Request for proposals

Accelerating the development of a point-of-care hematology device adapted to low resource settings

BACKGROUND

Hematology tests are included in the WHO and national essential diagnostic lists, as key tools to the healthcare systems in Low- and Middle-Income Country (LMIC) settings.[1,2,3] Currently, however, these tests are generally only available in central laboratories, where high-end instruments capable of high throughput analyses of blood components, such as flow cytometry, can be installed, operated, and serviced. Although smaller point-of-care (POC) hematology analyzers have been commercialized and have the potential to offer quick near-patient screening and guidance on patient management, they are not currently implemented in decentralized healthcare settings (Level 2 and below, included primary healthcare – PHC).

Implementation of such POC hematology devices in level 2 or below could have a major impact in the management of acute febrile illness and other conditions. Total and differential counts of white blood cells (WBC), as well as hemoglobin level measurements, could guide the identification of severe patients for subsequent referral to a hospital, or support diagnosis of bacterial infection to guide antibiotic therapy.[4]

One of the key challenges to implementation of POC hematology analyzers in decentralized settings is the extreme environmental conditions encountered. Currently, products in the market, have not been designed to withstand challenging transport and operating conditions, including high temperatures, dust, lack of continuous power supply, and low equipment maintenance.[5,6] In order to support access to hematology analyzers at first point of contact, FIND is seeking to accelerate the development of devices capable of 3- or 5-differential WBC counts and adapted to low healthcare levels in LMIC settings.

PROPOSED SOLUTIONS AND OBJECTIVES

The objective of this RFP is to accelerate the development of a small, robust, easy-to-use and low-maintenance POC device for 3- or 5-part WBC counting suitable for LMICs markets. Proposals are sought from in vitro diagnostics (IVD) test manufacturers committed to ensuring that the benefits of hematology tools reach not only the richest economies, but also LMICs.

Target characteristics of the hematology analyser adapted for primary care in LMICs are summarized in Table 1. FIND aims at supporting the adaptation of commercial and/or late-stage development devices with high potential and committed to meet Table 1 key product characteristics within 1 year of funding. The expectation is that by December 2022, an IVDR-compatible technical file will be ready for submission to regulatory authorities, with the goal of enabling market introduction across several LMICs from early 2023.

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Diagnosis for all

Table 1: Product requirements

Characteristic	Minimal	Optimal
PLATFORM CONSIDERATIONS		
Readout parameters	3-part differential white blood cells count	5-part differential white blood cells count plus other parameters, including total red blood cells counts, platelets, hematocrit and hemoglobin
Intended settings and intended users	Primary health centers and above healthcare levels. Target users include community health workers with minimal training and any health worker or laboratorian with a similar or superior training level.	
Sample type	Finger prick blood (without the need for a transfer device containing anticoagulant); the device should also work with EDTA venous blood.	
Sampling volume	<40 µl	<10µL
Consumables and reagents	A single reagent provided separately, as part of the kit. The rest of the reagents, if required, shall be embedded in the cartridge/cuvette	No additional reagents required. All reagents integrated in the cartridge/cuvette
Time-to result /test	<10min	<5min
Characteristic	**Minimal**	**Optimal**
PROCEDURAL AND OPERATIONAL CHARACTERISTICS		
Operating conditions	15-**35ºC;** 25-80% relative humidity; altitude up to 1500 m	5-**40ºC;** 25-90% relative humidity; altitude up to 3000 m
Cartridge shelf life and storage conditions	12 months at 4–35°C, 80% humidity, no cold chain required at any point	18–24 months at 4–45°C; 90% humidity, no cold chain required at any point
Transport conditions	Transport stress with fluctuations up to 50°C	
In-use stability (for open cartridge package)	15 min at maximum operating temperature and humidity	1h at maximum operating temperature and humidity

Ruggedness	Resistance to dust, sun light, shocks, etc.	
Power supply	Rechargeable external battery pack capable to run 20-40 tests can be provided.	Battery operated (internal rechargeable or disposable batteries)
Size	Small table-top reader	Handheld
Calibration & QC controls	No calibration required. Device shall be compatible with commercially available controls	No calibration required. Device shall be compatible with control provided by the manufacturer and controls available from other commercial sources
Data storage	Internal data storage	Expandable memory and cloud connectivity
Result display	On screen display + print out option	
Data extraction & Connectivity	Possibility to export data via USB and ideally LAN.	3G/4G/Wi-Fi/Bluetooth
Performance	Performance comparable to gold standard and statistically equivalent according to, CLSI guidelines EP07 or equivalent, throughout the temperature range and humidity range.	
Device failure rate throughout the operational range	<5%	<1%
Price per test (ASP)	<5 USD	<1 USD
Price of instrument (ASP)	<2,000 USD	<500 USD
Manufacturing	ISO 13485:2016 compliant	

The specific activities supported by FIND as part of this initiative will vary according to the needs of each applicant. In-scope activities include:

1. Reader, software, or assay modification development activities to adapt existing products to LMIC markets (i.e., increase operating temperature, reduce instrument cost, adapt the device to be battery operated, etc.)
2. Support field evaluation studies to support regulatory submissions and in-country product registration.

BENEFITS OF WORKING WITH FIND

FIND is an international non-profit organization that enables the development and delivery of much-needed diagnostic tests for poverty-related diseases. FIND acts as a bridge between experts in technology development, policy, and clinical care, reducing barriers to innovation and effective implementation of diagnostic solutions in low- and middle-income countries. FIND fosters global

health product development partnerships, engaging in active collaboration with over 150 partners, including health ministries, bilateral and multilateral organizations, research and academic institutes, commercial partners, private-public partnerships, NGOs and over 80 clinical trial sites. In addition to addressing market entry barriers for diagnostics, FIND supports the appropriate use of diagnostics in many countries through training programmes, quality assurance programmes, and laboratory strengthening work.

