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Request for Proposals

Product Development Award

Targeted Call-mAb

RiGHT
국제보건기술연구기금

Request for Proposals: PDA, Targeted Call

Innovation to Expand Access to Monoclonal Antibodies

Executive Summary

This year's Product Development Award (PDA) Targeted Call seeks proposals on **validating novel technologies to lower the costs of producing monoclonal antibodies (mAbs) to prevent and/or treat one of the three diseases: severe respiratory syncytial virus (RSV) disease, severe malaria, or a respiratory tract illness with a pandemic potential.**

The focus on mAbs reflects our recognition that access to mAbs remains highly inequitable globally. They remain largely limited to high-income countries in the world despite their growing role in improving public health by preventing or treating infectious diseases and non-communicable diseases (NCDs) globally. Funders of global health R&D, including the RIGHT Foundation, are increasing efforts to collaborate and mobilize resources to expand access to effective, safe, and affordable mAbs to low- and middle-income countries (LMICs) where there are needs.

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 with the ultimate goal of public procurement and equitable access at the national and/or regional level in the Global South in alignment 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 can 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 the 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.

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.

mAbs have been increasingly used to prevent and treat infectious diseases and non-communicable diseases (NCDs) such as cancer and inflammatory diseases. More than 100 mAbs have been licensed over the last 30 years,[1,2] most of which target NCDs. While only seven mAbs are licensed for infectious diseases to date,[1] there is a growing pipeline of mAbs for infectious diseases and antimicrobial-resistant bacteria to meet the needs of global public health. [2,3,4]

Despite the increasing recognition of mAbs as an essential tool to protect global public health, mAbs are prohibitively expensive for the public health systems of LMICs. As a result, few antibodies are registered in low-income countries, and those that are registered are largely unavailable within public health systems.[5]

One of the major barriers to access to mAbs is the cost of production, which reportedly ranges between $95-$200/gram, excluding the research and development costs[6]. Several innovative technologies have emerged recently that can potentially lower costs throughout the mAb development process from antibody isolation to manufacturing to delivery (Listed in Figures 12 – 14 in [2]). Validating and applying some of these platforms can contribute significantly to improving equity in access to mAbs globally.

2. Objective

Our main objective is to support efforts to **optimize or validate approaches to lower the costs of producing/manufacturing mAbs to prevent and/or treat one of the three diseases: severe respiratory syncytial virus (RSV) disease, severe malaria or a respiratory tract illness with a pandemic potential**.

If successfully completed, the approaches validated in the study should pave the way to a broader application against other infectious diseases and NCDs that proportionately affect the populations in low-resource settings.

3. Funding Scope

This RfP focuses on **optimizing or applying the innovative manufacturing methods recently described in the literature towards developing mAb products for one of the three target use-cases below** (See pp. 32 – 38 of [2] for examples of innovative manufacturing methods for mAbs).

- mAb to be used for passive immunization against severe RSV disease in infants in alignment with the WHO Preferred Product Characteristics for RSV mAb
- mAbs for prevention of severe malaria in alignment with the WHO Preferred Product Characteristics for malaria mAbs
- mAbs for prevention and/or treatment of diseases with a pandemic potential prioritized by WHO

We will not consider funding:

- Discovery-phase proposals to identify pre-clinical candidates
- 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
- 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). Inclusion of researchers, developers or advisors from the LMICs as the Principal Investigator or a collaborator is highly preferred.

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 our 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	• Severe RSV disease in infants • Severe malaria • Diseases with pandemic potential with no or insufficient countermeasures (see diseases with a pandemic potential prioritized by WHO)
Development stage	• From or near the initiation of the clinical development to regulatory approval and WHO prequalification (WHO PQ)

6. 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

7. 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 Preferred Product Characteristics for RSV, malaria • Potential to simplify and/or accelerate production of mAbs compared to the current best practice • 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

8. References

1. Antibody Society. Antibody therapeutics approved or in regulatory review in the EU or US. Accessed on 28 March 2024 at https://www.antibodysociety.org/resources/approved-antibodies/2017
2. International AIDS Vaccine Initiative (IAVI). Expanding access to monoclonal antibody-based products: A global call to action. Accessed on 28 March 2024 at https://www.iavi.org/news-resources/expanding-access-to-monoclonal-antibody-based-products-a-global-call-to-action
3. International AIDS Vaccine Initiative (IAVI). Pipeline. Accessed on 28 March 2024 at https://www.iavi.org/iavi-pipeline/
4. Access to Medicine Foundation. Access to Medicine Index 2018. (2018) Accessed on 28 March 2024 at https://accesstomedicinefoundation.org/resource/2018-access-to-medicine-index
5. Coherent Market Report. (2019) Monoclonal antibodies market: Global Industry Insights, Trend, Outlook, and Opportunity Analysis, 2018-2026.
6. Blackstone EA, Joseph PF. (2013) The economics of biosimilars. Am Health Drug Benefits 6(8):469-78

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Other Partners

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