

Call for Innovation

Accelerating the development of next generation malaria rapid diagnostic tools- Round 2

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.

According to the World Malaria Report (2021), there was a global increase in malaria cases from 227 million in 2019 to 241 million malaria cases in 2020¹. Whilst gains are being made in the fight against malaria, biological threats like the circulation of *pfhrp2/3* gene deletions make malaria diagnosis with HRP2-based RDTs quite challenging. As a result, the WHO now recommends that where *pfhrp2/3* gene deletions are reported (within countries or in neighbouring countries), representative baseline surveys are to be conducted among suspected cases. If >5% of false negative RDT results are attributed to these deletions, a change in RDT is necessary. However, RDTs not based on HRP2 are limited; moreover, WHO prequalified ones that can detect and distinguish between *Plasmodium falciparum* and *Plasmodium vivax* are non-existent.

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* and *P. knowlesi* detection. In addressing these challenges, it is imperative that emerging and evolving technologies for malaria diagnosis are tracked. FIND aims to support developers of promising innovations 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 innovators at all stages of the product development by providing guidance, expertise, and access to our specimen bank and other reference material.

PURPOSE OF THE CALL

The purpose of this call is to solicit proposals from diagnostic developers that are working on new malaria diagnostic solutions and that would like to benefit from access to intended-use setting for clinical evaluation.

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 5² or above) will be considered for participation in clinical studies to enable technical and operational assay optimisation to accelerate product development.

¹ World Health Organisation. World Malaria Report 2021.
<https://www.who.int/publications/i/item/9789240040496>

² TRL5, prototype in refinement for human studies

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 intended-use settings for short term clinical evaluation (from as early as Q4 2022) with the aim of high-quality feasibility and clinical data as part of FINDs ongoing trial platform. In view of the recommendation by WHO for countries with *pfhrp2/3* gene deletions accounting for >5% false negative to change RDT to alternative RDT options, the focus of this round will be on supporting tests based on non-HRP2 biomarkers.

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/>)
- Inclusion in a comprehensive landscape of malaria diagnosis technologies in development
- Access to specimens collected in a minimally or non-invasive way from febrile patients presenting at health centres
- Benefiting from FIND's technical and global health expertise and relevant network

For those selected for clinical evaluation studies:

- Participation in FIND-sponsored clinical studies conducted in countries with a high burden of *P. falciparum* and/or *P. vivax* to generate applicable clinical data with a clear goal to move the development forward
- Access to intended-use settings for short term, clinical evaluation
- Testing by trained lay providers and trained healthcare and/or trained laboratory technicians
- Testing in health centres without attached laboratories and/or primary health clinics with basic laboratories to explore feasibility of use in the intended use setting

Conditions to be considered for the clinical 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 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](#). Please select '**Malaria**' as the 'Disease Area' and '**Call for Innovation**' 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 24 February 2022**.



- 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 clinical study will be contacted about test importations and specific study questions between March and April 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 24 February 2022. A commitment to our timeline is required, where test will be available for commencement of clinical study by 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 Malaria, Fever and Infectious Diseases 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, HRP2-based tests, test platforms at Technology Readiness Level 1-4 (TRL 1-4). 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 six criteria:
 - Technology readiness level (TRL5 or higher)
 - Intended use case (parasitological confirmation of suspected symptomatic episodes of malaria to guide the management of clinical cases)
 - Availability of prototypes at study start
 - Availability of basic performance data
 - Suitability to site capacity
 - Predicted acceptability to use in high burden countries.

Short listed candidates will be selected in a consensus call of reviewers and will advance to Stage 2.

- **Stage 2.** This second evaluation will narrow down short-listed candidates to a list of finalists. Candidates will be evaluated using:
 - **Live Presentation** (by teleconference): Short-listed candidates will be invited to make a presentation to address a set of questions provided to the candidates in advance.
 - "Alignment Criteria" within the Assessment Matrix will be used. Scores from the Technical Assessment (completed in Stage 1) will also be considered

Stage 0	Stage 1	Stage 2
<i>Initial screening of all applicants</i>	<i>First evaluation to short-list candidates from eligible applicants</i>	<i>Second evaluation to narrow down short-listed candidates to a list of finalists</i>
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 six criteria (Technical Assessment score sheet will be used): <ul style="list-style-type: none"> • Technology readiness level (TRL5 or higher) • Intended use case • Availability of prototypes at study start • Availability of basic performance data • Suitability to site capacity • Predicted acceptability to use in high burden countries. 	Evaluation of short-listed candidates to be based on: <ul style="list-style-type: none"> • Live Presentation (by teleconference) • Scores from the Technical Assessment (completed in Stage 1) The review panel will score the candidate’s overall alignment with the goals of the EOI (“Alignment Criteria” within the Assessment Matrix will be used).

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 RFP 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 20 February 2022.