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REQUEST FOR PROPOSALS
from manufacturers of

Continuous glucose monitoring devices not commercialized in **Kenya and South Africa**, for **product evaluation and market introduction**

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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 co-convener of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, and a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation. Founded in Geneva, Switzerland, in 2003, we have regional hubs in Kenya, India, South Africa and Viet Nam. With partners across the public and private sectors, we are working to make sure that everyone who needs a test can get one. For more information, visit www.finddx.org.

BACKGROUND

The International Diabetes Federation's Atlas indicates that 537 million people worldwide have diabetes, and the majority are living in low- and middle-income countries (LMICs)[1]. Everybody living with type 1 diabetes (8.7 million people[2]) and 7–15%[3] 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 control their blood glucose levels. Multiple barriers impede regular glucose self-testing, such as the challenges of frequent finger-pricking, technical skill, and cost[4].

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 the day and night allows better adjustment of therapy and behaviour, helps to avoid episodes of hypoglycaemia, and improves HbA1c and general time in range.[5] All factors that are predicted to improve long-term outcomes for people with diabetes by avoiding or delaying the onset of complications[6]. In addition to long-term continuous use of CGMs, these technologies can be used for shorter periods of time to allow people with diabetes and their HCPs to understand the effect of different behaviours on glucose management and aid in therapy adjustment[7].

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 underlying the lack of availability are unaffordable prices, absence of locally-registered products, a scarcity of third-party payers, and a lack of awareness among people with diabetes and healthcare providers of how CGM usage can improve diabetes management.

[1] IDF Diabetes Atlas | Tenth Edition
[2] Type 1 Diabetes Index (t1dindex.org)
[3] Estimation of global insulin use for type 2 diabetes, 2018–30: a microsimulation analysis – *The Lancet* Diabetes & Endocrinology
[4] PPA-57567-barriers-and-facilitators-to-self-monitoring-of-blood-glucos (nih.gov)
[5] 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
[6] 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.
[7] Ziegler R. et al. Intermittent Use of Continuous Glucose Monitoring: Expanding the Clinical Value of CGM. *J Diabetes Sci Technol*. 2021 May;15(3):684-694

OBJECTIVES AND SCOPE

FIND is working to address this disparity, through a project called "Access to CGMs for Equity in Diabetes Management" or ACCEDE. We will work with partners including CGM manufacturers whose devices have been through stringent regulatory approval, and who have the willingness to offer their CGMs at accessible prices in both the public and private sectors in LMICs. Alongside pricing interventions, the project will build capacity through dedicated training on the effective use of CGMs for healthcare providers and people living with diabetes. Finally, by generating the clinical and health economic evidence that stakeholders in Kenya, South Africa, and other LMICs need to build investment cases for the sustainable financing of CGMs, the project will also lay the foundations for long-term expanded access to CGMs where health resources are limited but clinical need is significant.

FIND is looking to partner with CGM manufacturers, not yet commercialised in Kenya and South Africa, who are interested in:

1. Introducing their CGM technology in Kenya and South Africa in the next 6–18 months with the introducing support from FIND;
2. Supporting performance and usability evaluations for their CGM technology in Kenya and South Africa;
3. Providing the product at accessible prices for the public and private sector;
4. Offering a comprehensive package to buyers comprising customer service, technical support, product training, and post-market surveillance.

FIND aims to **enter into long-term agreements with manufacturers** on **market introduction, product pricing and support** in **Kenya and South Africa**, to ensure **consistent and sustainable supply** of the products in these markets.

MARKET POTENTIAL IN KENYA AND 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 [8]. To date, in Kenya and South Africa combined, there are more than 55,000 people living with type 1 diabetes, according to the T1D Index [9]. Currently, less than 10% of them use CGMs [10].

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% in the public and private sector, depending on the sector that the service is delivered [11].

[8] IDF Diabetes Atlas 10th Edition
[9] T1 Diabetes Index (T1dindex.org)
[10] Data on file at FIND
[11] FIND CGM market model

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].

