Request for Proposals

Developers of minimally- or non-invasive glucose self-monitoring technologies for participation in evaluation studies

ABOUT FIND

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world. We connect countries and communities, funders, decisionmakers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems. We are working to save 1 million lives through accessible, quality diagnosis, and save US$1 billion in healthcare costs to patients and health systems. We are a World Health Organization (WHO) Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation.

BACKGROUND

With the rise of diabetes and cardiovascular diseases, the global disease burden is shifting towards non-communicable diseases (NCDs) and an increasing number of low- and middle-income countries (LMICs) are experiencing a double burden of communicable and non-communicable diseases[1]. People with undiagnosed or uncontrolled NCDs, particularly diabetes, are at higher risk of infection-induced complications and death[2-5].

In diabetes management, regular self-monitoring plays a key role in achieving optimal glycaemic control and improving health outcomes for people living with diabetes[6].

Despite the established benefit of home-use technologies for self-testing, traditional tools for self-monitoring, i.e. glucose meters and strips and their invasive testing procedure via frequent finger prick blood, often present a burden to people with diabetes in managing their condition. Unsuitable technologies are considered a major barrier to appropriate self-monitoring of glucose[7].

Minimally invasive and non-invasive self-monitoring technologies hold great potential to encourage optimal self-management by making glucose testing easier. A recent landscape compiled by FIND identified over 60 such technologies, the large majority still in development[8].

Through partnerships with developers, FIND aims to accelerate the availability of these newer, minimally- or non-invasive glucose self-monitoring technologies for people with diabetes in LMICs.

OBJECTIVES

- With this request for proposals, FIND is seeking to **select developers** of minimally- or non-invasive glucose self-monitoring technologies for **performance and usability evaluations**.
- The aim of the evaluations is to understand which technologies have **high potential to meet performance and usability requirements** for diabetes management for people in LMICs.
- Based on the results of the evaluation, FIND may **select 1–2 developers for long-term partnerships** to accelerate final product development and implementation in LMICs (pending funding availability).

BENEFITS

- **Free of charge independent evidence generation** of the performance of your device by a renowned diabetes technology institute.
- **Data can be used by developers** to further inform product development or for regulatory submission.
- Potential to be selected by FIND for **development partnership**, including joint resource mobilization and development of market access strategies to accelerate final product development and implementation.

EVALUATION STUDIES

We plan to conduct two studies:

1. A performance study with participants who self-monitor their glucose during their diabetes management. The study will use state-of-the art reference tests for self-monitoring and include a component of lab-based reference testing in dedicated glucose excursion interventions. Final study design will depend on the type of monitoring device and technology. The study will be designed and conducted by a reputable institution with proven expertise in diabetes technology evaluations.
2. A usability study will be conducted in 1−2 LMIC settings with local users to collect user feedback and inform potential of user adoption.

Study data will be made available to developers to inform further product development or for regulatory submission. The results of the studies will be published in a peer-reviewed journal.

The studies will be sponsored by FIND; FIND will compensate the developers for devices required for the evaluations (up to 50 devices are expected to be necessary).

SCOPE and ELIGIBILITY

Developers can apply for participation in the studies if their technology meets the following criteria:

- The device is intended to be used for self-monitoring of glucose by people living with diabetes (type 1 or type 2).
- The device measures glucose levels either via a minimally- or non-invasive procedure; see definitions:

  Minimally invasive: A technology where a sensor is inserted into the subcutaneous space with a single insertion, involving minimal pain and providing glucose concentrations over an extended period.

  Non-invasive: A technology where the concentration of glucose is measured without inserting a device into the body; this can include optical or non-invasively accessible fluid-sampling technologies (e.g. saliva or sweat)
- If user calibration is needed, it should not require more than 2 calibrations per day (minimally invasive technology) OR it should not take longer than one week for calibration before measurement can begin (non-invasive technology)
- The device meets these development stage criteria:
  - Basic performance characteristics of the device should have already been tested and documented (in line with TRL 6 or above, see link)
  - Product launch is planned in the next 2 years

- Non-invasive products already approved by a stringent regulatory authority (SRA) will also be considered (SRA list see here)

Your device will not be eligible if any of the following apply:

- Any part of the device needs to be implanted for measurement (i.e. by a medical professional)
- Minimally invasive device already approved by a stringent regulatory authority
- Invasive devices sampling blood for each measurement, e.g. blood glucose meters

As a developer of the product, you should be:

- Interested in launching your product in low- and middle-income markets (e.g. Brazil, South Africa, India; see full list of countries in scope).
- Able to provide the following number of devices for the evaluations (paid by FIND): up to 50 (potentially fewer for non-invasive devices).

