EXPRESSION OF INTEREST (EOI)

Advancing research and development for women's health diagnostics in the Global South: call for collaborators from Africa, South and Southeast Asia

A. ABOUT FIND

FIND accelerates equitable access to reliable diagnosis around the world. We are working to close critical testing gaps that leave people at risk from preventable and treatable illnesses, enable effective disease surveillance, and build sustainable, resilient health systems. In partnership with countries, the World Health Organization (WHO) and other global health agencies, we are driving progress towards global health security and universal health coverage. We are a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation. For more information, please visit www.finddx.org.

B. BACKGROUND

THE GAP IN WOMEN'S HEALTH DIAGNOSTIC R&D GLOBALLY AND IN THE GLOBAL SOUTH

Despite advancements in health research and development (R&D) over recent decades, significant gaps remain in diagnostic solutions that address the specific health needs of women and girls. Historically, women's health diagnostics have been underfunded, with only a small proportion of R&D efforts focusing on accurate diagnosis of diseases and conditions that affect women uniquely, differently or disproportionately, such as reproductive health disorders, maternal health complications, gynaecological cancers, and cardiovascular and respiratory conditions.

This gap is especially pronounced in the Global South, particularly in regions such as Africa, South Asia, and Southeast Asia. These areas face a high burden of disease but often lack the necessary resources, infrastructure, and local research capacity to develop context-appropriate diagnostic innovations tailored to the needs of women and girls living in these areas. Diagnostic tools developed in Western contexts may not always be culturally, economically, or geographically appropriate for use in these regions. Furthermore, many existing and new diagnostic solutions, including biomarkers, have not been validated with diverse populations, limiting their effectiveness and scalability.

Without access to precise, affordable, and accessible diagnostic tools, conditions that disproportionately affect women in low-resource settings often go undetected or misdiagnosed. This results in missed opportunities for early treatment and interventions that could prevent or mitigate serious health outcomes. Without significant investment in diagnostic R&D, millions of women across the Global South will continue to face preventable health challenges that could be addressed through earlier and more accurate diagnosis.

FIND
Diagnosis for all

Opportunities in Women's Health Diagnostic R&D

Despite the gaps described above, there is immense potential for transformative change in women's health diagnostics in the Global South. The Global South is home to a growing number of innovative biotechnology companies, research institutions, and academic centres with the potential to lead groundbreaking research and technology development. R&D investment in these institutions could significantly impact outcomes for women and girls in the Global South in several critical areas:

1) Diagnostic Development for Priority Conditions Affecting Women in the Global South:

- **Testing Solutions for Maternal and Neonatal Health:** Maternal and neonatal health remains a significant concern in the Global South. The use of high-performing fit-for-purpose diagnostics for key conditions that lead to poor maternal and neonatal health outcomes is lagging due to limited availability of and access to gold-standard diagnostics, and reliance on clinical and syndromic management.
- **Research into Understudied Female-Specific Conditions:** Many diseases that disproportionately affect women in the Global South remain understudied and underfunded. For instance, fibroids are more prevalent among women of African descent, yet there is a lack of early detection and non-invasive treatment options. Similarly, abnormal uterine bleeding (AUB) can cause chronic anaemia and significantly impact women's quality of life, but it is often undiagnosed or misdiagnosed due to limited access to affordable diagnostics. Menopause is frequently overlooked in R&D, especially in the Global South, with the symptoms and long-term health effects—including hot flashes, osteoporosis, cardiovascular disease, and mental health issues— being underreported and poorly managed.
- **Diagnostics for Conditions that Affect Women Differently or Disproportionately in the Global South:** Certain conditions affect women differently or at higher rates than men but are not traditionally classified as "women's health" issues. For example, cardiovascular diseases (CVDs)—one of the leading causes of death among women globally—are increasingly prevalent in the Global South. CVDs may manifest with atypical symptoms in women, such as fatigue or shortness of breath, leading to delayed or missed diagnoses. Osteoporosis, which is common among post-menopausal women, remains undiagnosed or untreated in many low-resource settings due to a lack of diagnostic tools and awareness.