ELIGIBILITY CRITERIA FOR RESPONDING TO THIS RFP

FIND aims to **identify up to two manufacturers** interested in entering into a long-term agreement with FIND to **introduce and supply CGM devices in Kenya and South Africa**. Products will need to meet the following criteria:

1. **Stringent regulatory approval (SRA)**, preferably FDA approval or CE certification. Or in the process of obtaining SRA (within the next 3-6 months);
2. The CGM is **not registered for sale in Kenya or South Africa[12];**
3. The **CGM is 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). CGMs that are non-invasive or implantable are not eligible;
4. **Operating system (OS) compatibility**: minimum Android
5. Commitment **to work with FIND, to register** with the local health authorities and **launch the product in Kenya and/ or South Africa and other potential LMICs**.

All proposals submitted in response to this request for proposal will go through a predefined selection and award process, as explained below and in Appendix II.

[12] FIND reserves the right to consider submissions from new CGM manufacturers who have entered these markets very recently for commercial purposes.

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SELECTION AND AWARD PROCESS

The submission deadline for the proposal has been **extended** to **17 March 2023 at 23:59 CET.** The selection of proposals received in response to this RFP will be based on key selection criteria laid out in Appendix II. Applicants will be evaluated by a review panel consisting of up to four independent external reviewers, comprised of experts with backgrounds in technical R&D, product launch and implementation, people with lived experience of diabetes in LMICs, and two internal reviewers at FIND.

Proposals will be assessed, and partners selected through a systematic process designed to be objective, independent, and transparent to ensure that the most suitable manufacturers are selected, and potential conflicts of interest avoided. The review panel will use information submitted in the application (see Appendix I "Application requirements" below) as well as publicly available information. The review panel may request additional information or clarifications, if needed, in writing.

Applications will be evaluated in stages, as follows:

Stage 0: All applicants' eligibility will be verified and those that are "out of scope" will be excluded. Out of scope applications may include, but are not limited to, products without stringent regulatory authority approval, products that are non-invasive, or are minimally invasive but require a surgical procedure for sensor application, products already registered in Kenya and/or South Africa, product that are not compatible with Android operating system, or if the supplier is not committed to working with FIND to introduce their product in Kenya and/or South Africa at a price that will be acceptable for the private and public sector. Eligible applicants will advance to Stage 1.

Stage 1: This first evaluation will down select a list of applicants to a short list of approximately 3-5 applicants. An internal and external review panel will evaluate applicants using the submitted application materials (see Appendix I). More specifically, applicants will be evaluated on:

- Existing product specifications, scored in the sheet titled "Technical & Utility Assessment" & "Non-technical Assessment" in the Assessment matrix.
- Applicant presentation and supporting documentation, which details specific topics described in the application requirements.

The review panel will then score the applicants alignment to the goals of the RFP (see Appendix II and Appendix III). The applicants total score will then be calculated as a weighted sum of the scores across the assessment criteria. Selected applicants will advance to Stage 2.

Stage 2: Selected applicants will be invited to **participate in a teleconference** with the internal and external review panel. Applicants will be evaluated using:

- Follow-up live presentation (by teleconference): short-listed applicants will be invited to make a follow-up presentation to address a set of questions provided to the applicants in advance.

- Applicant presentation, which details specific topics described in the application requirements.
- Scores from the technical/utility and non-technical assessment (completed in Stage 1).

Thereafter, a shortlist of up to two applicants will be selected for performance and usability evaluation. *Note: applicants not selected will be notified; however, the details regarding non-selection will not be provided for every applicant*.

FIND plans to conduct a **performance and usability study in Kenya and South Africa** with participants who self-monitor their glucose during their diabetes management. The study will use an established and recommended reference test for self-monitoring and include a component of lab-based reference testing in dedicated glucose excursion interventions. The study will be designed and conducted by FIND in consultation with a reputable institution with proven expertise in diabetes technology evaluation. Study data will be made available to manufacturers and the results of the studies will be published in a peer-reviewed journal.

