



# **Call for partners for Supply of blood glucose meters, test strips and lancets for low- and middle-income countries via the FIND marketplace**

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## 1. Introduction

With the rise of diabetes and cardiovascular diseases (CVD), the global disease burden now includes noncommunicable diseases (NCDs). An increasing number of low- and middle-income countries (LMICs) are experiencing the double burden of infectious and noncommunicable diseases, putting tremendous financial strain on healthcare systems and patients.

Patients suffering from NCDs are particularly vulnerable to financial hardship due to the necessity of lifelong management of their condition, often resulting in suboptimal disease management. In LMICs, patients suffering from diabetes are more prone to diabetes-related complications due to – amongst other factors – their inability to self-monitor blood glucose levels regularly because of the high cost of and limited access to glucose tests strips.

Many LMICs have fragmented procurement systems, leaving each procurer (public and private) to negotiate prices with suppliers individually, often resulting in uncontrolled end user prices. The Foundation for Innovative New Diagnostics (FIND) aims to streamline and pool procurement of blood glucose monitoring commodities through an online marketplace, across several pilot LMICs (up to nine). To underpin this project, FIND plans to enter into strategic alliances with the countries and other partners to strengthen procurement systems, accelerate development of LMIC-appropriate tests, increase test availability, reduce prices, and generate robust data.

Making available glucose testing commodities on the marketplace will support the country governments to achieve the World Health Organization (WHO) Independent High-Level Commission on NCDs recommendations to ensure access to essential medicines and technologies within national Universal Health Coverage (UHC) benefit packages for NCD services [1].

Furthermore, FIND recognizes that diabetes is primarily managed by the person with diabetes (PWD) outside of the healthcare system. Aside from access to blood glucose meters, test strips and lancets, PWDs also need decision support solutions, education and coaching to effectively manage their condition. Healthcare providers and the broader care team/community are important stakeholders in overall patient management, also requiring support and education to effectively and efficiently provide diagnosis, treatment and therapy optimization for PWDs.

## 2. Objective of partnership

FIND is looking for an in vitro diagnostics (IVD) industry partner to address the following two objectives of this partnership:

1. Supply blood glucose meters, tests strips, and lancets to the public and private market of some or all of the pilot LMICs currently in scope, through a volume-based and innovative-pricing strategy via the FIND online marketplace, including a concept of in-country supply and delivery to control end user prices.
2. Develop a concept beyond supply availability to address health system strengthening and patient empowerment, such as education, customer service, support, and post-market surveillance.

### 3. FIND marketplace, volumes and pricing

#### Marketplace

In LMICs, diagnostic tests often do not exist, are inaccessible or only available at a prohibitive cost. Market failures result in poor access to diagnostics, driven among other things by:

- Variable, fragmented or absent country demand
- Fragmented procurement stakeholders (suppliers, distributors, purchasers, final customer)
- Non-transparent and uncoordinated procurement and supply chain processes
- Lack of affordability of diagnostic products and services
- Inconsistent or inadequate procurement data at national level

FIND is exploring ways to address these market failures and secure more sustainable access to affordable, quality diagnostics. Taking a broader look at end-to-end supply chains and how we can remove or circumvent supply chain barriers will require looking outside of traditional diagnostic supply chain models. LMICs have long borne the brunt of a broken supply chain for diagnostics, yet in other areas, including smartphones and other commodities, we know that there are ways to do better. Innovative supply chains for best in-class diagnostics require robust market data, Demand aggregation, rapid quality assurance mechanisms, technology and know-how transfer to companies that can mass produce, and, importantly, end-to-end planning from manufacturer to patient.

To do this, FIND is testing the feasibility of building a diagnostics marketplace, which will match supply and demand for the highest priority diagnostics identified by a selection of LMIC procurers. At this stage, pilot countries within the scope of the FIND marketplace are Bangladesh, Brazil, Ethiopia, India, Peru, Senegal, South Africa, Tanzania, and Uganda.

This new initiative aims at taking the following measures:

- Aggregate global demand to inform procurement
- Pool procurement across countries to establish reliable supply and establish fair market pricing for public and private sector actors
- Understand demand patterns to predict and stabilize manufacturing and supply requirements
- Tackle supply chain and procurement bottlenecks
- Create innovative supply chain solutions

#### Blood glucose test strip volumes

It is estimated that the FIND marketplace has the potential to cover 20% of the public and 12% of the private blood glucose test strip market in the target countries by year five. Based on market research of past blood glucose test strip volumes and projected market growth, this amounts to a total volume of approximately 1,178 million test strips over five years in the nine pilot countries. Estimated blood glucose test strip volumes per year and country to be procured through the FIND marketplace are provided in Table 1.

