

Call for Innovation

Accelerating the development of next generation malaria rapid diagnostic tools

BACKGROUND

FIND is a global non-profit organization dedicated to support the development, evaluation, and delivery of high-quality, affordable diagnostic tests for poverty-related diseases. As part of this mission, FIND is committed to support and accelerate the development of new malaria diagnostic tools to bridge the expanding gap left by the increasing spread of *hrp2/3*-deleted *P. falciparum* parasites and the need for improved *P. vivax* detection. Tracking emerging and evolving technologies for malaria diagnosis is an integral piece in addressing these challenges. FIND aims to provide developers of promising innovations with the help they need to move from validated prototype to market access. Access to high quality specimens and study sites is critical at many stages of product development as well as during the subsequent data generation for regulatory approval and WHO prequalification. FIND is dedicated to support all of the stages of product development by providing guidance, expertise, and access to our specimen bank and other reference materials.

PURPOSE OF THE CALL

The purpose of this call for innovation is to solicit proposals from academic institutions and private companies that are working on new malaria diagnostic solutions and that would like to benefit from access to reference materials, specimen bank samples or field access for early feasibility studies.

FIND intend to use the results of this call to update our current understanding of the malaria diagnostic pipeline and to inform its diagnostic pipeline tracker (<https://www.finddx.org/dx-pipeline-status/>). In addition and critically, selected products with available prototypes (in line with technology readiness level 5¹ or above) will be considered for participation in feasibility studies to enable technical and operational assay optimisation to accelerate the development towards design-lock.

OBJECTIVES

The objective of this call is to identify malaria innovations that have the potential to address the technical and operational limitations of current malaria RDTs, particularly in view of:

- the emergence of *P. falciparum* parasites with *hrp2/3* deletions
- the need for improved tools to identify all *Plasmodium* species
- the need for improved surveillance

The aim is to identify advanced technologies (proof-of-concept and prototype available) that can benefit from early access to field sites for short term, targeted feasibility testing (from as early as Q1 2020 up to Q3 2020) with the aim of high quality feasibility and operational data as part of FINDs ongoing trial platform.

BENEFITS OF PARTICIPATING IN THIS INITIATIVE

¹ TRL5, prototype in refinement for human studies

- Increased visibility by being a part of FIND's Dx pipeline tracker (see <https://www.finddx.org/dx-pipeline/>)
- Potential access to investment and collaborations by being included in a comprehensive landscape of malaria diagnosis technologies in development
- Early access to field sites for short term, targeted feasibility testing
- Benefiting from FIND's technical and global health expertise

For those selected for feasibility studies:

- Participation in FIND-sponsored clinical studies conducted in countries with a high burden of *P. falciparum* and/or *P. vivax* to generate applicable feasibility data with a clear goal to move the development forward
- Access to specimens or data collected in a minimally or non-invasive way from febrile patients presenting at health centres
- Testing by health-care workers with minimum training and/or trained laboratory technicians
- Testing in health centres without attached laboratories and/or primary health clinics with basic laboratories

Conditions to be considered for the in-country feasibility study:

Selection for the feasibility study will be done based on availability at study start, suitability to site capacity and predicted acceptability to use in high burden countries. The basic performance characteristics of the diagnostic tools in development should have already been tested and documented with contrived or culture samples (in line with TRL 5 or above).

HOW TO APPLY

Expression of interest (EOI) and submission template are to be submitted via FIND's Technology Scouting Submission Webform (<https://www.finddx.org/technology-review/webform/>). Please select '**Malaria**' as the 'Disease Area' and '**Call for Innovation**' as the 'Disease Area Subtype 2' on the form.

TIMELINES

- EOI and submission template (and other supporting documents) are to be submitted via the Webform before **17:00 CEST on 22 November 2019**.
- 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 participants in the in-country feasibility study will be contacted about test importations and specific study questions between November 2019 and January 2020.
- FIND will provide participants in the study with the required data at the end of the enrollment

GENERAL CONSIDERATIONS

FIND will treat all technical detail in submissions as confidential and use the information only for internal evaluation. Confidentiality agreements will be signed with the teams selected for in-country feasibility study or upon request by submitting parties.

FOR QUESTIONS, CONTACT:

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