FIND intends to catalyse the development of a POC hematology device suitable for LMICs by establishing the right partnerships and providing assistance and resources in areas such as R&D, product validation, regulatory and clinical affairs, manufacturing, quality systems and processes. Through this RFP, FIND will be supporting R&D activities as a first step to implementation of POC hematology devices at low level healthcare settings in LMICs.

Furthermore, this programme can facilitate connections and networking opportunities with a broad ecosystem of partners, working towards support for product introduction, commercialization, and scale-up.

WHO IS INVITED TO RESPOND TO THIS RFP?

This Request for Proposals (RFP) is for **manufacturers** of commercialized and late-stage development **POC hematology devices** (3- or 5- parts WBC differential) interested in receiving financial support for adapting their devices to be suitable and deployed in LMICs.

Support provided:

A budget envelope of ~$1.5 million USD will be available to support 1 or 2 proposals that offer the best value for money. Funding negotiations will be conducted independently for each proposal and will be tailored to the applicant's needs and the specifics of each business case.

TIMELINES

The **deadline to respond to the RFP is 11:59pm CET, 26 July 2021**.

PARTNER 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. Proposals will be assessed by a FIND internal and external panel of expert reviewers.

The evaluation of proposals will be conducted over a 3-week period following the closure of the RFP. Selected applicants will be notified and invited to participate in a teleconference call to present their proposal. Proposals selected for funding negotiations will then engage with FIND, who will follow its own procedures for due diligence, contracting, and monitoring. We anticipate funding awards and contract execution by October 2021. Studies will run for 1 year after contract execution (expected Q4 2021 to Q4 2022) and no longer than December 2022.

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

Applications will be assessed on the product's potential to meet key product requirements (see Table 1) within 1 year (Q4 2022) and the company's ability to serve LMIC demand quickly thereafter. Applicants will be assessed based on the following criteria:

- Fit of the proposed solution to the key product requirements presented in Table 1
- Product development capabilities of the organization
- Manufacturing expertise/capacity
- Strength of team
- Distribution capacity in the target markets (LMICs)
- Quality and regulatory strength
- Technology readiness and time to market
- Clinical evaluation plan (if applicable)
- Projected cost in relation with milestones and realistic timeline to delivery in the 12-month period
- Strong interest in LMICs markets

HOW TO APPLY AND PROPOSAL REQUIREMENTS

Proposals must be submitted via the FIND's Technology Scouting Submission Webform. Please, select 'Hematology' as the 'Disease Area' and 'RFP: POC hematology device' as the 'Disease Area Subtype' and proceed with the online submission. Please also upload a proposal in a PowerPoint format along with any supporting materials.

The PowerPoint proposal should contain no more than 20 slides and include the following information:

Device value proposition

- Value proposition and expected impact:
    - An overview of the WBC 3-diff or 5-differential part solution, including product characteristics and specifications, with a clear side-by-side reference to its alignment with the product requirements described in **Table 1**. Please provide explicit information about the cost per test indicating the shipping terms applied (e.g., ex works, landed costs, retail price) and currency.
- Summary of existing evidence supporting any claims (e.g., product performance, manufacturing, and distribution capacity)
- Timelines, including detailed stage of development, proposed activities, and deliverables
- Estimated funding need and other support requirements
- Vision for introduction and distribution of hematology devices in LMICs

Company experience and track record

- High-level company background (e.g., key products and markets, distribution footprint, vision for LMIC markets)
- Production overview including manufacturing capacity and utilization, expansion plans (if applicable)
- Company / key staff detail on experience relevant to this RFP (e.g., experience with LMIC markets, and stringent regulatory authorities)

- Freedom to operate and existing licensing agreements, and declaration of any relevant interests
- The proposal should demonstrate a long-term intention to sustain business
- Applicants should be open to ongoing monitoring of the programme (e.g., access targets, business sustainability, and quality)

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

QUESTIONS AND FURTHER INFORMATION

Please contact: POC_Hematology_RFP@finddx.org. Questions will be accepted and responded expediently while the RFP remains open.

APPENDIX 1: GOVERNANCE, ELIGIBILITY, AND PARTNER EXPECTATIONS

This RFP will be executed **according to FIND governance, policies, and procedures**. These are summarized below; full details can be found on the FIND website.

Low- and middle-income country access and quality

Applicants are expected to commit to:

- Abiding by the FIND global access policy.
- Submitting a product to WHO prequalification programme and/or stringent regulatory authority, as relevant.
- Establishing and sustaining the highest IVD quality standards, in particular during production scale-up.
- Undertaking activities in LMICs to support market introduction and access (e.g., customization of supporting materials, local registration, sales, and distribution activities).

References:

1. World Health Organization Model List of Essential In Vitro Diagnostics First edition. 2018
2. India National Essential Diagnostics List. 2019
3. World Health Organization. The selection and use of essential in vitro diagnostics. 2021
4. Fernandez-Carballo BL et al. Distinguishing bacterial versus non-bacterial causes of febrile illness –a systematic review of host biomarkers. Journal of infection. 2020
5. Obeidi N et al. Evaluation of the effect of temperature and time of incubation on complete blood count (CBC) tests. African Journal of Biotechnology. 2012
6. Kaur A et al. Effect of temperature fluctuation and transport time on complete blood count parameters. American journal of clinical pathology. 2019