While this RFP's scope and timelines align with the PEPFAR and the Global Fund HIV rapid test initiatives, the business plans presented must be sustainable, even in the event of not receiving procurement orders from these institutions.

Supported activities will vary according to the needs of each applicant. They may include, but are not limited to:

- Support for product development, including technology transfer of product and necessary training, verifications, and validations.
- Investment in new, expanded, or optimized RDT manufacturing capacity, e.g., capital expenditure, equipment, workforce training.
- Evidence generation, e.g., laboratory studies, clinical trials, and usability studies of sufficient size to meet global and local regulatory processes.
- Support for in-country registration activities, e.g., studies that meet national program requirements.
- Investments that strengthen operations, e.g., automating workflows related to inventory, supply chain, sales; quality management; and post-market surveillance.
- Activities undertaken by the manufacturer to source key inputs locally, either through in-house development or development of the local supply chain for raw materials and components.
- Technical assistance or training across a variety of areas, for example in:
  - Building quality management capacity (e.g., training, consulting, reviews, digitization, mock-site inspections).
  - Regulatory planning; dossier submission.
  - Hiring and staffing advice, workforce training.
  - Business model analysis, and planning.
  - Go to market advice and planning.
  - Commercialization activities, including building out a regional sales and distribution network.
  - Post-market surveillance.

## FUNDING AWARDS

African Regional RDT Suppliers are encouraged to submit proposals with a budget envelope between **US\$ 200 000 to US\$ 2 million**. Funding negotiations will be conducted independently and confidentially for each proposal; the form and amount of the award will be tailored to the application. The awardee will be asked to commit to global access terms (affordable price) and/or Foreground Intellectual Property accessibility if any product development is funded.

This initiative includes a potential partner matchmaking component through the complementary invitation for expression of interest (EOI). Hence, applicants are encouraged to identify areas where partnerships with external firms might add value. FIND and Unitaid will, depending on needs, make introductions to potential partners through the matchmaking component of this initiative.

Alongside financial support and matchmaking opportunities, the direct benefit of this program includes technical assistance from FIND and Unitaid and may include (but is not limited to) connections and networking opportunities with a broad ecosystem of partners, including potential development banks/financiers, product development/tech transfer partners, clinical trial partners and specimen banks, consultants with manufacturing, quality systems, business, and commercialization expertise.

## TIMELINES

The timeline for this initiative is as follows:

- The selection process for African Regional RDT Suppliers will include on-site assessments of short-listed candidates. Selection and negotiation of contracts are planned for the 4<sup>th</sup> quarter of 2023 and the first quarter of 2024.
- **Activities funded through this call should occur in 2024 and 2025.**
- Activities should be undertaken within a long-term framework that aims for fully integrated RDT supply (i.e., manufacturing through to marketing and sales) and end-to-end manufacturing (manufacturing from raw materials) by 2030. Applicants should provide a viable roadmap demonstrating how they will achieve any milestone that they are not already meeting.

## ELIGIBILITY CRITERIA

This RFP targets **African Regional RDT Suppliers** that are committed to developing financially sustainable, scaled RDT businesses that are first and foremost responsive to regional demand for quality assured, affordable RDTs. The applicants to this RFP must:

- be an incorporated company, located in one of the 55 African Union member states
- be already engaged in supplying RDTs regionally in some capacity, e.g., either through manufacturing of critical raw materials, finished RDTs, or distribution of RDTs
- have a strong business model and business plan to ensure financial sustainability (beyond any donor-supported HIV RDT preferential procurement)
- by year-end 2025, have a clear roadmap to supply the public sector (either a Ministry of Health and/or donor-funded procurement) with at least one RDT at a relevant scale. This implies that the RDT supplier is the legal manufacturer, the RDT has necessary regulatory authorizations and registrations, the RDT is manufactured under stringent quality standards<sup>3</sup>, and the RDT is sold at an affordable price.
- have a clear roadmap to develop by 2030 end-to-end RDT manufacturing capabilities in-house for at least one of the RDTs in their portfolio.

