Expression of Interest (EOI): Developers and manufacturers of diagnostic solutions for neonatal sepsis for low- and middle-income countries.

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. Over the past few years, FIND has been involved in accelerating the development and implementation of innovative antimicrobial resistance (AMR) solutions (diagnostic technologies, digital solutions, AMR data) relevant in the context of antimicrobial stewardship. As part of its strategic priorities for the coming years, FIND will leverage funding from GAMRIF (press release: Testing to combat antimicrobial resistance in low-resource settings gets US$10 million boost from extended FIND–GAMRIF partnership - FIND (finddx.org)) to continue its effort towards fighting AMR challenges in low- and middle-income countries (LMICs). Sepsis is a life-threatening medical condition and is a significant cause of morbidity and mortality in neonates (aged 28 days or less) and remains among the leading causes of neonatal death in LMICs. Early and accurate diagnosis or exclusion of neonatal sepsis allowing appropriate management including antibiotic therapy may reduce the burden of neonatal sepsis and protect new and existing antibiotics through antimicrobial stewardship.

This expression of interest (EOI) is issued as part of FIND's landscaping activities to identify developers and manufacturers of diagnostic solutions (diagnostic technologies and digital solutions) for neonatal sepsis that can play a role in improving infant mortality affecting populations in LMICs.

ELIGIBILITY CRITERIA OF EOI

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

- Use case: The diagnostic solution proposed must have a use case for severity assessment or for diagnosis/confirmation/exclusion of sepsis in young infants (age ≤ 59 days), including neonates (age ≤ 28 days) or for guiding referral to a hospital from primary care of young infants at risk of sepsis. Tests with a use case for adult sepsis but using biomarkers validated or in the process of being validated for neonatal sepsis (please refer to the literature[1]) may be considered.
- Stage of development: TRL4 or above, at minima early prototype or breadboard with integration of all critical components and initial analytical data (see Appendix 1)
- Willingness to enter LMIC market under global access terms

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
- Developers or manufacturers of reagents and standard laboratory equipment (e.g. desks, tubes)

[1] Diagnosis of neonatal sepsis: the past, present and future | Pediatric Research (nature.com)

BENEFITS FOR DEVELOPERS/MANUFACTURERS

The following opportunities could be considered for the applicants with technologies relevant in the context of a diagnostic solution in the scope of this EOI:

- In-kind support such as technical guidance, expert consultancy support, sourcing of critical reagents, independent evaluations of prototype assays to inform the development
- Be part of a public directory showcasing their work (e.g. AMR test directory - FIND (finddx.org))
- Recognized as eligible partners for projects related to product development/evaluation in the context of neonatal sepsis

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.

HOW TO APPLY

Submit proposals via the FIND technology scouting submission form.

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