FIND would cover the cost of the evaluation and purchase the products for 50 end-users to implement CGM for a period of up to 14 days. Manufacturers will be requested to provide an additional 10–20% sensor volume free of charge, to mitigate any potential delays that product replacement may have on the study continuation.

Only products that are found to meet expectations with respect to accuracy and usability performance from the evaluation will be **considered for long-term agreements with FIND.**

A decision to enter into contract negotiations for long-term agreements will be made and communicated to applicants **by April 2024**.

Due diligence: due diligence (DD) to verify the applicant submissions and claims will proceed in parallel with contract negotiations. The DD process may include site visits and/or phone/video conferencing, as well as requests for additional information. Should the DD reveal any unresolvable inconsistencies with this RFP and/or donor requirements and restrictions, applicant exclusion at this late stage is still possible. FIND may outsource conduct of DD to an independent third party, following FIND procedures.

HOW TO APPLY

Submit applications via the FIND's **Technology Scouting Submission Webform**. Please select 'NCDs' as the 'Disease Area' and 'RFP: CGM Kenya and South Africa' as the 'Disease Area Subtype' and proceed with the online submission. Template for the assessment matrix can be downloaded from the submission portal. Please upload your completed assessment matrix, PowerPoint presentation, and additional supporting documents as specified in Appendix I by **17 March 2023 23:59 CET**.

Please note: there is a 25 MB per form submission limit.
The assessment matrix template can be downloaded here.

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TIMELINE SUMMARY

Date	Process step	Location / Contact
3 February 2023	Publication of call for proposals	FIND website
10 March 2023	Deadline to submit questions	NCDs@finddx.org
Extension **17 March 2023**	Deadline for proposal submission **Stage 0:** ineligible applicants are excluded	Assessment matrix and PowerPoint presentation uploaded to Technology Scouting Submission Webform. *Additional supporting documentation and links to videos/ training materials can be sent to NCDs@finddx.org if they exceed the 25MB form limit.
14 April 2023	**Stage 1:** end of proposal evaluation period	Any additional information or clarifications required by the reviewers will be sent to the respective applicant in writing prior to this date.
19 April 2023	**Stage 2:** notification of manufacturers of invitation to participate in a teleconference with internal and external review panel	Via individual email correspondence. Preparation requirements for live meetings will be communicated in advance.
26 April – 2 May 2023	**Stage 2:** meetings with manufacturers	Virtual
8 May 2023	**Completion of Stage 2:** notifications of selected manufacturer/s for performance evaluation and subsequent price negotiations with FIND (only if accuracy and usability performance expectations are met)	Via individual email correspondence

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

QUESTIONS & FURTHER INFORMATION

Please email questions to NCDs@finddx.org. Questions will be accepted and responded to expediently until 13 February 2023. Please include the title **RFP CGM Kenya and South Africa** in the subject of the email.

All submitted questions (and corresponding answers) will be publicly available at:
https://www.finddx.org/about-us/donors-and-partners/calls-for-partners#monitoring

Should you require a meeting with FIND to discuss the RFP in more detail before the submission date, please send an email to NCDs@finddx.org, requesting a meeting. Please include in the subject of the email: **Meeting request RFP CGM**.

CONFIDENTIALITY

FIND considers any application and supporting documents received under the RFP 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.

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Appendix I: application requirements

Proposal submissions shall include the following important information and documentation:

1. Assessment matrix (in Excel) containing the information requested in the **Stage 0/*eligibility check, technical/utility and non-technical considerations worksheets.***

2. A **PowerPoint presentation** that includes the following:
   a) Introduction about the organization, including a brief history, corporate focus/mission, length of time active in diabetes care medical devices and/or diagnostics
   b) Introduction to the product, evolution of the product since launch; application and use of the product, functionality, features, mobile integration, include images and links to videos
   c) Product improvement plan over next 3–5 years, e.g.: expected registration updates (new age category) or non-adjunctive use, or additional product features like alarms, follow features, stability, etc.
   d) Sales volume evolution globally and within LMICs over the last two years (2021−2022)
   e) Sales volume projections for global expansion 2023−2025
   f) Legal entity, corporate governance, and management structure
   g) Biographies of the leadership team and senior management who will be directly responsible for the implementation of the partnership
   h) Any current and past corporate social responsibility activities for diabetes supplies or other diagnostic devices in LMICs
   i) List of any other diabetes-related diagnostics solutions provided by the organization, e.g.: blood glucose meters, HbA1c, etc.
   j) Links to online product demonstration videos
   k) Links to peer-reviewed publications on the product

