

/ PRODUCT DEVELOPMENT AWARD

TARGETED CALL



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 by the governments of 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.

Applications can be submitted until 10:00AM KST on November 30, 2023. 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.

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, IAVI pipeline analysis].

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 [4].

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 [5]. 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 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
<ul style="list-style-type: none">• 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 our [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 & duration	<ul style="list-style-type: none"> 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 style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 November 30, 2023**
- Short-listed candidates will receive invitations to submit full proposals

7. Evaluation Criteria

Category	Criteria
Responsiveness to public health needs	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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)

	<ul style="list-style-type: none"> • Probability of technical and regulatory success • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 Oct.9, 2023 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 Oct.9, 2023 at <https://www.iavi.org/news-resources/expanding-access-to-monoclonal-antibody-based-products-a-global-call-to-action>
- [3] Access to Medicine Foundation. Access to Medicine Index 2018. (2018) Accessed on Oct.9, 2023 at <https://accesstomedicinefoundation.org/resource/2018-access-to-medicine-index>
- [4] Coherent Market Report. (2019) Monoclonal antibodies market: Global Industry Insights, Trend, Outlook, and Opportunity Analysis, 2018-2026.
- [5] Blackstone EA, Joseph PF. (2013) The economics of biosimilars. Am Health Drug Benefits 6(8):469-78



RIGHT Foundation
Research Investment for Global Health Technology Foundation

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