

Enabling regional supply of diagnostic tests in LMICs

Expression of interest: strengthening the regional supply of *in vitro* diagnostics in LMICs

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 persists today. While these manufacturing facilities have realized important economies of scale among other benefits, the lack 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 in vitro diagnostic (IVD) manufacturing, through expanding and strengthening regional markets. Several longstanding barriers hinder regional IVD 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 identify potential solutions jointly](#).

Robust regional IVD markets will take time to develop, yet many countries and regional and global partners have initiated new efforts to accelerate and strengthen regional IVD markets LMICs. Specifically, the Africa Collaborative Initiative to Advance Diagnostics (AFCAD) aims to promote local manufacturing, build regulatory capacity, and global market negotiation. The 2023 G20 gatherings in India prioritized expanding the vaccine, therapeutic, and diagnostic production in LMICs.¹ Indonesia’s TKDN policy also encourages local participation in IVD/aims to develop IVD markets. In Latin America, the Member States of the Pan American Health Organization (PAHO) recently adopted a resolution to promote multisectoral action to increase regional production capacities for and improve access to essential health technologies, including IVDs.² At the global level, WHO, PEPFAR, The Global Fund, and Unitaid have launched initiatives to accelerate quality-assured HIV rapid test manufacturing in Africa.

Building on these initiatives, FIND and Unitaid are launching **this Expression of Interest (EOI) to identify regional and global partners interested in advancing regional manufacturing and supply of IVDs in**

¹ https://www.g20.org/content/dam/gtwenty/gtwenty_new/document/G20-New-Delhi-Leaders-Declaration.pdf

² https://iris.paho.org/bitstream/handle/10665.2/58314/PAHOIMTRPCOVID19230002_eng.pdf?sequence=1&isAllowed=y

LMICs.³ Specifically, we seek to identify IVD value-chain actors that have potential to accelerate LMIC supply of IVDs that meet regional needs, i.e., high-quality, affordable IVDs, produced at relevant scale.

OBJECTIVE

The long-term vision for this initiative is to improve supply resilience and access to critical diagnostics in LMICs by strengthening regional IVD suppliers and developing the broader IVD supply ecosystem in LMICs. We aim to enable local suppliers to meet regional demand for quality-assured, affordable diagnostics, 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 IVD value chain in those LMIC countries and regions lacking a resilient IVD supply base so that local suppliers meet a greater proportion of regional demand.

The EOI will provide critical information to inform **FIND and Unitaid's future investments** and efforts to accelerate and strengthen regional IVD supply in LMICs. Specifically, through this EOI, we seek an advanced understanding of potential projects, partnerships and stakeholders that could meaningfully strengthen the IVD supply base in Priority LMIC regions.⁴ This EOI will likely result in **future funding opportunities** (i.e. targeted Requests for Proposal to the EOI respondents) and matchmaking opportunities for interested applicants.

SCOPE

We seek proposals intending to strengthen regional IVD supply in LMICs. Depending on the applicant's role in the diagnostics value chain, and its geographic location, proposals will vary. Given the breadth of actors working across the IVD supply value chain, we envision the following broad types of proposals:

- **Regional Supply Strengthening Project:** Projects to strengthen regional IVD supply capacity in LMICs resulting in increased proportion of regional IVD demand met by the regional suppliers, and/or meeting an unaddressed regional priority public health IVD need.
- **Matchmaking/partnership requests:** partners seeking to partner with, sell to, or work with a regional IVD supplier(s) in a way that will strengthen the regional IVD supply base.
- **Professional services:** Partners with specialized expertise and services that may be essential to Regional IVD supplier(s).

APPLICANT PROFILE

This EOI targets suppliers and stakeholders with an interest (commercial or non-commercial) in strengthening LMIC regional IVD supply. This EOI is deliberately broad, and open to a variety of

³ Note: this EOI is one component of a broader initiative to enable the regional supply of diagnostics tests in LMICs. FIND and Unitaid have recently launched an RFP to support African RDT Supply (now closed): https://www.finddx.org/wp-content/uploads/2023/10/20231020_rfp_african_made_rdt_FV_EN.pdf

⁴ Priority LMIC regions are LMIC regions with limited IVD supply capabilities for quality-assured, affordable IVDs, resulting in a heavy reliance on IVD imports for key public health IVDs and/or with high-priority IVD needs that global markets do not address.

enterprises, and other actors working across the IVD value chain. We welcome applicants based both in and outside of LMIC regions.

Applicants should be:

- Focused on **quality-assured, fit-for-purpose, affordable public health priority IVDs**, for example, diagnostics deemed essential by the WHO (e.g., [included in the WHO Essential Diagnostic List](#)) or highly prioritized by local MoHs.
- Committed to strengthening local IVD supply in **priority LMIC regions (largely Africa, Latin America, and South-East Asia)**, where IVD manufacturing capacity is limited, resulting in high reliance on imports for public health needs, or inadequately addressed IVD needs.

We encourage applicants from companies and partners that are:

- **Regional IVD Suppliers, located in LMICs**, whose business development will directly increase the proportion of regional diagnostics demand met locally.
- **LMIC-based companies** that focus on specific functions in the diagnostics value chain (e.g. raw materials production, product development, distribution), that have an interest in engaging more fully in the regional IVD value chain, or that have a value proposition/product of interest to Regional IVD suppliers.
- **Diagnostics value chain actors based anywhere in the world** with a diagnostics-related value proposition/product that will benefit Regional IVD Suppliers.
- **Professional service providers** based anywhere in the world offering specialty IVD services for Regional Diagnostics Suppliers.