3. **Additional materials to be provided:**

Please note: these materials are to be sent as attachments to NCDs@finddx.org. The Excel and PowerPoint presentation can be uploaded to the **Technology Scouting Submission Webform**.

- A copy of the instructions for use (IFU) and user/product manual for the proposed product/s
- Proof of stringent regulatory authority approval (*preferred format PDF certificate*)
- List of Android mobile devices & iOS versions that are compatible with the device/application
- Examples of diabetes management reports available on the application and download for the end user and healthcare providers
- Examples of training resources available

Appendix II: assessment criteria

Criterion	Description
Product quality	SRA approval; manufacturer quality management system; product recalls and performance studies; adjunctive/non-adjunctive use
Technical and utility* specifications	Technical and utility requirements, including device configuration, e.g.: sensor wear time, calibration requirements, adjunctive/non-adjunctive use
Product price	Unit pricing for sensors and transmitters
Commercialisation strategy & commitment to LMIC expansion	List of LMICs where the product is registered and/or available for sale, commitment to introduce product in Kenya and South Africa
Training and customer support	Educational and training support for healthcare providers and people with diabetes; provision of in-country customer support and technical assistance, product replacement
Company setup	Company strength and experience in the diabetes care business

*Specifications based on the draft target product profile for non-invasive and minimally invasive glucose self-monitoring devices in LMICs, data on file at FIND

Appendix III: evaluation matrix (used by the reviewer panel)

Stage 0: eligibility assessment:

Criterion	Description	Scoring Guideline
Regulatory status	SRA approval has been obtained (list of SRAs is http://www.stoptb.org/assets/documents/gdf/drugsupply/list_of_countries_sra.pdf). Certificate(s) provided. (Q1, Q6 and supporting documentation - SRA certificate)	0 = no evidence of SRA approval 1 = evidence of one or more SRA approvals
Non-invasive or minimally-invasive requiring implantation	The technology is registered as non-invasive or the product is registered as minimally invasive but requires a surgical procedure for implantation of the sensor.	0 = product is non-invasive or minimally invasive and requires a surgical procedure for implantation 1 = product is minimally invasive and doesn't not require implantation
Availability in South Africa and Kenya	The product is not yet registered and available in Kenya and/ South Africa	0 = product is available in Kenya and South Africa 1 = product is not registered and available in Kenya and South Africa
Operating System Compatibility	The product is compatible with Android operating system	0 = the product is only compatible with iOS 1 = the product is compatible with Android and iOS or Android only
Commitment to introduce the product in Kenya & South Africa	Manufacturer has indicated a commitment to introduce the product in Kenya & South Africa, and considering accessible prices	0 = No 1 = Yes

Stage 1: technical and utility:

