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Diagnosis for all

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Call for EXPRESSION OF INTEREST from **manufacturers** of **Continuous Glucose Monitoring** (**CGM**) devices

Summary

What should you be interested in?

Working with FIND to discover Kenya and South Africa as interesting markets for launch of your CGM.

Who are you?

A manufacturer (not distributor) of a CGM that is not yet commercially available in Kenya and South Africa.

What CGMs are we looking for?

- Minimally invasive CGMs (using a sensor to measure glucose in the interstitial fluid)
- CGM with stringent regulatory approval (CE-mark or FDA) or close to this approval (in the next 9 months)
- For more technical specifications see the main document

What will we do together under this EOI?

Discover the Kenyan and South African diabetes market through in-person meetings with healthcare professionals, private health insurers, people living with diabetes using CGMs, and other key stakeholders.

What is expected from you?

A genuine interest to launch your CGM in these two markets and make them available in the public and private sector.

How are we selecting manufacturers under this EOI?

We will apply specific selection and prioritization criteria to all manufacturers who apply to the EOI. We will select up to three manufacturers to undergo the market immersion activities.

What could follow after the EOI?

We are planning a small performance evaluation of some CGMs, and if found acceptable, we will work with the manufacturer to prepare for market introduction. Note that this activity is separate from the EOI and will only be open to manufacturers selected for market immersion and fully committed to local product launch.

How do you apply for the EOI?

Read the content of this document to check if you are eligible, complete the EOI data form under "7. HOW TO APPLY" and submit the requested information by the 28th August 2023.

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1. BACKGROUND

To date, 537 million people worldwide have diabetes, and the majority are living in low- and middle-income countries (LMICs)[i]. Everybody living with Type 1 Diabetes (8.7 million people[ii]) and 7–15%[iii] of people with Type 2 Diabetes require insulin. For these people, monitoring the level of glucose in their blood several times a day is critical to enable them to use insulin safely and manage their blood glucose levels. Multiple barriers impede regular glucose self-testing, such as the challenges of frequent finger-pricking, technical skill, and cost[iv].

Continuous glucose monitoring devices (CGMs) have transformed the ability of people with diabetes and their healthcare providers (HCPs) to manage diabetes.

Continuous availability of glucose data throughout day and night allows better adjustment of therapy and behaviour, helps to avoid episodes of hypoglycaemia and improves HbA1c and general time in range.[v] These are all factors that are predicted to improve long-term outcomes for people with diabetes by avoiding or delaying the onset of complications[vi].

In high-income countries, CGMs have become the standard of care for Type 1 Diabetes, however for LMICs, access to this technology is still very limited. The main reasons for this are the lack of accessibility due to unaffordable prices, absence of locally registered products, a scarcity of third-party payers willing to cover CGMS, and a lack of awareness among people with diabetes and healthcare providers of how CGM usage can improve diabetes management.

2. OBJECTIVES AND SCOPE OF THE EOI

FIND is working to address this disparity, through a project called "Access to CGMs for Equity in Diabetes Management" or ACCEDE[vii].

We want to work with CGM manufacturers whose devices have been through stringent regulatory approval or who are in the process of obtaining stringent regulatory approval, and who are interested in introducing the devices into Kenya & South Africa within the next 12-18 months, at accessible prices.

Alongside pricing & access interventions, the project builds capacity through dedicated training on the effective use of CGMs for healthcare providers and people living with diabetes.

Through operational research and building of an investment case, the project will also lay the foundations for long-term expanded access to CGMs where health resources are limited but clinical need is significant.

With this Call for Expressions of Interest, FIND is looking to identify CGM manufacturers of products not yet commercialised in Kenya and South Africa, who are interested in introducing their CGM device in Kenya & South Africa in the next 12-18 months with the support from FIND.

3. MARKET POTENTIAL IN KENYA & SOUTH AFRICA FOR CGMs

The global number of people with Type 1 Diabetes is projected to double by 2040, growing from 8.7m today to 17.5m [viii]. To date, in Kenya and South Africa combined, there are 55 000 people living with Type 1 diabetes, according to the T1D Index [ix]. Currently, less than 10% of them use CGMs [x].

In addition, the use of insulin in Type 2 Diabetes is growing and with it the need for intensive monitoring. In Kenya, the Type 2 Diabetes insulinisation rate is projected to be approximately 18%, and in South Africa between 26% - 45% depending on the public and private sector [xi].