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<sup>3</sup> Stringent quality standards: manufacturing and marketing of IVDs under an appropriate Quality management System that would meet the authorization and on-going compliance requirements of WHO PQ or a Stringent Regulatory Authority (SRA). Currently, SRA for IVDs refers to stringent assessment (high-risk classification) by the Founding Members of the Global Harmonization Task Force.

- be committed to produce and supply quality-assured RDTs, including a portfolio that is responsive to regional needs and production at scale relevant to regional demand.
- Be committed to share with FIND and Unitaid key M&E data such as (but not limited to) sales, volume, price.

***Note: Although this is not an eligibility criterion, applicants are encouraged to share any sustainable manufacturing plans and initiatives they wish to put in place to reduce any negative impact on the environment.***

Applicants should provide a viable roadmap demonstrating how they will achieve any milestone that they are not already meeting. Thus, the following applicants are eligible:

- RDT developers, based in Africa, planning forward-integration into RDT manufacturing, marketing, and sales.
- African-based producers of key raw materials for manufacturing RDTs that are forward integrating into RDT product development, manufacturing, and marketing.
- African RDT distributors with regional footprints that are planning to backward integrate into product development and manufacturing.

***Note: African partners not meeting the RFP criteria are encouraged to apply to the complementary EOI that would be published on the FIND website by 31 October 2023.<sup>4</sup>***

## SELECTION PROCESS

African Regional RDT Supplier selection for funding will be based on the strength of the applicant, and the impact of the proposal, assessed through standard criteria (outlined below and in the Assessment Matrix), as well as broader portfolio investment objectives.

### Portfolio investment objectives

The selection process aims to build a regional portfolio through awards to multiple African Regional RDT Suppliers. The portfolio approach aims to:

- Balance regional geographic and RDT market needs.
- Mitigate risk and increase near-term availability of regionally supplied RDTs by considering African Regional RDT Suppliers with a range of experiences, capacities, and business maturities.
- Optimize the potential impact of the portfolio of suppliers on regional RDT markets and economic development overall.
- Support two or more African Regional RDT Suppliers intending to supply international donor agencies, Ministries of Health, or other major global health procurers with regionally relevant, public health priority RDTs by the end of 2025.

### Selection criteria

At a high level, selection will be based on the potential to sustainably supply quality assured, affordable RDTs at scale to regional markets. Selection will consider the applicant's current RDT business and its near- and long-term business plans. The process will assess the applicant's potential to have a sustained impact

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<sup>4</sup> Any African company not intending to cover the full supply-side value chain for RDTs, but with an interest in engaging with African Regional RDT suppliers or engaging in the RDT value chain more broadly is encouraged to apply to the EOI.

on the regional RDT markets, (i.e., to capture a meaningful share of regional RDT demand or to address a local need that is neglected by global RDT suppliers), and the applicant's potential contribution to broader economic development in the region.

