FIND
Diagnosis for all

Expression of Interest (EOI): Developers of molecular true point-of-care devices with interest in outbreak diseases.

BACKGROUND

FIND is a global non-profit organization dedicated to accelerating the development, evaluation, and delivery of high-quality, affordable diagnostic tests for poverty-related diseases. Since its foundation, FIND has been involved in accelerating the development and implementation of innovative solutions that simplify diagnostic workflows. As part of its strategic priorities for the coming years, FIND aims to accelerate the development, validation and launch of new molecular rapid tests that can address barriers to access and improve case detection at primary healthcare and community levels in low- and middle-income countries (LMICs).

True molecular point-of-care platforms that enable molecular testing at the lowest level healthcare settings, such as primary care, as well as community and at-home testing have been developed and commercialized for COVID-19 testing and represent attractive opportunities for decentralized diagnostics in LMICs. As the COVID-19 diagnostics market declines, there is an opportunity for developers to explore new applications for their technologies in the context of outbreak-prone diseases and to benefit from supportive initiatives from government and global health agencies.

In that context, FIND is building on advances catalysed by the COVID-19 pandemic to expedite the development of molecular true point-of-care tools that can support acute outbreak management, and strengthen in-country capacity for outbreak detection and rapid response for known and emerging pathogens such as:

Family	Diseases / Pathogens	Main sample type	WHO's R&D Blueprint[1]	Primary impacted regions
Paramyxoviridae	Nipah virus disease	Throat swab	Yes	South East Africa, Southeast Asia
Paramyxoviridae	Hendra virus	Throat swab	Yes	Australia
Flaviviridae	Yellow fever	Capillary whole blood	Yes	Africa, central and South America
Flaviviridae	Dengue	Capillary whole blood	Yes	Americas, Southeast Asia and the Western Pacific
Flaviviridae	Zika	Capillary whole blood	Yes	Americas, Southeast Asia and the Western Pacific, Africa
Arenaviridae	Lassa fever	Capillary whole blood	Yes	West Africa
Filoviridae	Ebola virus disease	Capillary whole blood	Yes	Sub-Saharan Africa
Filoviridae	Marburg virus disease	Capillary whole blood	Yes	Sub-Saharan Africa
Bunyaviridae	Rift valley fever	Capillary whole blood	Yes	Sub-Saharan Africa (especially eastern and southern Africa), Arabia
Bunyaviridae	Crimean-Congo hemorrhagic fever (CCHF)	Capillary whole blood	Yes	Eastern and Southern Europe, the Mediterranean, northwestern China, central Asia, Africa, the Middle East, and the Indian subcontinent.
Togaviridae	Chikungunya	Capillary whole blood	Yes	Americas, Africa, Asia and the Indian subcontinent
Trypanosomatidae	Leishmaniasis (visceral or cutaneous)	Capillary whole blood		VL: Brazil, east Africa and India CL: Americas, the Mediterranean basin, the Middle East and central Asia
Trypanosomatidae	Chagas disease	Capillary whole blood		Latin America

[1] Prioritizing diseases for research and development in emergency contexts

SCOPE OF EOI

This expression of interest (EOI) is issued as part of FIND's landscaping activities to map and identify developers of **molecular true point-of-care devices** interested in developing IVD solutions for one or more of the aforementioned diseases / pathogens.

The EOI will provide essential information to inform FIND on future investments and efforts to promote the development of molecular true point-of-care devices that can support acute outbreak management in LMICs. Specifically, through this EOI, we seek to understand potential partners interested in developing such solutions. This EOI may lead to future **funding opportunities for development**, such as targeted Requests for Proposal to the EOI respondents.

DEFINITION

Molecular true point-of-care platforms enable molecular testing at the lowest level of healthcare settings (level 0 or level 1, see appendix 2), such as primary care, as well as community and at-home testing. The main features of these true point-of-care molecular platforms are listed below:

- Handheld or portable (i.e. can be carried, usually below < 5kg)
- Battery operated or battery compatible (i.e. low power consumption that allows operations for a few hours with a portable charger / power bank)
- No laboratory equipment required with all necessary materials and reagents included in the kit
- Operated by lay users or health workers with limited training in laboratory practices
- May include both hub/consumable and fully disposable form factors

ELIGIBILITY CRITERIA OF EOI

The following criteria must be met by the developers/manufacturers to respond to this EOI:

- Type of organisations: Original developer / manufacturer of the molecular true point-of-care devices.
- Diagnostic products and technology: Point-of-care molecular assays to detect nucleic acids (as opposed to immunoassays).
- Stage of development: The molecular device must have passed the feasibility phase and be in development (phase known as "Design, development and transfer to manufacturing") or already commercialized. However, the assay can be at any stage of development, including concept phase.
- Disease of interest: The applicant must have an interest in developing an assay for one or more of the aforementioned diseases / pathogens.
- Use case: Address the screening and/or diagnosis of one or more of the aforementioned diseases / pathogens at or near the site of patient care.
- Use settings: At the community level or in healthcare settings without laboratories with none or minimal infrastructure (no lab equipment, no cold chain, unreliable power supply).
- Ease-of-use: The proposed diagnostic solution and workflow must be designed for lay users or healthcare workers with no or minimal training in laboratory practices. Simple pipetting and sample transfer steps that do not require precise timing or volumes (e.g. no use of micropipettes but instead come with pre-set volume droppers).
- Footprint: The proposed molecular device must be handheld or portable (i.e. can be carried, usually below 5 kg and below 30 cm in all dimensions), ideally battery-operated or compatible with battery operations from a third-party powerbank.
- Self-sustained kit: No laboratory equipment required with all necessary materials and reagents included in the kit.
- Willingness to enter LMIC market.

