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Request for Proposals

Product Development Award

Targeted Call-STI

RiGHT
국제보건기술연구기금

Request for Proposals: PDA, Targeted Call

Point-of-care diagnostic tests for sexually transmitted infections

Executive Summary

This year's Product Development Award (PDA): Targeted Call seeks proposals that will **accelerate development of and access to point-of-care diagnostic tests for high priority sexually transmitted infections (STIs)**: **gonorrhoea, chlamydia, trichomoniasis and syphilis**.

The global response to STIs has stagnated in past decades and urgently needs a strategic refresh. This involves restating priorities in the context of a rapidly evolving global health environment, leveraging novel technology, and securing political commitment and funding to ensure sustained and equitable access to public health goods.

Effective programs to combat STIs rely on accurate diagnostics and validated screening strategies. Point-of-care (POC) tests enable improved clinical management of patients, reduced use of antimicrobials, and identification of asymptomatic infections. As a result, POC tests will lower the costs for both health service users and providers. This RfP engages product development teams advancing products from the stage of pre-clinical validation through regulatory approval.

By the end of the PDA, grantees are expected to have achieved a series of specific and measurable milestones toward WHO Prequalification (PQ) or national regulatory approval in low- and middle-income countries (LMICs). The ultimate goal of this award is to develop and make available POC tests against the target STIs that are accurate, easy to use, and provide rapid results and secure channels for public procurement and equitable access at the national and/or regional level in the Global South in alignment with the local governments' priorities.

Collaboration with LMIC partners within grants is highly encouraged. Applicants will be required to articulate a plan to engage local stakeholders early and to reflect the needs and priorities of LMICs. Successful projects may be extended through a Bridging Award, whereby subsequent development stages towards licensure and WHO PQ can be funded.

Applications will be accepted until **10:00AM KST** on **27 May 2024**.

The RIGHT Foundation evaluates proposals in the context of global public health needs, potential impact, and RIGHT Foundation's investment priorities. The RIGHT Foundation reserves the right to

consider or decline proposals at its sole discretion throughout the proposal evaluation process. This RfP is released in coordination with FIND, and applicants responding to the scope of both RIGHT Foundation and FIND will be eligible for co-funding (Refer to Section 6).

1. Introduction

The RIGHT Foundation is a Korean non-profit organization supported by the Korean Ministry of Health and Welfare, Korean life science companies, and the Bill & Melinda Gates Foundation. RIGHT Foundation aims to alleviate the burden of infectious diseases that disproportionately affect the people in low and middle-income countries.

Four curable STIs, gonorrhoea (Neisseria gonorrhoeae), chlamydia (Chlamydia trachomatis), trichomoniasis (Trichomonas vaginalis), and syphilis (Treponema pallidum), still cause 374 million new cases per year globally.[1] The risk is disproportionately concentrated in LMICs and is compounded by limited access to screening, diagnostics, and treatment. [2] STIs, a majority of which are asymptomatic, impact sexual and reproductive health through stigmatization, infertility, cancers, and pregnancy complications. [3,4] Infection can also significantly increase the risk of HIV.[5]

Diagnostics for STIs are critically important for global health, especially in LMICs, where healthcare resources are often limited. Early and accurate diagnosis of STIs can prevent serious health complications, such as infertility, transmission to newborns, and increased susceptibility to other infections like HIV.[6] POC diagnostics, which provide rapid results at the site of patient care, have the potential to revolutionize the management of STIs in LMICs. These technologies allow for immediate diagnosis and treatment decisions, greatly reducing the delay associated with traditional lab-based tests. By enabling faster and more accurate diagnoses, POC diagnostics can improve health outcomes, reduce transmission rates, and alleviate the burden of STIs on individuals and healthcare systems in resource-constrained settings.[6] This impact is crucial for enhancing public health and advancing toward the goal of universal health coverage.

This RfP is guided by the WHO's Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022-2030, and outcomes of this targeted award directly contribute to achieving Sustainable Development Goals 3.7 and 3.8, which focus on universal access to sexual and reproductive healthcare and universal health coverage.

2. Objective

Our main objective is to **support the development and validation of diagnostic tests that detect at least one of gonorrhoea, chlamydia, trichomoniasis, or syphilis, and which are to be implemented at POC or near POC**. These products should be embedded within a development program that prioritizes public procurement channels, and manufacturing and commercial strategies must clearly

align with a commitment to Global Access. Products that seek WHO PQ will be prioritized.

3. Funding Scope

This RfP focuses on **advancing the development of point-of-care diagnostics for sexually transmitted infections and accelerating the availability of these tests for global health use.** Both molecular and lateral flow tests will be considered for funding. Multiplex platforms designed for near-POC use will also be considered.

Projects funded through this RfP should develop at least one of the following:

- Molecular or non-molecular point-of-care test for gonorrhoea
- Molecular or non-molecular point-of-care test for chlamydia
- Molecular or non-molecular point-of-care test for trichomoniasis
- Molecular or non-molecular point-of-care test for syphilis

Diagnostic tests should be designed in alignment with the technical specifications published in Point-of-care tests for sexually transmitted infections: Target Product Profile (2023).

We will not consider funding:

- Discovery-phase proposals to identify pre-clinical candidates
- Basic research studies to improve understanding of pathogens, infections or disease
- Proposals without any data to support the proof of principle
- Proposals for setting up research facilities or capital equipment
- Duplicate technologies without a substantive advantage over the current best practice
- Concepts without a clear hypothesis or rationale for improved efficacy, potency, safety and/or ease of use over the current tools in clinical use or tools currently in development
- Proposals with a target use-case that fails to reflect the gaps, needs and the end-users' perspectives in LMICs
- Development of products with characteristics that will pose a barrier to equitable access to the populations in LMICs

4. Eligibility Criteria

Partnership requirement

The applicant team must include *at least one Korean entity* with R&D expertise to make a significant contribution to the project (eligible entities listed below). LMIC representation within the applicant team, when appropriate, is highly encouraged.