SELECTION CRITERIA

We kindly ask you to provide the following information in your proposal for review and selection of partners:

- Information on your device as outlined in Tab 1 of this Excel sheet: link (or available via the Technology Scouting Submission Webform)
- Availability of essential documents for your device, as required, to obtain approval to conduct evaluation studies of glucose monitoring technologies with German authorities: see list in Tab 2 of the Excel sheet
- A PowerPoint presentation that includes the following:
  - General: Introduction to your company, team, strategy, market presence
  - Product: Images of the device, performance data, business model, anticipated launch timelines and any other information you would like to provide
- Instructions for use (IFU) and user manual

In the selection process, FIND may ask about the financial viability of your company to understand the potential for future investments should further financial resources become available.

Any information shared with FIND during this RFP process will be kept confidential. A confidentiality agreement can be signed if preferable.

SELECTION PROCESS

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

- The evaluation of proposals will be conducted over a 5-week period following the close of the RFP. Proposals will be assessed by a panel of expert reviewers.
- Up to eight proposals will be shortlisted: shortlisted applicants will be notified and invited to participate in a teleconference call to present their company and device.
- Devices from up to five developers will be selected for inclusion in the evaluation.

TIMELINES

Date	Process step	Location / contact
15 June 2021	Publication of RFP	FIND website
11 July 2021	Deadline for proposal submission	https://www.finddx.org/technology-review/webform/
12 July–15 August	Proposal evaluation period	NCDs@finddx.org
16 August 2021	Notification of shortlisted development suppliers*	Via individual email correspondence
16–30 August 2021	Telephone conferences with shortlisted developers	Via individual email correspondence
6 September 2021	Notifications of selected developers	Via individual email correspondence
Q4 2021–Q2 2022	Planning and conduct of studies	NCDs@finddx.org

*Developers not shortlisted or selected will also be notified at the same time.

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

HOW TO APPLY

Your proposal is to be submitted via FIND's Technology Scouting Submission Webform. Select "NCDs" as *Disease Area* and "Diabetes" as *Disease Area Subtype* on the form.

Please upload your completed submission Excel template, PowerPoint presentation, IFU and user manual.

Questions ahead of proposal submission can be emailed to the address provided below.

RESPONSIBILITIES

- FIND will cover all costs of the evaluation studies.
- FIND will provide selected developers with a generic study protocol summary once finalized.
- FIND will provide selected developers with an individual performance report and raw data.
- Developers will make available all necessary documents, as required, for submission to authorities to obtain study approval.
- The Evaluation centre will publish test performance results in a peer-reviewed journal.

FOR QUESTIONS, CONTACT: NCDs@finddx.org

References:

1 Jamison, D. T. Disease Control Priorities, 3rd edition: improving health and reducing poverty. *Lancet* **391**, e11-e14, doi:10.1016/S0140-6736(15)60097-6 (2018).

2 Apicella, M. *et al.* COVID-19 in people with diabetes: understanding the reasons for worse outcomes. *Lancet Diabetes Endocrinol* **8**, 782-792, doi:10.1016/S2213-8587(20)30238-2 (2020).

3 Chang, A. Y., Cullen, M. R., Harrington, R. A. & Barry, M. The impact of novel coronavirus COVID-19 on noncommunicable disease patients and health systems: a review. *J Intern Med* **289**, 450-462, doi:10.1111/joim.13184 (2021).

4 Marais, B. J. *et al.* Tuberculosis comorbidity with communicable and non-communicable diseases: integrating health services and control efforts. *Lancet Infect Dis* **13**, 436-448, doi:10.1016/S1473-3099(13)70015-X (2013).

5 Samaras, K. The burden of diabetes and hyperlipidemia in treated HIV infection and approaches for cardiometabolic care. *Curr HIV/AIDS Rep* **9**, 206-217, doi:10.1007/s11904-012-0124-x (2012).

6 Meetoo, D., Wong, L. & Fatani, T. 'Knowing where I am': self-monitoring of blood glucose in diabetes. *Br J Nurs* **27**, 537-541, doi:10.12968/bjon.2018.27.10.537 (2018).

7 Ong, W. M., Chua, S. S. & Ng, C. J. Barriers and facilitators to self-monitoring of blood glucose in people with type 2 diabetes using insulin: a qualitative study. *Patient Prefer Adherence* **8**, 237-246, doi:10.2147/PPA.S57567 (2014).

8 Zhang, J. Y., Shang, T., Thomas, A., Arnold, M., Vetter, B.N., Klonoff, D.C.,. Products for Monitoring Blood Glucose with Optical Noninvasive, Fluid Sampling Noninvasive, and Minimally Invasive Glucose Monitoring Technologies. *Journal of Diabetes Science and Technology - in press* (2021).