	Criterion	Description	Scoring Guideline	Weight
Quality	**Regulatory approval**	Stringent regulatory approval has been obtained **(Q1, Q6)**	0 = no evidence of SRA 1= evidence of 1 or more SRA (non-CE or FDA) 2 = evidence of one or more SRA (one of which is CE or FDA)	5
	Age registration	Product is registered to be used in children > 2 years of age **(Q7, Q10, Q11)**	0 = product is registered to be used in adults only 1= product is registered to be used in adults only; but supplier indicated they are in the process of obtaining the registration for children > 2 years 2 = product is registered to be used in children > 2 years of age	4
	Indication (Age)	Product is registered to be used in pregnancy **(Q7, Q13, Q14)**	0 = product is not registered for use in pregnancy, or data is not available or no response received 1= product is not registered for use in pregnancy; but supplier indicated they are in the process of obtaining the registration for pregnancy 2 = product is registered to be used in pregnancy	4
	Indication (Application)	Product is registered for non-adjunctive use **(Q7, Q12)**	0 = product is not registered for non-adjunctive use 1= product is registered for non-adjunctive use	4
	Product recalls	The product has not been subject to a product recall from any SRA **(Q86)**	0 = Product has experienced at least one product recall 1= Product has experienced no product recalls from the information provided	3
	Performance_Analytical accuracy	In the absence of internationally recognised performance standards for CGM accuracy, please review the MARD as provided in the instructions for use. Additional score will be provided for independent publications with MARD values in line with the IFU **(Q37)**	0 = As per the IFU, MARD is > 15% 1= As per the IFU, MARD is between 10-15% 2 = As per the IFU, MARD is between 10-15%, and additional independent publications provided confirm this 3 = As per the IFU, MARD is <10% 4 = As per the IFU, MARD is <10%, and additional independent publications provided confirm this	5
	Interferences	Inferences testing according to CLSI EP07 and EP37; and list of substances with significant interference including in package insert **(Q39, Package insert)**	0 = Testing has not been conducted according to the standards or no evidence provided 1= Testing has been conducted according to the standard 2 = Testing has been conducted according to the standard and declaration to the user of substances in product materials	4
	Independent, real world data, published	Product has published, independently evaluated performance data **(Q 81)**	0 = No evidence of independently evaluated performance 1= Limited evidence (a single publication) and / Evidence available but performance not satisfactory 2 = Evidence of independently evaluated performance, showing adequate performance	2

	Criterion	Description	Scoring Guideline	Weight
Technical_General	**Sensor wear time**	The duration of time the sensor is suitable and indicated for use **(Q 22)**	0 = less than or equal to 10 days 1= between 10 -14 days 2 = longer than 14 days	4
	Sensor warm up time	The amount of time it takes to obtain a glucose value when starting a new sensor **(Q 23)**	0 = takes > 1 hour 1= takes less than 1 hour but longer than 30 min 2 = it takes 30 minutes 3= less than 30 minutes	3
	Calibration requirement	Requirement for calibration **(Q 34, Q 35)**	0 = calibration is needed once or more everyday 1= calibration is limited to the warm up period or max 24 hours 2 = the product is factory calibrated, no user calibration needed	5
	Transmitter lifetime	How long the transmitter is suitable for use, until it needs to be replaced **(Q16, Q17, Q18)**	0 = transmitter is replaceable with a frequency of < 1 year 1= rechargeable transmitter, warranty > one year 2 = transmitter is integrated with the sensor	4
	Transmitter battery requirements	Power source for the transmitter **(Q19, Q20, Q 21)**	0 = transmitter has integrated single-use batteries 1= transmitter uses a rechargeable battery, battery life < 7 days 2 = transmitter uses a rechargeable battery, battery life > 7 days 3 = transmitter is integrated with the sensor, and does not require an additional power source	4
	Ingress Protection	Protection against insertion and immersion of the sensor/transmitter in water **(Q 51)**	0 = sensor/transmitter is not suitable for insertion in water 1= sensor/transmitter is protected up to a depth of 1 meter for 30 minutes or less 2 = sensor/ transmitter is protected up to a depth of > 1 meter and for > 30 minutes	3
	Measurement range	Quantifiable range: 2.2 to >= 33.3 mmol/L (<=40 to >=600 mg/dL) **(Q31)**	0 = neither meets upper nor lower limit of measurement range 1= meets or exceed either the upper or lower limit of measurement range 2 = meets or exceed both the upper and lower limit of measurement range	2

