Call for R&D

Evaluation of multimodal vital sign devices for performance and usability in primary health care settings

BACKGROUND

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. Across the organisation 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.

FIND is committed to support and accelerate the development of tools for patients' early severity monitoring and triage in LMIC settings. Measurement and appropriate interpretation of vital signs (e.g. pulse, blood pressure, body temperature, respiratory rate, oxygen saturation) of patients presenting to health care facilities is an important aspect of early severity assessment and patient management. The absence of timely information on vital signs can result in failure to identify deterioration of condition. However, evidence on vital sign measurements on admission and during follow-up are currently lacking in particular at the primary health care (PHC) level in most LMIC settings. An observational study investigating documentation of vital signs by clinicians in over 54,000 admission episodes in 13 hospitals in Kenya showed that in only 57% of cases temperature, pulse, and respiratory rates were recorded, while in 8.4% none of the vital signs were documented[1]. The reasons for vital signs not being measured or incompletely measured are varied but among them are technological barriers, i.e., lack of appropriate individual devices, the lack of training of health care workers, cost of devices, and patient load. Hence multimodal device (measuring more than one vital sign at the same time) suited for LMIC could improve early severity assessments and impact care and outcomes. Furthermore, given the ongoing COVID-19 pandemic, monitoring of vital signs has become critically important for aiding preliminary patient physical assessments. For instance, in COVID-19 patients but also other syndromes, oxygen saturation (SpO2) along with respiratory rate are frequently evaluated to make referral decisions (home care vs hospital care) and decisions on whether a patient needs mechanical ventilation and oxygen supplementation. In addition, blood pressure monitoring may help the assessment of comorbidities. Thus the 'art of decoding vital signs', i.e. the assessment of physiologic characteristics of the patient including monitoring and interpretation of vital signs will not only facilitate screening and triage of severe patients, but also inform the physician's timely decision making on admission and referral care.

PURPOSE OF THE CALL

The purpose of this call is to solicit proposals from technology developers that are working on vital sign monitoring devices and that would like to benefit from access to intended use setting for performance evaluation.

[1] Ogero M, Ayieko P, et al. Journal of Global Health 2018

FIND intends to use the results of this call to update our current selection of multimodal devices for vital signs measurements through a comprehensive landscape review. In addition, and critically, selected products with available prototypes (in line with technology readiness level 6 or above)[2] will be considered for participation in accuracy and usability studies to support developer on the R&D pathway by enabling technical and operational device optimisation to accelerate product development and utilisation.

OBJECTIVES

The objective of this call is to identify multimodal vital sign devices that can be used in LMIC settings. The selected devices will then be evaluated in a field setting using a prospective, observational method comparison study with the following primary objectives:

- To evaluate the accuracy of the multimodal vital sign devices as compared with reference standards to provide feedback to developers
- To assess perspectives of front-line health care workers and caregivers regarding the potential usability and acceptability of devices to provide pragmatic feedback to developers on usability in the intended use setting

BENEFITS OF PARTICIPATING IN THIS INITIATIVE

- Increased visibility by being a part of FIND's Dx pipeline tracker (see https://www.finddx.org/dx-pipeline/)
- Benefiting from FIND's technical and global health expertise and relevant network

For those selected for accuracy and usability evaluation studies:

- Participation in FIND-sponsored studies to generate applicable data, with a clear goal to move the development forward
- Access to intended-use settings for short term, accuracy evaluation
- Evaluation by the final end users - trained healthcare workers

Conditions to be considered for the accuracy study in intended-use setting:
Selection will be done based on availability at study start, suitability to site capacity and predicted acceptability to use in the LMIC settings. The basic performance characteristics of the device in development should have already been tested and documented (in line with TRL 6 or above).

HOW TO APPLY

Expression of interest (EOI) and submission template are to be submitted via FIND's Technology Scouting Submission Webform. Please select '**Fever'** as the 'Disease Area' and '**RFP: Evaluation of multimodal vital sign devices**' as the 'Disease Area Subtype' on the form.

TIMELINES

- EOI and submission template (and other supporting documents) are to be submitted via the webform before **11:59 CEST** on **15 March 2022**.

[2] Biomedical DoD Technology Readiness Levels (TRLs): Medical Devices (https://tier7.us/biomedical-dod-trls-medical-devices/)

- Submission review and adjudication of support needs will be performed by FIND staff according to a predefined grading system. FIND staff will contact applicants in case of any questions soon after the submission deadline.
- Solutions identified as potential partners in the accuracy study will be contacted about device importations and specific study questions between April and May 2022.
- FIND will provide partners in the study with the required data at the end of the enrollment.

SELECTION CONDITIONS

For this EOI, applicants who are selected are expected to:

- Commit to FIND Code of Conduct and Ethics
- Sign a materials transfer agreement with FIND

SELECTION PROCESS

The deadline for receipt of submissions is 15 March 2022. A commitment to our timeline is required, where devices will be available for commencement of accuracy study by the beginning of Q3 2022. The selection process is designed to be objective, independent, and transparent to ensure that the most suitable technologies are supported, and potential conflicts of interest are avoided. Candidates will be evaluated by an internal review panel comprised of staff at FIND from the Technology Scouting team, and the Pneumonia and Fever team. The review panels will use information submitted in the application as well as publicly available information. The review panels may request additional information or clarifications, if needed, in writing. Applications will be evaluated in stages, as follows (see Table below):

- **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, device platforms at Technology Readiness Level 1-5 (TRL 1-5). Eligible candidates will advance to Stage 1.
- **Stage 1.** An internal review panel will evaluate all eligible candidates using the submitted application materials. More specifically, candidates will be evaluated on the following criteria:
    - Device use
    - Device design
    - Performance and validation data
    - Regulatory approval
    - Predicted acceptability to use in the LMIC settings.

  The "Assessment matrix" tab in the Device Selection Criteria spreadsheet will be used for scoring. Final candidate devices will be selected in a consensus call of internal reviewers. The project team will communicate to the selected product developers for further information and clarification on multimodal devices.

Stage 0	Stage 1
Initial screening of all applicants	***Evaluation of candidates from eligible applicants***
Verification of applicant eligibility. Applicants that are not eligible will be excluded.	Evaluation of eligible candidates to be performed by internal reviewers. Candidates will be evaluated based on the following criteria (Device Selection Criteria 'score' will be used): • Device use • Device design • Performance and validation data • Regulatory approval • Predicted acceptability to use in the LMIC settings.

CONFIDENTIALITY

All information supplied to the applicant by FIND, including the EOI and all other documents relating to the EOI process, must be treated as confidential, and not disclosed to any third party unless the information is already in the public domain or is required to be disclosed and vice versa. FIND considers any application and supporting documents received under the EOI as confidential. If required, FIND can sign a Confidentiality Disclosure Agreement with interested applicants prior to submission. FIND shall not disclose the submission to third parties without the prior written agreement of the submitter. All members of the review panel shall also be under confidentiality 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 the FIND team.

FOR QUESTIONS, CONTACT:

Please email questions to: rfp_mf@finddx.org
Questions will be accepted and responded to expediently until 10 March 2022.