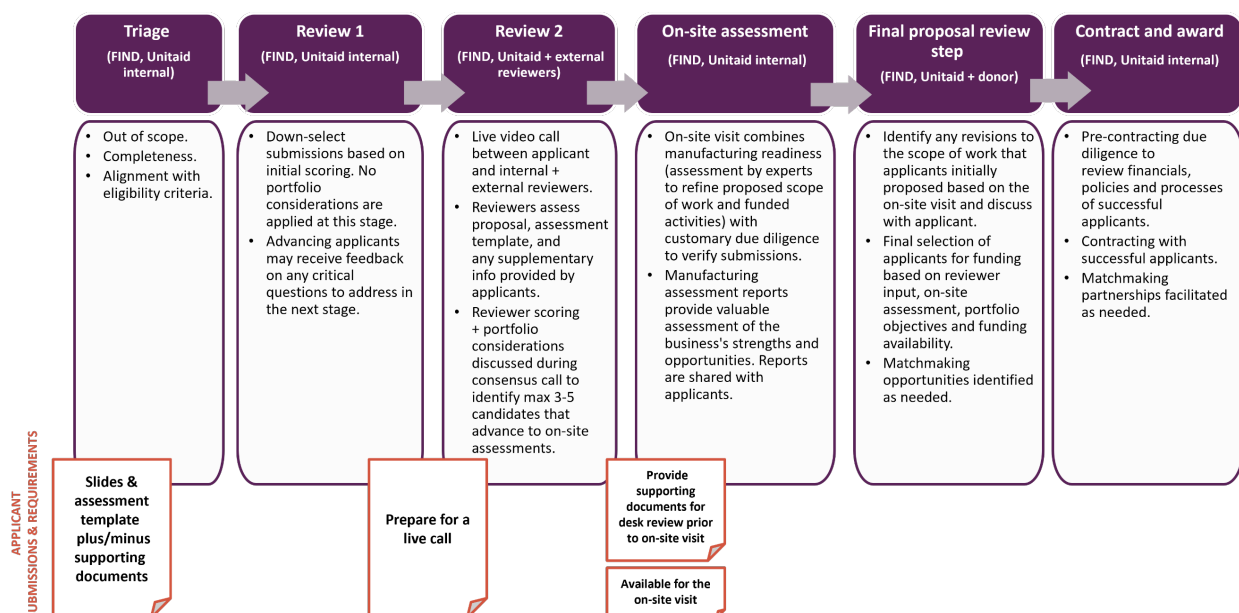
As such, the selection process will consider the African Regional RDT Supplier's business holistically. Key selection criteria include:

- Strength and capabilities of the existing business and current team members; strength of plans for future growth, addressing critical success factors, and feasibility of execution.
- RDT product portfolio and fit with regional RDT demand and market development.
- RDT product quality, product performance, usability, and evidence that is on par with market leading RDTs and global health procurement standards.
- Commitment to global access terms, in particular, the Regional RDT Supplier's ability and commitment to pursue low-cost strategies that balance reasonable margin with pricing that is affordable to regional buyers.
- Scope of operations (e.g., product development, end-to-end manufacturing, marketing/sales, and distribution), both current and in the future; gaps and feasibility of addressing these.
- Quality Management Systems (QMS) and regulatory capacities, gaps, and feasibility of plans to address the identified gaps.
- Sales and distribution capabilities, gaps, and opportunities to address the identified gaps.
- Ability to meet the near- and long-term milestones, specifically:
  - By December 31, 2025, supply the public sector (either a MoH, or donor-funded procurement mechanism, e.g., PEPFAR, PMI, the Global Fund, UNICEF) with at least one regionally relevant RDT, at a scale of at least 100,000 RDTs. This implies that the RDT supplier is the legal manufacturer, the RDT has necessary regulatory authorization and registrations, the RDT is manufactured under a robust QMS system, and sold at an affordable price.
  - By 2030, have the capability for end-to-end RDT manufacturing, meaning manufacturing finished products starting with reagents and raw materials, for at least one RDT in their portfolio.

## AWARD PROCESS

The **deadline for receipt of submissions is 11:59 PM CET 12<sup>th</sup> November 2023**. A commitment to a compressed timescale is required.

The selection and award process will include a check to assess applicant eligibility and completeness (self-declaration form, PowerPoint presentation, and Assessment Matrix); followed by an internal shortlisting review, conducted by FIND. Companies advancing will be invited to a video conference for a short presentation, and to submit additional information. The presentation and materials will be reviewed by a panel of internal and external experts; the panel will aim to identify companies that will undergo an on-site manufacturing readiness assessment and due diligence visit, conducted by FIND and external experts, which will ultimately inform the final selection decisions and the funded scope of work. The figure below outlines the envisioned process.



