

# / PRODUCT DEVELOPMENT AWARD GENERAL CALL





Request for Proposals: PDA, General Call

## Innovation to develop vaccines, therapeutics/biologics and diagnostics as global public goods

#### **Executive Summary**

The Product Development Award (PDA) General Call seeks proposals aimed at **developing new or improved vaccines, therapeutics, biologics, or diagnostic platforms as global public goods** for prevention and control of infectious diseases that disproportionately affect the population in the settings of limited resources. There are important changes to the PDA General Call from the previous PDAs. First, submissions will be received until December 31, 2024 on a rolling basis (applicable only for the General Call). The call may be extended or amended, depending on the RIGHT Foundation's programmatic needs. Second, the target health conditions have been expanded to include non-communicable diseases (NCDs) that can exacerbate the clinical outcomes of infectious diseases in low-resource settings. Third, the funding scope for diagnostics has an emphasis on developing molecular diagnostic platforms for true or near point-of-care (POC) diagnostic tests that can significantly contribute to closing the global diagnostic gap (please review latest recommendations in [1-2]).

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 by the governments of the low- and middle-income countries (LMICs) with the ultimate goal of public procurement at the national and/or regional level in Africa, Asia, or Latin America in alignment the local governments' priorities.

Collaboration with LMIC partners is highly preferred. Applicants will be asked to articulate a plan to engage local stakeholders early to reflect the needs and priorities of the LMIC governments. Upon successful completion of the grants, grantees will be invited to apply for supplemental funding via the Bridging Award to advance the funded work towards licensure and WHO PQ.

The RIGHT Foundation evaluates proposals in the context of global public health needs, potential impact, and the RIGHT Foundation's investment priorities and portfolio. The RIGHT Foundation reserves the right to consider or decline proposals at its sole discretion throughout the proposal evaluation process.

#### 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.

This year's PDA General Call expands the funding scope to include NCDs that can increase the likelihood of infection or exacerbate the clinical outcomes of infectious diseases in low-resource settings. For diagnostics, this RfP seeks to support efforts to develop true- or near POC molecular diagnostic platforms for diseases for which effective and affordable diagnostics are limited.

Inclusion of NCDs for our funding scope reflects our recognition that NCDs are a significant source of global health inequity with 77% of all global NCD related deaths occurring in low-and middle-income countries [3]. The top four contributors of NCD deaths globally are cardiovascular diseases, cancer, chronic respiratory diseases and diabetes [3]. Certain infectious agents can cause cancer, and hypertension and diabetes can exacerbate the clinical outcome of infectious diseases [4-6], making the double burden of infectious diseases and NCDs a particular public health concern in LMICs. While the root causes of NCD mortality in LMICs are multiple, including poverty and commercial determinants of health [7], effective and affordable medical countermeasures to detect, screen and treat NCDs can significantly improve public health among the disadvantaged populations globally, including those in LMICs [3].

## 2. Objective

This RfP seeks to support a broad range of efforts to **develop and make available vaccines**, **therapeutics/biologics and diagnostics that can significantly improve effectiveness**, **safety, or access across regions.** Specific areas of interests are described under "Funding Scope".

## 3. Funding Scope

	Funding Scope
Vaccines	<ul> <li>Vaccine concepts with new antigens or antigenic epitopes to improve efficacy, breadth or duration of protection against multiple related species, strains, serotypes, groups or variants</li> <li>Clinical development of novel immunogens designed with the structure-guided approach or reverse vaccinology 2.0 [8-10]</li> <li>New formulations or adjuvants to extend the duration of immunity (i.e., long-lasting immune memory)</li> </ul>

Platform technologies that can reduce complexity and cost of manufacturing to support local production in LMICs Innovative delivery platforms to close immunization gaps in marginalized communities • Optimization of existing vaccines to improve the route of administration, and/or reduce the number of doses Therapeutics/ New small molecules or biologics that target the molecular sites from **Biologics** new understanding of the pathogen, host-pathogen interactions, mechanisms of infection or mechanism of severe disease New or improved approaches to reduce doses and treatment duration • New combination of previously characterized compounds to improve potency, safety and expand the target population to include high-risk groups (e.g., pregnant women) • Optimizing production method to reduce complexity and costs to support local production in LMICs **Diagnostics** • True or near point-of-care (POC) molecular diagnostic platforms that can offer: High sensitivity and specificity o Detection near patient Fast turnaround time o Routine multi-disease tests across >80% of primary healthcare facilities o Low-cost and easy-to-use platforms Simple device-based and instrument- free technologies (see reference [1] for background information) New platforms to simultaneously detect multiple pathogens using minimal specimen volume Innovative platforms to detect multidrug resistance (e.g., antimicrobial resistance) and analyze results to guide treatment and patient management in support of appropriate use of antibiotics Improvements in existing diagnostics to reduce complexity for end users across diverse resource settings (e.g., rural, community settings), to reduce cost and assay time

#### 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 in Table 1). Inclusion of researchers, developers or advisors from the LMICs as the Principal Investigator or a collaborator is highly preferred.