2) Diagnostic Solutions Adapted to Low-Resource Settings:

- **Portable, Affordable, and Point-of-Care Diagnostics:** Women in resource-limited, underserved areas or humanitarian settings often lack access to essential diagnostic services due to the absence of laboratory facilities and the prohibitive costs of available technologies. Portable devices—such as point-of-care ultrasound (POCUS) technologies, rapid diagnostic kits, and other point-of-care technologies—can be deployed in low-resource settings, allowing healthcare providers to deliver diagnostic services to women without relying on traditional infrastructure. Developing scalable, affordable point-of-care diagnostic technologies is essential for improving health outcomes for women across the Global South.

The Need for a Collaborative Network in the Global South

To fully harness the potential of the Global South in advancing R&D for women's health diagnostics, there is a need to proactively identify R&D partners and build a collaborative network of stakeholders across Africa, South Asia, and Southeast Asia. Establishing a comprehensive database of biotechnology companies, academic institutions, and research entities focused on women's health diagnostics will help foster partnerships, accelerate innovation and bring visibility to ongoing R&D efforts in the Global South.

By creating a network of collaborators, stakeholders can pool resources, share data, and leverage expertise while avoiding duplication of efforts. This network would promote interdisciplinary research, drive the development of context-specific solutions, and ensure that diagnostic innovations are scalable and accessible to women across diverse regions. Furthermore, a robust collaborative network can attract global investment, influence health policy changes, and raise the profile of R&D for women's health diagnostics in the Global South on international agendas. Building a collaborative R&D network in the Global South is critical to closing the diagnostic gap in women's health. Such efforts will help to ensure that women and girls across these regions can access the high-quality diagnostic services they need, improving their health and well-being.

In response to the need for cross-sectoral partnerships highlighted in the *Women's Health Innovation Opportunity Map*, developed by the National Institutes of Health (NIH) and the Bill & Melinda Gates Foundation (BMGF), FIND is initiating a mapping exercise of stakeholders currently working in R&D for women's health diagnostics in the Global South

C. SCOPE OF EOI

The primary objective of this EOI is to map and identify stakeholders currently working in R&D of diagnostic solutions for women's health in Africa, South Asia, and Southeast Asia.

ELIGIBILITY CRITERIA FOR EOI

The following criteria must be met to qualify for this EOI:

- **Type of organization:** Manufacturers, biotechnology companies, academic institutions and developers working on diagnostic R&D, at any stage from discovery to market entry, for conditions that affect women and girls uniquely, differently or disproportionately across the life span, from puberty into post-menopause.
- **Geographical focus:** Organizations located in Africa (any of the 54 countries), South Asia (Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan, or Sri Lanka), and Southeast Asia (Indonesia, Vietnam, Laos, Brunei, Thailand, Myanmar, the Philippines, Cambodia, Singapore, or Malaysia). Organizations located outside of these countries but with significant diagnostic R&D activities in these countries, preferably working with an in-country stakeholder with equal partnership, are welcome to apply.
- **Language of submission:** We will accept submissions in English or French. Due to limited capacity, we cannot evaluate submissions in any other language. Please note that the assessment will focus on the clarity of content rather than the ability to write.

- **Diagnostic products:** This EOI primarily focuses on *in vitro* diagnostic devices (IVDs), imaging solutions, and non-invasive diagnostic devices that can be deployed in low-resource settings and at lower levels of care (L0–L1). This includes artificial intelligence (AI)- enhanced IVDs, imaging solutions, and non-invasive diagnostic devices.

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

- Organizations located outside or without significant diagnostic R&D in the specified regions.
- Organizations working on mobile health solutions or applications.
- Distributors.