## APPLICATION REQUIREMENTS

The review process will require additional information and submissions from short-listed companies, however, the initial application consists primarily of a slide presentation summarizing the African Regional RDT Supplier's business and approach to having regional RDT market impact, information related to the assessment criteria, as well as a self-declaration form.

Applicants shall provide a slide deck of **no more than 20 slides** that must include the following information, and must use the provided PowerPoint template (see **HOW TO APPLY** for templates and forms):

### Company overview

- Company overview (e.g., ownership, size, revenue, relationships with key institutional buyers)
- Strategy and business model overview, current and future. Note in particular the components of the value chain currently performed in-house vs. functions that are obtained through partnership and outsourcing.
- RDT portfolio, including:
  - On-market products: note key markets/customers, annual volumes, COGS, ex works prices; product development approach (in-house or tech transfer); product regulatory approvals/registrations, key clinical studies supporting performance, and
  - Pipeline: RDTs in development or planned, with indicative timelines
- Evidence of experience and expertise, or key personnel with experience in areas relevant to this RFP, i.e., experience with product development; quality (QMS, regulatory, post-market surveillance); RDT manufacturing; and sales and distribution in the region (product forecasting, introduction, sales, and distribution). Description of near and long-term staffing plans and hiring strategy.
- Manufacturing capabilities overview

- a. Current manufacturing capacity and utilization, and process map (including activities performed in-house vs outsourced; key suppliers/partners).
  - b. Expansion plans, if any (with budget, timelines, partners, and activities).
- 6. Quality Management Systems overview
  - a. Experience with SRAs/WHO PQ/GMP
  - b. Quality certifications, ISO 13485 auditor, etc.
  - c. Quality and regulatory staffing and profiles
- 7. Sales and distribution capabilities overview
  - a. Distribution model, capacity, existing geographic footprint.
  - b. Experience selling to various regional channels, experience with public sector and donor-funded procurement; approach to local registrations, demand forecasting and demand creation; and post-sales support.
  - c. Describe any plans to expand/strengthen sales and distribution capacity.

#### Roadmaps for meeting milestones

- 8. Roadmap for meeting 2025 supply milestone (sales of regionally relevant RDTs to a local MoH or donor-funded procurement mechanism).
  - a. Target product: additional detail, especially studies supporting performance and usability.
  - b. Target markets and activities to support product adoption, procurement, and distribution.
  - c. Plan for becoming procurement eligible (e.g., ERPD/WHO PQ) by the end of 2025.
- 9. If applicable, a manufacturing roadmap for end-to-end manufacturing by 2030, costed at a high level and including timelines and critical activities.

#### Value proposition, expected impact, and funding/resource requirements.

- 10. Long-term vision and expected impact: description of the impact the company plans to have on regional RDT markets in the near and longer term, (e.g., any targets around market share or volume allocations to regional markets), commitments to access pricing, and efforts to maximize equitable access.
- 11. Describe the funding, resources, and capabilities necessary to realize this impact/these targets and the high-level plans for securing the necessary resources and developing critical capabilities.
- 12. RFP ask: Describe the resources requested from this initiative and how they will position the company to achieve the longer-term impact. Including funding needs and timelines broken out by activities and deliverables. Indicate any areas where partner matchmaking or technical assistance may be beneficial.
- 13. Risk analysis: describe the potential challenges and risks to the business, as well as critical success factors.

## HOW TO APPLY

Submit applications via the FIND [RFP Submission Webform](#). Please ensure that you are applying for the RFP titled REQUEST FOR PROPOSALS 1: RDTs Made in Africa, for Africa, and proceed with the online submission. Templates for the Applicant Presentation, Assessment Matrix, and self-declaration can be downloaded from the submission portal. Please upload your completed **Applicant Presentation, Assessment Matrix, and a completed self-declaration form**, along with any supporting documents by **12<sup>th</sup> November 2023 by 11:59 pm CEST**.