The following categories of organizations are not in the scope of this EOI:

- Academic teams which lack a development partner or without a clear plan towards commercialization
- Distributors
- Organizations without significant diagnostic R&D and manufacturing in the specified scope (i.e. not point-of-care, not molecular, or without any interest in the aforementioned diseases / pathogens).

BENEFITS FOR DEVELOPERS/MANUFACTURERS

Applicants with technologies relevant in the context of a solution in the scope of this EOI will be contacted to discuss the following potential opportunities:

- Listing in the test directory, providing enhanced visibility: https://www.finddx.org/tools-and-resources/dxconnect/test-directory/
- Recognized as eligible partners for projects related to product development/evaluation in the context of diagnostics in LMICs. This EOI may lead to future funding opportunities for development, such as targeted Requests for Proposal to the EOI respondents.

EOI APPLICATION FORMAT

Applicants shall provide a brief slide deck of no more than 20 slides, either using their corporate deck or the PowerPoint template provided via the submission portal.

HOW TO APPLY

Submit proposals via the FIND technology scouting submission form.

CONFIDENTIALITY

FIND acknowledges that the information received from Applicants under the EOI may be of a confidential nature. FIND shall use the same degree of care with Applicant's confidential information as it uses to protect its own confidential information. If required, FIND can sign a CDA with interested Applicants prior to proposal submission. FIND will communicate the confidential information only to its employees, independent contractors, institutional donors and other financial sponsors, legal, financial, scientific or technical advisors (together "Representatives") who: (a) need to know such confidential information for FIND's internal purposes, and (b) such Representative has previously agreed in writing to be bound by terms and conditions substantially similar to those contained in this EOI, including but not limited to confidentiality and non-use restrictions. Review of proposals will be carried out by an internal FIND team as well as a team of external experts (which may or may not include members of FIND's independent Scientific Advisory Committee), all of whom are under confidentiality and are 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.

APPENDIX 1

Technology Readiness Level	Description	Detail
TRL 1	Basic technology principles	Scientific literature reviews and market surveys; unmet need and potential solutions articulated
TRL 2	Technology concept formulated	Potential applications identified, research plans and protocols developed
TRL 3	Experimental proof-of-concept	Preliminary demonstration of scientific principles using laboratory models and methods
TRL 4	Technology components validated in laboratory	Component validation in laboratory environment *Some laboratory practices (e.g. kit extraction) still used*
TRL 5	Technology validated in operational environment	Component/breadboard validation for target setting (e.g. LMIC, POC) *All components for device are developed and demonstrated*
TRL 6	Technology demonstrated in operational environment	Prototype demonstration: full process but not final integration *Appropriate for in-house alpha testing*
TRL 7	Integrated system demonstration in target setting	Prototype demonstration: fully integrated system *Appropriate for beta-testing; can be sent out for evaluation*
TRL 8	System complete and qualified	Validation studies completed; in process for regulatory approval
TRL 9	Commercial system ready for operation	System can be marketed

APPENDIX 2

Table: Definition of health system infrastructure levels according to Ghani et al. and the Maputo Declaration[2]

Characteristics	Level 0	Level 1	Level 2	Levels 3 and 4
Description	In the community or home	Lowest level of healthcare system with a laboratory	First level of referral healthcare and laboratories	Second and higher levels of referral healthcare and laboratories
Examples of locations	In homes, health fairs, health posts, clinics with no lab, pharmacies	Health centres (Africa), rural health centres (Asia and Latin America)	Hospitals (Africa), urban health clinics (Asia and Latin America), clinical labs in the developed world	Hospitals (Latin America and Asia), national clinical/reference laboratories (Africa), surveillance laboratories, research laboratories
Electricity	Not reliably available	Not reliably available	Available, expected to have refrigeration	Available
Clean water	Not reliably available	Not reliably available	Available	Available
Physical lab infrastructure and lab equipment	No laboratory	Not all facilities have labs. If present, minimal lab (e.g. microscope, centrifuge) or moderate lab (see level 2 description)	Moderately equipped lab (e.g. additional equipment for basic chemistry and manual immunoassays)	Well-equipped laboratories (e.g. automated and advanced equipment)
Personnel	Community healthcare worker, nurse, family member, pharmacist, traditional medicine practitioner	Nurses, sometimes physicians, laboratorians with a range of training	Nurses, physicians, moderate and well-trained laboratorians	Nurses, physicians, well-trained laboratorians

[2] Ghani AC, Burgess DH, Reynolds A, Rousseau C. Expanding the role of diagnostic and prognostic tools for infectious diseases in resource-poor settings. Nature. 2015;528:S50–52. The Maputo Declaration on strengthening of laboratory systems. Geneva: World Health Organization; 2008 (http://www.who.int/diagnostics_laboratory/Maputo-Declaration_2008.pdf, accessed 27 December 2019).