BENEFITS FOR APPLICANTS

Organizations meeting the requirements of the EOI will be contacted to discuss the following potential opportunities:

- Participation in a collaborative network that fosters partnerships, accelerates innovation and enhances the development and accessibility of diagnostic tools tailored to women's health needs in the Global South.
- Match-making with organizations across different regions to accelerate product development.
- In-kind support such as technical guidance, expert consultancy, access to biospecimens, and independent evaluations of prototype assays to inform product development.
- Listing in a women's health diagnostic R&D organization directory, providing enhanced visibility.
- Recognition as an eligible partner for FIND projects related to product development/evaluation of diagnostics for women's health.

EOI APPLICATION FORMAT

The EOI should include the following information, submitted in Microsoft Word or PDF, using the following format:

1. **Organization Information (0.5 pages)**

- Name of Organization: Provide the full name of the biotech company, academic institution, or research entity, along with the organizational website.
- Registration and Country of Operation: Provide details of the country/countries where the organization is registered and operates.

- Status in Country: Specify whether the organization is a private company, public research institute, university, or non-profit organization. Indicate any relevant government approvals or accreditations.
- Organisation size: Specify the number of current employees
- Organisation QMS: If you have any quality management system in place, please specify.
- Achievements: Top-5 milestones in the last 5 years about IVD products

- Contact Details: Include primary contact person, email, and phone number for follow-up communication.

2. Women's Health Diagnostics R&D Focus Areas (0.5 pages)

- Provide an overview of the specific women's health diagnostics on which the organization is currently focused. Previous R&D work can be included if the organization still intends to advance it along the product development pipeline.
- Specify the diseases or conditions the R&D is targeting.
- Specify the target age groups.

3. Type of Diagnostic Product (1.5 pages)

- Product Description: Briefly describe the diagnostic product being developed. Indicate whether it is an imaging solution, a non-invasive diagnostic device, or an IVD.
- Intended Use Case: Briefly outline the intended use cases.
- Biomarker Focus: Specify the biomarkers being studied or developed for diagnostic purposes.
- Technology Platform: Include any relevant technology platforms used.
- Level of Health Care: Indicate the level of health care at which the diagnostic product would be deployed.

4. Stage of Product Development (1 page)

- R&D Stage: Indicate the current stage of development for the diagnostic product using one of the following categories:
    - Discovery (e.g., biomarker identification or early-stage R&D).
    - Preclinical development.
    - Clinical trials (specify phase if applicable).
    - Regulatory approval and market entry.
    - Post-market introduction and scaling.
- Planned Milestones: Briefly outline the next steps or key milestones in the development or commercialization process.

5. Collaborative Interests (0.5 pages)

- Potential Areas for Collaboration: Describe areas where the organization seeks collaboration (e.g., co-development, clinical trials, regulatory support, market entry).
- Existing Partnerships: List any current collaborations with other organizations, academic institutions, or government entities in the Global South or internationally.

6. Climate Impact (0.5 pages)

- Environmental harm: Specify current or planned efforts to minimise the negative impact on the environment caused by the organization's R&D activities.

- Sustainable practices: Briefly describe plans to adopt practices that will support the needs of communities most affected by climate change.

7. Supporting Documentation (Optional)

- Provide any additional documents supporting the EOI submission, such as any PowerPoint presentations, white papers, or research publications relevant to the diagnostic R&D being described, in a zipped folder.

How to apply

Submit applications via the FIND EOI Submission form. Please ensure that you are applying for the EOI titled **Advancing Research and Development for Women's Health Diagnostics in the Global South: Call for Collaborators from Africa, South and Southeast Asia** and proceed with the online submission. Please upload your completed application, along with any supporting documents by **20th December 2024 by 11:59 pm CEST**. An incomplete dossier will not be considered for review.