	Criterion	Description	Scoring Guideline	Weight
Technical_ Operating Conditions	**Sensor Operating conditions – temperature**	Temperature range 5 – 45 degrees celsius **(Q49)**	0 = neither meets upper nor lower limit of measurement range 1= meets or exceed either the upper or lower limit of measurement range 2 = meets or exceed both the upper and lower limit of measurement range	4
	Sensor Operating conditions – humidity	Humidity range 10–70% relative humidity **(Q50)**	0 = neither meets upper nor lower limit of measurement range 1= meets or exceed either the upper or lower limit of measurement range 2 = meets or exceed both the upper and lower limit of measurement range	3
	Transmitter Operating conditions – temperature	Temperature range 5 – 45 degrees celsius **(Q52)**	0 = neither meets upper nor lower limit of measurement range 1= meets or exceed either the upper or lower limit of measurement range 2 = meets or exceed both the upper and lower limit of measurement range	4
	Transmitter Operating conditions – humidity	Humidity range 10–70% relative humidity **(Q53)**	0 = neither meets upper nor lower limit of measurement range 1= meets or exceed either the upper or lower limit of measurement range 2 = meets or exceed both the upper and lower limit of measurement range	3

	Criterion	Description	Scoring Guideline	Weight
	Sensor application	assistance of a third party) **(Q63)**	1= sensor can be inserted autonomously	2
Utility	**Component configuration**	Is the sensor and transmitter integrated **(Q15, Q16)**	0 = Sensor and transmitter are separate components 1= Transmitter and sensor are a single component	4
	Alarms and alerts	Are there a braod range of alarms, that can be customisable and also displayed in different ways (audio, vibrate, visual) **(Q 65,Q66,Q67,Q68)**	0 = Limited alarms, limited customisation 1= Range of alerts and alarms, customisable, limited form (audio only) 2 = Extensive range of alerts and alarms, customisable, available in various forms (audio, vibrate and visual)	3
	Follow feature	The product supports a follw feature, allowing family members etc, to remotely follow/ access the glucose profile realtime. **(Q 69)**	0 = Follow feature is not available 1= Follow feature is part of the future product development plan 2 = Follow feature is incorporated within the product, activated with consent by the user	3
	Data display	Where are the glucose results displayed for the end user **(Q15, Q29)**	0 = A compatible smartphone is needed to obtain the result OR the product is indicated for professional use only 1= A device reader/ standalone is a component of the prdocut 2 = A device reader and a compatible smartphone are devices compatible to obtain the glucose result	4
	Sensor Size	Considering the sensor length and breadth **(Q 41)**	0 = Sensor is >50mm in diameter and > 5mm in thickness 1= Sensor is < 50mm but > 35mm in diameter and >5 mm in thickness 2 = Sensor is < 35 mm in diametes and <5mm in thickness	3
	Sensor site application	The sensor is registered to be applied to different sites **(Q40)**	0 = Sensor is registered to be applied to one site only (eg: upper arm) 1= Sensor is registered to be applied to > one site eg: upper arm, abdomen	4
	Real-time or Instermiitently scanned	The process to obtain glucose results on the device reader/ smart phone **(Q9, Q72)**	0 = Product requires an intervention eg: swipe of the reader to obtain a result 1= Glucose readings are automatically transferred to the reading device using blue-tooth	2
	Sensor discretion	Colour of the sensor and over patches **(Q47,Q48)**	0 = sensor colour is black or white 1= sensor colour is black/white but also supplied with over patches to match/ suit different skin tones	2
	Sensor adhesive sensitivity	Sensor adhesive is hypo allergenic. **(Q44, Q45)**	0 = Sensor adhesive is not hypoallergenic 1= Sensor adhesive is hypoallergenic	5

Stage 1: non-technical:

	Criterion	Description	Scoring Guideline	Weight
Product price	Ex Works price of the sensor	Ex-works price for sensor has potential to lower access pricing barrier in LMICs **(Q93)**	0 = <20% difference to prices currently in the market (ref: SA market) 1 = price is 20-40% lower than currently in the market (ref: SA market) 2 = price is > 40% lower than curently in the market (ref: SA market)	5
	Ex Works price of the transmitter	Ex-works price for transmitter has potential to lower access pricing barrier in LMICs **(Q95)**	0 = <20% difference to prices currently in the market (ref: SA market) 1 = price is 20-40% lower than currently in the market (ref: SA market) 2 = price is > 40% lower than curently in the market (ref: SA market)	5
	Ex Works price of the reader	Ex-works price for the reader has potential to lower access pricing barrier in LMICs **(Q97)**	0 = <20% difference to prices currently in the market (ref: SA market) 1 = price is 20-40% lower than currently in the market (ref: SA market) 2 = price is > 40% lower than curently in the market (ref: SA market)	5