***Note: Applicants who do not submit a self-declaration form as part of their submission will not be eligible.***

## QUESTIONS & FURTHER INFORMATION

Please email questions to [dx-manufacturing@finddx.org](mailto:dx-manufacturing@finddx.org) with the subject line: “RFP: Rapid diagnostic tests made in Africa, for Africa”.

## CONFIDENTIALITY

FIND and Unitaid consider any application and supporting documents received under the RFP as confidential. All information supplied by the applicant to FIND and Unitaid, under the RFP and all other documents relating to the RFP process (provided by FIND and Unitaid and/or the applicant), must be treated as confidential, and not disclosed to any third party unless the information (i) is already in the public domain or (ii) is required to be disclosed to an Authorized Entity (including consultants, donors, or other financial sponsors, legal, financial, scientific or technical advisors, potential project implementation partners who have: (a) need to know such confidential information for the purpose of reviewing this RFP, and (b) such Authorized Entity has previously agreed in writing, to be bound by stringent terms and conditions including but not limited to confidentiality and non-use restrictions. If required, FIND and Unitaid can sign a Confidentiality Disclosure Agreement with interested applicants prior to proposal submission. FIND and Unitaid shall not disclose the proposal to third parties, without the prior written agreement of the proposal submitter, except to an Authorized Entity as detailed in (ii) above. All members of the review panel, including the Authorized Entity, shall also be under confidentiality 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 and Unitaid team.

## COMPLAINTS

Applicants who disagree with any actions or decisions taken in the course of the RFP evaluation may file a complaint in writing to FIND ([dx-manufacturing@finddx.org](mailto:dx-manufacturing@finddx.org)), detailing the grounds for the complaint and referring to the applicable provisions in the RFP or other regulations. The complainant may also use FIND's [Ethics Hotline](#) as a channel for raising complaints anonymously. FIND shall acknowledge the complaint within three (3) days of receipt and respond within ten (10) working days thereafter.

## APPENDIX 1: GROUNDS FOR EXCLUSION

In addition to the country-of-origin eligibility requirements stated above (i.e., African Union member state), country of origin is an exclusion criteria where international embargoes or sanctions by the United Nations apply.

Applicants/Bidders shall not be selected for a Contract if, on the date of proposal submission or the intended date of award, they:

- are bankrupt, being wound up or ceasing their activities, are having their activities administered by courts, have entered receivership, or are in any analogous situation.
- have been:
  - convicted by a final judgment or a final administrative decision or subject to financial sanctions by the United Nations, the European Union and/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;
  - convicted by a final court decision or a final administrative decision by a court, the European Union or national authorities in the Partner Country or in Switzerland for sanctionable practice during any Tender Process or the performance of any Contract or for an irregularity affecting the EU's financial interests.
- have been subject, within the last five years to a Contract termination fully settled against them for significant or persistent failure to comply with their contractual obligations during Contract performance, unless (i) this termination was challenged and (ii) dispute resolution is still pending or has not confirmed a full settlement against them.
- have not fulfilled applicable fiscal obligations regarding payments of taxes either in the country where they are constituted or in Switzerland (governing law will be Switzerland);
- are subject to an exclusion decision of the World Bank, or any other multilateral development bank, and are listed in the respective table with debarred and cross-debarred firms and individuals available on the World Bank's website or any other multilateral development bank, and cannot demonstrate, with supporting information along with their DoU, that the exclusion is irrelevant in the context of this RFP.
- have given a misrepresentation in supplying the information requested by FIND as a condition to participate in this RFP.

*Kindly complete the self-declaration form provided in the submission portal (see HOW TO APPLY). To note: "yes" answers to these questions should indicate, preferably with accompanying evidence, what remedial measures have been taken by the entity to resolve the issue in question. FIND will not exclude Applicants where we consider the measures to be sufficient and appropriate, and where Applicant reliability can be clearly demonstrated.*