Evaluation Process:

The submission will be evaluated based on the following criteria (not limited to):

- Relevance to Women's Health Diagnostics: Does the organization's R&D address critical women's health issues in the Global South?
- Innovation and R&D Focus: How innovative are the diagnostic products, biomarkers, or technologies being developed?
- Stage of Product Development: At what stage is the diagnostic product (discovery, clinical trials, etc.)? Is there a clear development pathway?
- Geographic Focus and Impact: Is the organization based in or focused on Africa, South Asia, or Southeast Asia, and can their diagnostic solutions have a significant impact in these regions?
- Feasibility and Scalability: Can the diagnostic solutions be scaled for low-resource settings?
- Climate Impact: Are the organization's products and supply chains climate-smart? Do they minimize environmental harm, increase resilience to climate change, and address the needs of communities most affected by climate change?
- Collaborative Potential: Does the organization demonstrate interest and potential for collaboration in R&D efforts?

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 Confidential Disclosure Agreement (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) have 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 and may include 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 questions concerning confidentiality should be addressed to the FIND team through **womenhealth-rfp@finddx.org**.

QUESTIONS & FURTHER INFORMATION

Please email questions to **womenhealth-rfp@finddx.org. Questions will be accepted and responded to expediently up to and including 1st December 2024.** Submitted questions (and corresponding answers) and any changes to the EOI, including changes in the timeline, will be publicly available at https://www.finddx.org/womenshealth/FAQ.

TIMELINES:

	Activity	Expected date
1	Publication of EOI	20th October 2024
2	Closing for submission of written queries	1st December 2024
3	Closing of EOI	20th December 2024
4	Initial screening	15th January 2025
5	Detailed evaluation completion	28th February 2025
6	Shortlist notifications and follow-up	5th March 2025
7	Engagement with identified organizations and next steps	25th March 2025

LIST OF ACRONYMS AND DEFINITIONS

Term	Definition
Biomarker	A defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes or responses to an exposure or intervention. For examples, please refer to the FDA-NIH biomarker working group.
Diagnostic Value Chain	The stages involved in the development, validation, regulation, and deployment of diagnostic products, from biomarker discovery to clinical trials, regulatory approval, market entry, and access in healthcare settings.
In Vitro Devices	A medical device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.
Levels of Care	L0 – Community Care (Non-facility-based). L1 – Primary Care (First-level facility-based care). L2 – Secondary Care (District hospital-level care or district hospital laboratory). L3 – Tertiary Care (Provincial or regional hospital-level care or reference laboratory).
Non-Invasive Diagnostic Tools	Diagnostic methods that do not require skin penetration or insertion into the body, such as ultrasound, imaging, and certain biomarker tests.
Point of Care	Refers to healthcare services or diagnostic tests provided at or near the site of patient care, allowing for immediate decision-making and treatment.
Point-of-Care Diagnostics	Diagnostic tools and technologies that can be used at the site of patient care, without complex laboratory equipment.
Point of Care Imaging Solutions	Diagnostic tools and technologies that use imaging techniques (such as ultrasound and X-rays) and can be deployed at lower-level facilities or at the site of care with limited health worker capacity and equipment.

REFERENCES

1. Global Health 50/50. (2021). Gender Equality: Flying Blind in a Time of Crisis. Available at https://globalhealth5050.org/wp-content/uploads/Global-Health-5050-2021-Report.pdf

2. Guttmacher Institute. (2019). Adding It Up: Investing in Sexual and Reproductive Health. Available at https://www.guttmacher.org/report/adding-it-up-investing-in-sexual-reproductive-health-2019

3. WHO. (2021). Global Strategy for Women's, Children's, and Adolescents' Health. Available at https://platform.who.int/data/maternal-newborn-child-adolescent-ageing/global-strategy-data

4. National Institutes of Health & Bill & Melinda Gates Foundation. (2023). Women's Health Innovation Opportunity Map. Available at https://cambercollective.com/2023/10/11/opportunity-map/

5. Lancet Commission on Women and Health. (2015). Women and Health: The Key for Sustainable Development. Available at https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)60497-4/abstract

6. Lancet Editorial (2023). A Broader Vision for Women's Health. Available at https://doi.org/10.1016/S0140-6736(23)01570-2
7. WHO. (2019). Global Health Estimates: Disease Burden by Country. Available at https://www.who.int/data/global-health-estimates