It is important to note that these volumes are not guaranteed. The FIND marketplace operates via an in-country demand generation model.

Public market (millions of strips)							Private market (millions of strips)						
	Volumes 2019	Year 1	Year 2	Year 3	Year 4	Year 5		Volumes 2019	Year 1	Year 2	Year 3	Year 4	Year 5
Ethiopia	31.5	1.6	3.4	5.2	7.7	10.3	Ethiopia	10.5	0.1	0.5	1.2	2.1	2.6
Senegal	2.1	0.1	0.2	0.3	0.5	0.7	Senegal	3.9	0.02	0.2	0.4	0.8	1.0
South Africa	60.0	3.0	6.4	9.8	14.8	19.7	South Africa	110.0	0.6	5.7	12.5	21.6	27.3
Tanzania	19.2	1.0	2.1	3.1	4.7	6.3	Tanzania	4.8	0.02	0.2	0.5	0.9	1.2
Uganda	5.8	0.3	0.6	0.9	1.4	1.9	Uganda	1.4	0.007	0.1	0.2	0.3	0.4
Bangladesh	17.4	0.9	1.9	2.9	4.3	5.7	Bangladesh	98.6	0.5	5.1	11.2	19.3	24.5
India	83.7	4.2	9.0	13.7	20.6	27.5	India	474.3	2.4	24.7	54.1	93.0	117.6
Brazil	476.2	23.8	50.9	78.1	117.1	156.2	Brazil	119.0	0.6	6.2	13.6	23.3	29.5
Peru	24.5	1.2	2.6	4.0	6.0	8.0	Peru	45.5	0.2	2.4	5.2	8.9	11.3

**Table 1** Estimated blood glucose test strip volumes per year and country to be procured through the FIND marketplace.  
Source: FIND market model, IQVIA, Mordor Intelligence, BCG, IDF Atlas 2019

## Pricing

The price target for blood glucose meters and test strips available on the FIND marketplace is set to match average public tender prices of the target countries. Business models that include tiered pricing or subscription-based pricing can be considered; feasibility of implementation will be discussed on a case-by-case basis. Any proposed pricing model shall include the full value chain through to the end user.

## 4. Products

### Diabetes supplies and innovative solutions/interventions

Initially, FIND is aiming to make available **blood glucose meters with test strips, and lancets** from several IVD manufacturers (more than one per country). Several different types of glucose meters and test strips can be made available, per manufacturer. All products services need to meet the following criteria:

- CE certification or FDA approval is in place or in process for approval by year end 2020 (other stringent regulatory approvals [SRA] can be considered if they meet the same requirements as CE or FDA; for a list of SRAs see [this link](#))
- Glucose monitoring system meets the requirements of the EN ISO 15197:2015 accuracy criteria
- Reliable product supply is established in the respective countries
- PWDs and healthcare providers have access to customer support services (maintenance, technical support, complaint management, product training)
- PWD and healthcare provider product training, educational material and support is available, and in local language
- Product lifecycle management ensures consistent product supply (test strips and compatible blood glucose meter) for at least 3 years from the day of launch on the marketplace
- Blood glucose meters and strips are priced as outlined under the section “Pricing”
- Product pack sizes offered support the needs of PWDs, considering mostly out of pocket spending on healthcare
- Technical requirements are met as outline in the Excel sheet accompanying this document

All applications meeting these criteria and including all necessary documentation, will go through a predefined selection process (see section 6 and Appendix I).

Additionally, **point-of-care HbA1c devices and test cartridges** and **continuous/flash glucose monitoring devices** can be made available on the FIND marketplace, if these instruments are part of the IVD manufacturer's product portfolio and are in alignment with an affordable and sustainable pricing model.

Further **innovative solutions** that impact **last mile distribution** and/or **healthcare system strengthening through digital integration** are also recognized in this partnership request.

Recognizing the importance of accurate blood glucose monitoring, IVD manufacturers should be open to agree to independent in market accuracy testing.

## 5. Proposal submission

The expected proposal content is outlined in Appendix I. Ahead of submission, clarifying questions may be directed by email to [NCDs@finddx.org](mailto:NCDs@finddx.org). A member of the FIND team will respond via email to any request submitted no later than 5 working days before the final submission deadline.

The submission deadline for the proposal is **07 June 2020 at 23:59 CEST** (Central European Summer Time).

FIND considers any proposal received as confidential. If required, FIND can sign a confidential disclosure agreement (CDA) with interested suppliers prior to proposal submission. FIND will not disclose the proposal to third parties without the prior written agreement of the proposal submitter. The review of proposals will be carried out by a team comprising internal FIND experts and independent external experts. External reviewers are under confidentiality agreements and are recused if found to have a potential conflict of interest. Any specific questions concerning confidentiality should be addressed to the FIND team.