#### Table 1

#### Eligible entities for Korean or international partners

- For-profit companies engaged in life science 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 our grantees and their collaborators* to agree to our <u>Global Access Policy</u>, 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

	Vaccines, Therapeutics, Biologi	cs Diagnostics		
Award amount & duration	Co-funding required for at least 5 entities. Not applicable if the project.	Up to 4 billion Korean won per project for up to 36 months Co-funding required for at least 50% of the project cost from for-profit entities. Not applicable if the project team consists of only academic institutions and/or non-profit organizations.		
Target health conditions	<ul> <li>Infectious diseases with a disproportionate burden in LMICs or infectious diseases with a pandemic potential.</li> </ul>	<ul> <li>Neglected tropical diseases (NTDs) especially Visceral Leishmaniasis (see the <u>WHO list</u> of NTDs)</li> </ul>		

	Non-communicable diseases (NCDs) that can be caused by or exacerbated by infectious diseases or can exacerbate the clinical outcomes of infectious diseases in LMICs (e.g., cervical cancer, hypertension, diabetes)	<ul> <li>Sexually transmitted infections (e.g., chlamydia and gonorrhoea, HepB, syphilis, HIV)</li> <li>Antibiotic resistant bacteria listed under the WHO Priority 1 and 2</li> <li>Malaria, tuberculosis, dengue, cholera</li> <li>Hypertension, diabetes</li> </ul>
<b>Development</b> stage		clinical development or validation d WHO prequalification (WHO PQ)

## **6. Application Guidelines**

- Completed Intent to Apply (ITA) must be submitted in PDF format to our <u>Grant Management System</u>
- Submissions will be received on a rolling basis until December 31, 2024
- Short-listed candidates will receive invitations to submit full proposals

## 7. Evaluation Criteria

Category	Criteria
Responsiveness to public health needs	<ul> <li>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</li> <li>Value-add over the current best practice</li> </ul>
Strengths of proposal	<ul> <li>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)</li> <li>Probability of technical and regulatory success</li> <li>Suitability for local manufacturing in resource-limited settings across diverse regions</li> <li>Suitability for scalability</li> </ul>
Paths to potential impact	<ul> <li>Implementation plan to achieve equitable access within public health systems in LMICs via regulatory approval, WHO PQ, registration in LMICs</li> <li>Commitment and capabilities to implement the Global Access Policy</li> </ul>
Team-level capability	<ul> <li>Capabilities of the Principal Investigator (e.g., proven track-record of success in the related domain, relevant expertise)</li> <li>Strength of the project team</li> <li>Quality of the collaboration among the team members</li> </ul>

#### 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

#### 8. References

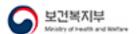
- [1] Jani IV & Peter TF. Nucleic Acid Point-of-Care Testing to Improve Diagnostic Preparedness. 75: 723–728, 2022, Clin Infect Diseases
- [2] Flemming KA et al. The Lancet Commission on diagnostics: transforming access to diagnostics. 398:1997-205, 2022, Lancet
- [3] WHO. Non-Communicable Disease: Key facts. Accessed on Oct.9, 2023 at <a href="https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases">https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases</a>
- [4] American Cancer Society. Viruses that can lead to cancer. Accessed on Oct.9, 2023 at <a href="https://www.cancer.org/cancer/risk-prevention/infections/infections-that-can-lead-to-cancer/viruses.html">https://www.cancer.org/cancer/risk-prevention/infections/infections-that-can-lead-to-cancer/viruses.html</a>
- [5] Seegert AB et al. Hypertension is associated with increased mortality with patients with tuberculosis in Guinea-Bissau. 109:123-128, 2021, Int J Infect Diseases
- [6] Mendenhall E et al. Non-communicable disease syndemics: poverty, depression, and diabetes among low-income populations. 389(10072):951-963, 2017, Lancet
- [7] Gilmore AB et al. Defining and conceptualizing the commercial determinants of health. 401:1194-213, 2023, Lancet
- [8] <u>Burton DR. What Are the Most Powerful Immunogen Design Vaccine Strategies? Reverse Vaccinology 2.0 Shows Great Promise.</u> 2017, Cold Spring Harb Perspect Biol
- [9] <u>Kwong PD. What Are the Most Powerful Immunogen Design Vaccine Strategies? A Structural Biologist's Perspective</u>, 2017, Cold Spring Harb Perspect Biol
- [10] <u>Rappuoli R. Reverse vaccinology 2.0: Human Immunology Instructs Vaccine Antigen</u> <u>Design</u>, 2016, J Exp Med



## THE RIGHT FOUNDATION IS SUPPORTED BY

#### / FULL PARTNER



















#### / ASSOCIATE PARTNER





#### / LOCATION

#03145 4F Dongduk Building, 68. Ujeongguk-ro. Jongno-gu. Seoul, Republic of Korea

/ EMAIL RFP@rightfoundation.kr / WEBSITE

/ CONTACT US

https://rightfoundation.kr/en/

+82-2-6337-9400