Eligible entities for Korean or international partners
• For-profit companies engaged in life sciences or healthcare • Non-profit research organizations and foundations • Government research institutions • Academic institutions • Public health laboratories

Commitment to Global Access

As a funding condition, we require *all grantees and their collaborators* to agree to the RIGHT Foundation Global Access Policy, and to articulate a clear path to achieving global access.

Our Global Access Policy represents the core principle of the RIGHT Foundation to achieve our mission of improving health and health equity. "Global Access" means (i) all information and knowledge gained from grants, projects or other investments funded by the RIGHT Foundation should be promptly and broadly disseminated; and (ii) products, data and other innovations resulting from the funded work should be made accessible to LMICs in terms of price, quantity, quality, and timeframe to ensure equitable access by those in need regardless of their resource constraints.

5. Award Description

	Description
Award amount	• Up to 4,000,000,000 Korean Won (KRW)
Funding available	• Up to 5 projects totalling 20,000,000,000 KRW
Co-funding requirement	• Applicants consisting of at least one for-profit entity must commit to co-funding of at least 50% of total project costs. • Applicants consisting of non-profit entities, (e.g. academic institutions, governmental institutions, non-profit organizations, etc) are exempt from co-funding requirements
Project duration	• Up to 36 months
Target diseases	• Gonorrhoea • Chlamydia • Trichomoniasis • Syphilis
Development stage	• From or near the initiation of the clinical validation phase to regulatory approval and WHO PQ

6. Co-funding opportunity

This RfP is released in coordination with FIND, an international non-profit organization focused on the development and delivery of priority diagnostic tests for poverty-related diseases. Applicants with proposals that meet FIND's RfP criteria are encouraged to apply to both RIGHT and FIND for co-funding. The benefits of co-funding include increased project funding and access to FIND's expertise in technical development, policy, and clinical care.

Co-funding eligibility:

- Proposals meet RIGHT Foundation RfP eligibility criteria (Refer to Section 4)
- Proposals meet FIND RfP eligibility criteria
- Proposals comply with the review procedures for both RIGHT Foundation and FIND

Terms and conditions:

- All proposals will be reviewed by RIGHT Foundation and FIND independently, and the selection status of one funder does not impact eligibility for funding by the other.
- Proposals may be selected for funding by RIGHT Foundation, FIND, or by both funders.
- Successful applicants will be awarded funding for two-thirds of total project costs (i.e. one-third contributions from each of RIGHT Foundation, FIND, and grantee) or up to the maximum award amount of each funder, respectively.
- FIND offers both funding and in-kind support to grantees. Applicants may elect to propose a technical partnership with FIND. FIND technical support responsibilities include, but are not limited to:
    - Technical guidance and expert consultancy support for product development
    - Field evaluation activities (study site selection, protocol development, study management, data collection, etc.)
- Co-funded projects must adhere to the project reporting requirements of both RIGHT Foundation and FIND, respectively.

7. Application Guidelines

- Completed Intent to Apply (ITA) must be submitted in PDF format to our Grant Management System
- Submission deadline is **10:00AM KST on 27 May 2024**
- Eligible candidates will receive invitations to submit a Full Proposal

8. Evaluation Criteria

Category	Criteria

Responsiveness to public health needs	• Alignment with global health priorities, unmet health needs in low- and middle-income countries, WHO-recommended target product profile or preferred product characteristics, where available • Value-add over the current best practice
Strengths of proposal	• Scientific quality/merit (e.g., strength of evidence for the proposed work and analysis plan for QC/QA, potential impact on global public health, feasibility) • Probability of technical and regulatory success • Compliance with WHO TPP technical specifications • Suitability for local manufacturing in resource-limited settings across diverse regions • Suitability for scalability
Paths to potential impact	• Implementation plan to achieve equitable access within public health systems in LMICs via regulatory approval, WHO PQ, registration in LMICs • Commitment and capabilities to implement the Global Access Policy
Team-level capability	• Capabilities of the Principal Investigator (e.g., proven track-record of success in the related domain, relevant expertise) • Strength of the project team • Quality of the collaboration among the team members
Alignment with RIGHT Foundation strategy	• Alignment with the RIGHT Foundation's strategic priorities and approach • Strategic value in the context of the RIGHT Foundation investment portfolio

9. References

1. Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021. Accountability for the global health sector strategies 2016– 2021: actions for impact. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/handle/10665/341412, accessed 6 March 2023).
2. Accelerating the global Sexually Transmitted Infections response: report on the first informal Think-Tank meeting. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO
3. World Health Organization. Global strategy for the prevention and control of sexually transmitted infections: 2006-2015. Geneva: WHO, 2007.
4. World Health Organization. (2018). Fact sheet: human papillomavirus (HPV) and cervical cancer. Geneva: WHO. Retrieved March 6, 2024, from http://www.who.int/news-room/fact-sheets/detail/human-papillomavirus-(hpv)-and-cervical-cancer.

5. World Health Organization. (2023). Fact sheet: sexually transmitted infections (STIs). Geneva: WHO. Retrieved March 6, 2024, from https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis).
6. Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022-2030. Geneva: World Health Organization; 2022 (https://apps.who.int/ iris/handle/10665/360348, accessed 6 March 2023).

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