## 6. Supplier selection process

The selection of submissions to this Call will be based on key selection criteria laid out in Appendix I: Expected proposal content.

Proposals will be assessed and partners selected through a systematic process designed to be objective, independent, and transparent to ensure that the most suitable IVD industry partners are selected and potential conflicts of interest are avoided.

- The evaluation of proposals will be conducted over a 6-week period following the close of the call. Proposals will be assessed by a minimum of two internal and two external reviewers
- Up to five proposals will be shortlisted: shortlisted applicants will be notified by 20 July 2020 and invited to participate in a teleconference call to answer in-depth and clarifying review questions
- A decision to enter into negotiations for long-term agreements for the partnership will be made and communicated to applicants no later than 30 Aug 2020

## 7. Timeline summary

Date	Process step	Location / contact
12 May 2020	Publication of Call for Proposals	FIND website
31 May 2020 (23:59 CEST)	Deadline to submit questions	NCDs@finddx.org
07 June 2020 (23:59 CEST)	Deadline for proposal submission	NCDs@finddx.org
19 July 2020	End of proposal evaluation period	
20 July 2020	Notification of shortlisted IVD suppliers*	Via individual email correspondence
30 August 2020	Notifications of selected candidates for long-term agreement negotiations*	Via individual email correspondence

\*Suppliers not shortlisted or selected for long-term agreement negotiations will also be notified at the same time

Note: Timelines may be subject to change and changes will be communicated accordingly

## References

[1] WHO. *Time to deliver: report of the WHO Independent High-level Commission on Noncommunicable Diseases*. 2018 [cited 2020 29-Jan]; Available from:  
<https://apps.who.int/iris/bitstream/handle/10665/272710/9789241514163-eng.pdf?ua=1>

## Appendix I: Expected proposal content

Every submitted proposal shall provide the information itemized here below in a Word document, using the structure and numbering shown in points 1. and 2. Additional information as per point 3. shall be provided separately. In addition, every submitted proposal shall provide the completed [Excel template for the General, Financial and Technical Specifications](#).

### 1. Organization

- 1.1. Name and contact details of main contact
- 1.2. Brief history of the company, corporate focus/mission; length of time active in diabetes care medical devices
- 1.3. Legal entity and corporate governance structure
- 1.4. Management structure
- 1.5. Biographies of leadership team and senior management who will be directly responsible for the implementation of the partnership

### 2. Supply, support and commercialization:

Descriptions of:

- 2.1. Global logistics organization (manufacturing location, distribution concept) and current supply chain in target countries
- 2.2. Upstream supply chain for the production of blood glucose meters, test strips and lancing
- 2.3. Risk mitigation strategies to ensure continuity of supply and supply chain sustainability
- 2.4. Business model to meet pricing requirements (in the absence of volume guarantees)
- 2.5. Innovative model or solution for last mile reach and end user price control
- 2.6. Customer support system and structure
- 2.7. PWD and healthcare provider training, education and support
- 2.8. Any current and past corporate social responsibility activities for diabetes supplies or other diagnostic devices in LMICs

Evidence for the above in the form of statistics (e.g. KPI results for logistic/supply, number of customer enquiries/complaints handled, trainings held in countries etc.) and relevant examples of past successes should be included in the submission (within the 10-page limit).

### 3. Additional materials to be provided:

- For the proposed product: Instructions for Use; User Manual; List of all components planned to be included in the proposed product (ideally with picture)
- Examples of training resources

## Appendix II: Manufacturer assessment criteria

Criterion	Description
Product quality and technical specifications	Compliance with EN ISO 15197:2015 criteria; Regulatory status; Technical requirements
Product price and meter access	Unit pricing for strips, meters and lancets; Product life cycle
Country coverage and access	Coverage of the FIND pilot target countries and market access
Manufacturing and supply chain infrastructure	Quality management system; Reliable supply chain; Innovation in supply; Product recalls and stock outs
PWD and healthcare provider support	Quality of educational and training support for PWDs and healthcare providers; Quality of in-country customer support, meter replacement processes, technical assistance etc.
Business model	Business model that supports sustainable access to self-monitoring of blood glucose; Supplier supports PWDs outside of the healthcare system; Product solution meets the needs of PWDs; Solutions proposed that strengthen elements of the healthcare system; Availability of other complementary diagnostic solutions, like HbA1c for point of care use and continuous/flash glucose monitoring solutions.
Company setup	Company strength and experience in the diabetes care business

Questions & answers – visit [website here](#).