	Criterion	Description	Scoring Guideline	Weight
Commercialisation strategy	Availability in LMICs	The product is available and registered for sale in LMICs **(Q77, Q78, Q79, Q80)**	registration for sale in HIC only 1 = product is available for sale in at least one LMIC 2 = product is available for sale in > 5 LMICs	4
	Duration the product has been available/ commercialised	The duration (in years) of how long the product has been available on the market **(Q 77)**	0 = product available in markets for < 12 months 1 = product available in markets for 1-3 years 2 = product availale in markets for > 3 years	3
	Sensor production capacity	Continuity of supply, based on current production capacity and current and future demand predictions. **(Q82, Q84, Q87)**	0 = current production capacity is limited 1 = current production capacity is adequate to meet demand 2 = current production capacity is adequate to meet increase in demand by 30%	4
	Transmitter production capacity	Continuity of supply, based on current production capacity and current and future demand predictions. **(Q83, Q85, Q87)**	0 = current production capacity is limited 1 = current production capacity is adequate to meet demand 2 = current production capacity is adequate to meet increase in demand by 30%	4
	Product lead time	Time from ordering to release for shipping **(Q89)**	0 = on-demand manufacturing with 60-90 day lead time 1 = on-demand manufacturing with 45 day lead time 2 = global product warehouses with low lead time for orders	2
	Transport conditions	Ease of transport and reduction of transport cost **(Q 61)**	0 = cold chain necessary 1 = cold chain recommended 2 = cold chain not necessary	4
	Expiration date	Long shelf life of the sensor **(Q 59)**	0 = Expiration date <12 months 1 = Expiration date 12 -23 months 2 = Expiration date is > 23 months	4

	Criterion	Description	Scoring Guideline	Weight
Commitment to introduce product in Kenya & South Africa	Commitment to register & introduce the product in Kenya & South Africa	The supplier has agreed to commit to registering & introducing the product in Kenya and South Africa, in collaboration with FIND **(Q5, Q92)**	0= Supplier has not agreed to registering and introducing the product if selected, in Kenya and South Africa 1= Supplier has agreed to registering and introducing the product if selected in either Kenya or South Africa 2 = Supplier has agreed to registering and introducing the product if selected in both Kenya and South Africa	5
Training & Customer Support	Languages - product manual/instructions for use	Instructions for use are available in several languages **(Q64)**	0 = only available in English 1= available in English and French or Spanish 2 = available in English, French/Spanish and other languages	2
	Training and Support	Supplier has a range of training material available, using different channels, and available in different languages **(Q99, Q100)**	0 = Training materials available, limited to analogue, english only 1= Training materials available, analogue and digital channels including videos, limited to english only 2 = Broad range of training materials available, various channels and multiple languages	3
	Product replacement process	in place **(Q91)**	0 = no product replacement process is in place 1= product replacement process is in place	4
	Technical support	Ease of access to product support by customers. The score reflects the option **(Q98)**	0 = technical support available via global call centre but not via a regional or in-country call centre 1= technical support available via regional call centre but not via an in-country call centre 2 = technical support is available via in-country call centre and representatives	4

	Criterion	Description	Scoring Guideline	Weight
Company setup	Company strength	Company product portfolio (Powerpoint presentation)	0 = Start up with limited portfolio 1= Diagnostics company with limited diabetes portfolio OR Diabetes-care only with broad portfolio (including cardiometabolic disorders) 2 = Diagnostics company specialising in innovative technology	2
	Post-market surveillance	place **(Q90)**	0 = no post-market surveillance concept 1= post-market surveillance concept	4
	Quality system	Supplier has a certified quality management system in place **(Q88** and supporting documentation - quality standard certificate)	0 = quality system in place without certification 1= certified quality system in place 2 = ISO 13485 and/or FDA Quality System Regulation certification in place	5