The table below illustrates potential examples of applicants and proposals, our intention is to be illustrative and not exhaustive.

Table X: Illustrative examples of possible EOI applicants and proposals

	Applicant and proposal	Impact
Project	Quality assured molecular test manufacturer in LMICs seeking funds to increase production capacity and automate line, to serve regional demand and to improve economies/COGS.	Increased share of LMIC regional molecular test demand met by regional supplier.
	International IVD manufacturer seeking co-funding to establish a new company in LMIC region for product development or/and manufacturing or/and marketing, and selling quality assured RDTs meeting local needs, affordably.	Increased share of LMIC regional RDT demand met by regional supplier.

	Microbiology reagent supplier in LMIC seeking funds to upgrade QMS in order to meet regional public sector buyer's quality standards.	Quality improvements and approvals obtained result in increased sales to LMIC laboratories serving the public sector.
	LMIC company developing POC sensors for non-communicable diseases seeking funds to enable expanded distribution in new markets on the continent.	Greater uptake of locally produced POC sensors in the region.
	LMIC company with RDTs for regionally relevant NTD tests.	Priority regional RDT needs met by local supplier.
Matchmaking/ Partnership	LMIC-based producers of key reagents and raw materials looking for introductions to potential customers, i.e. African RDT manufacturers.	Local sourcing increases supply security.
	LMIC region distributors with large geographic footprints and IVD experience and interest in supporting regional IVD industry by matchmaking with emerging local IVD manufacturers	Distribution experience leveraged to enhanced uptake of regionally produced IVDs.
	HIC developers/manufacturers of Prequalified/SRA HIV RDTs, but would be interested in tech transfer,	Tech transfer and mentoring supports MoH adoption and PEPFAR procurement of HIV RDTs manufactured in Africa.
	LMIC based research/academic institutions with IVD product development capabilities, specimen banks, or clinical trials capabilities interested in partnering with regional IVD suppliers to support development of tests for regionally relevant NTDs.	Development of IVD for priority NTDs accelerated and produced regionally, meeting a priority unmet regional need.
Professional Services	<p>Expertise and services offered at affordable rates to Regional LMIC suppliers:</p> <ul style="list-style-type: none"> • Consultancy with QMS, regulatory and dossier preparation expertise. • LMIC based biotech recruiting/HR • Manufacturing and supply chain expertise • Product development professional advice and services. • IVD-specific business or management consulting services • Regional trade and tax law services • Organizations and professionals working to strengthen policies (e.g., trade, tariff, competition, regulatory) that enable regional value chains and markets. • Etc. 	Strengthening / acceleration of Regional IVD Supplier's ability to meet regional demand through access to expertise.

BENEFITS

While there is no immediate, direct funding associated with this EOI, the process will inform future funding opportunities, advocacy, and efforts.

Immediate direct benefits to applicants expressing interest in partnerships, are potential introductions to other stakeholders where there is an opportunity for mutually beneficial partnerships on key value-creating activities. After reviewing all EOI (and related RFP) submissions, with both applicants' consent, FIND and Unitaid will facilitate partnerships between applicants. If an EOI applicant partners with a funded project or supplier, (e.g., either through the current [RFP](#) or future RFPs), the EOI applicant may receive funding through this partnership.

HOW TO APPLY

Submit applications via the [FIND EOI Submission Webform](#). Please ensure that you are applying for the EOI titled *Expression of Interest: strengthening the regional supply of in vitro diagnostics in LMICs*, and proceed with the online submission. The EOI application is intentionally brief. In addition to basic company information and regional interests, the form requests:

- A brief business overview focused on capabilities, products and experience relevant to this EOI role in the IVD supply chain/ value-creation functions performed.
- A brief proposal describing how the applicant could enable or strengthen the regional IVD supply in LMICs.

HOW TO APPLY

1

Who are you?

2

Near term LMIC regional IVD market interests

3

What do you propose to enable regional supply of Dx in LMICs?

Contact information

- Contact name
- Company
- HQ & Operations location


Which in vitro diagnostics (tick those that apply)

- RDTs
- Molecular
- Other immunoassay
- Growth based
- Sequencing
- Microscopy
- Biophysics
- Chemical/Biochemical
- Other(s): _____

Brief overview of **current** business, expertise, IVD value chain functions performed (*max ~250 words*)

Which LMIC priority regions* will you focus on in the next 5 years?

Our priority is those LMIC regions with limited diagnostics supply, highly reliant on imports.



- Describe your proposal/value proposition to enable regional supply of Dx in LMICs, depending on your role in IVD industry (*max ~500 words*)
 - **Regional supply strengthening project:** Describe the proposed project and its impact on the regional IVD market
 - **Matchmaking/partnership proposal:** Describe how you would like to partner with, sell to, or work with a Regional IVD supplier(s).
 - **Professional services offered:** Expertise and services offered to Regional IVD supplier(s)
- Optional uploads. Applicants with projects are strongly encouraged to submit 5-10 slides detailing the project, budget, activities, and timelines.
- Are you interested in FIND-facilitated partnership/matchmaking introductions?
 - Yes
 - Maybe
 - No

TIMELINE

We will review the first round of submissions in the second half of January 2024; thereafter, we expect to review applications on a bi-monthly basis.

QUESTIONS & FURTHER INFORMATION

Please email questions to dx-manufacturing@finddx.org with the subject line: “Expression of interest: Strengthening the regional supply of IVDs in LMICs”.

CONFIDENTIALITY

FIND and Unitaid consider any application and supporting documents received under the EOI as confidential. All information supplied by the applicant to FIND and Unitaid, under the EOI and all other documents relating to the EOI 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 EOI, 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. If applicable, 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.