Through the ACCEDE project, CGM users in Kenya and South Africa could double by 2025, and trigger regional expansion, **opening up a potential market of 213'000 people with Type 1 Diabetes and 21.5m with Type 2 Diabetes in Eastern and Southern Africa** [8,9]

4. ELIGIBILITY CRITERIA FOR RESPONDING TO THIS EOI

Any manufacturer with a CGM product that meets all of the following requirements is eligible to respond to this EOI:

1. **Stringent regulatory approval (SRA**), preferably FDA approval or CE certification.
2. **O**r in the **process of obtaining SRA** within the next 9 months;
3. The manufacturer has no CGM product within their portfolio that is **commercially available in Kenya or South Africa[xii];**
4. The **CGM is minimally-invasive** (a technology where a sensor is self-inserted into the subcutaneous space with a single insertion and providing glucose concentrations over an extended period). CGMs that are non-invasive or implantable are not eligible;
5. A **genuine interest** by the manufacturer to launch their CGM in Kenya and South Africa in the public and private sector

5. SELECTION PROCESS

The selection of EOIs received will be based on key criteria laid out below (see evaluation matrix Appendix I). Applicants will be evaluated by a review panel consisting of one external reviewer, two external individuals with lived experience with diabetes and two internal reviewers at FIND.

We will select up to three manufacturers.

SELECTION CRITERIA

Product quality	SRA approval/ approval in process; timeline for SRA approval; adjunctive/ non-adjunctive use; age indication and timelines for claim extension, if not available at launch
Configuration, technical & utility specifications	Sensor wear time, calibration requirements, clinical & analytical accuracy, product configuration

6. BENEFITS AND CONDITIONS

Following the selection process, successful manufacturers will be invited to participate in a **market immersion** in South Africa, taking place from the **23rd-28th October 2023*.**

The market immersion will include meetings with healthcare professionals familiar with prescribing CGMs, private health insurers, people living with diabetes using CGMs and other key stakeholders. In addition, registration to attend a local Diabetes Congress is included. Face to face meetings will also include experts from Kenya.

Manufacturer to cover the cost of the flight to OR Tambo International Airport, South Africa and any visa related costs. FIND will cover the costs for accommodation and conference registration and facilitate all stakeholder engagements for up to two representatives from the manufacturer.

7. HOW TO APPLY

Submit applications via the FIND's Submission Webform. A template for the EOI Data Input Form can be downloaded from the submission portal. Please upload your completed EOI Data Input Form, along with any supporting documents by **28 August 2023.**

8. QUESTIONS & FURTHER INFORMATION

Please email questions to: NCDs@finddx.org. Questions will be accepted until 24 August 2023. Please include the title **ACCEDE_EOI** in the subject of the email.

9. TIMELINE SUMMARY

Date	Process step	Location / Contact
17 August 2023	Webinar & overview of the EOI *Interested manufacturers who are unable to attend the webinar, can request a separate teleconference with FIND prior to 24th August*	Zoom
24 August 2023	Deadline to submit questions	NCDs@finddx.org Please mark the email subject as **ACCEDE_EOI**
28 August 2023	Deadline for EOI submission	EOI Data form to be completed and submitted via the online form.
15 September 2023	Notification of selected manufacturers for market immersion	Manufacturer will be notified via individual email correspondence from FIND
23-28 October 2023	Market immersion in South Africa (Gauteng) for selected manufacturers	Gauteng, South Africa

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

CONFIDENTIALITY

FIND considers any application and supporting documents received under the EOI as confidential. FIND will not disclose the proposal to third parties without the prior written agreement of the proposal submitter but will be allowed to share with members of the review panel who have entered in a confidentiality agreement with FIND for these review purposes 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 FIND.

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, decision-makers, 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. For more information, visit www.finddx.org.

REFERENCES

[i] IDF Diabetes Atlas | Tenth Edition
[ii] Type 1 Diabetes Index (t1dindex.org)
[iii] Estimation of global insulin use for type 2 diabetes, 2018–30: a microsimulation analysis - The Lancet Diabetes & Endocrinology
[iv] PPA-57567-barriers-and-facilitators-to-self-monitoring-of-blood-glucos (nih.gov)
[v] Elbalshy M. et al.. Effect of divergent continuous glucose monitoring technologies on glycaemic control in Type 1 Diabetes mellitus: A systematic review and meta-analysis of randomised controlled trials. Diabet Med. 2022 Apr 20:e14854
[vi] Nordwall M. et al. Impact of HbA1c, followed from onset of Type 1 Diabetes, on the development of severe retinopathy and nephropathy: the VISS Study (Vascular Diabetic Complications in Southeast Sweden). Diabetes Care. 2015 Feb;38(2):308-15.
[vii] https://www.finddx.org/publications-and-statements/find-and-the-helmsley-charitable-trust-partner-to-improve-access-to-continuous-glucose-self-monitoring-devices-in-kenya-and-south-africa/
[viii] IDF Diabetes Atlas 10th Edition
[ix] T1 Diabetes Index (T1dindex.org)
[x] Data on file at FIND
[xi] FIND CGM market model
[xii] FIND reserves the right to consider submissions from new CGM manufacturers who have entered these markets very recently for commercial purposes.