

GHIT Fund Discovery Investment Target Research Platform in Partnership with Grand Challenges Request for Proposals Reference Number: GHIT-RFP-TRP-2015-001

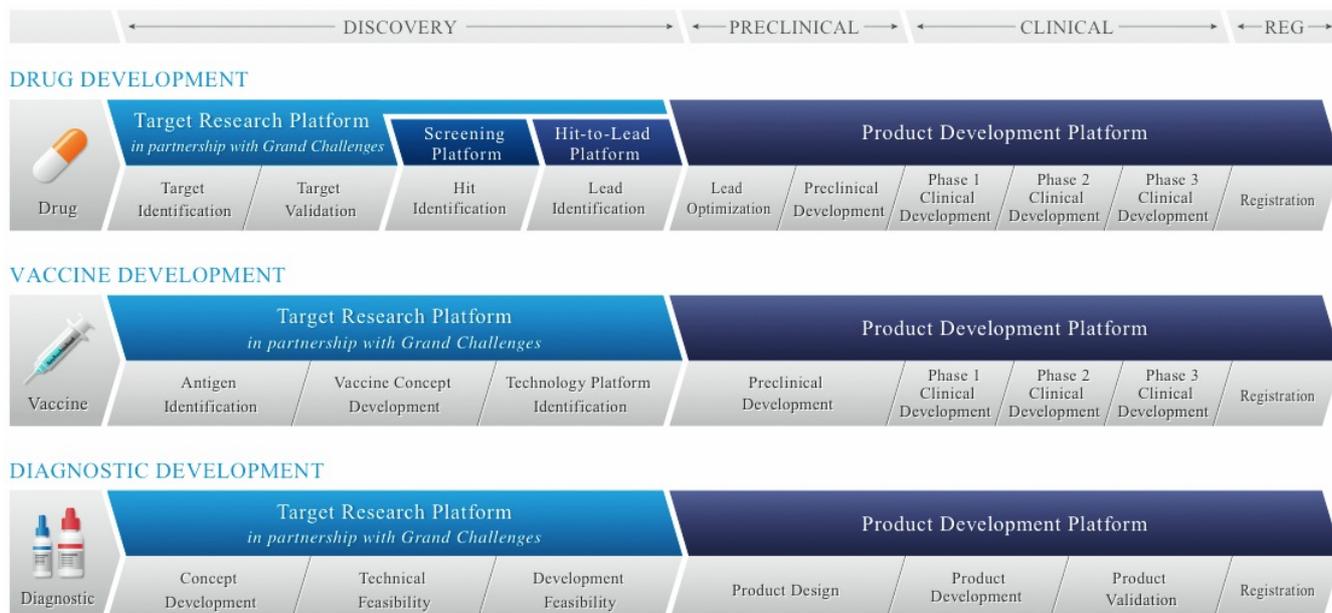
GHIT Fund Background

Over a billion people in the developing world suffer from infectious diseases, creating a need for new low-cost, high-impact health technologies. Response to this need in recent years has resulted in the development of new products, many of which have been the result of partnerships between pharmaceutical companies, academic and research institutions, and Product Development Partnerships (PDPs). These partnerships have proven to be an effective method for developing impactful global health technologies.

The Global Health Innovative Technology Fund (GHIT Fund) is a non-profit organization focused on promoting the discovery and development of new health technologies, including drugs, vaccines, and diagnostics for infectious diseases prevalent in developing countries. The first fund of its kind in Japan, the GHIT Fund is supported by the Japanese Government, Japanese pharmaceutical companies, and the Bill & Melinda Gates Foundation. The GHIT Fund aims to advance Japan's wealth of health technology innovation for the discovery and development of new technologies for developing world patients and populations affected by infectious disease. To this end, the GHIT Fund will catalyze R&D partnerships between Japanese and non-Japanese organizations and support these partnerships through GHIT Fund investments.

Funding Opportunity

The GHIT Fund endeavors to facilitate collaboration and funding of global health technology R&D, to build momentum, and to demonstrate action and results. The Target Research Platform in Partnership with Grand Challenges (TRP) is one of three platforms within the GHIT Fund's Discovery Investment focus area and is the GHIT Fund's newest platform.



These investments are intentionally broad in potential scope and focus on new technologies and novel approaches. The TRP is currently focused on technologies and approaches that address unmet or priority needs within malaria, tuberculosis, Chagas disease, and leishmaniasis.

The proposed collaboration project may include, but is not limited to:

- Novel mechanisms of action for therapeutic targeting
- Pathogen component targeting to impact disease rather than infection
- Novel vaccine concepts, targets, and constructs
- New and improved approaches to diagnostic assays

The following table provides more detailed examples of potentially eligible and ineligible TRP investments.

Drug Intervention Investment Scope Examples	
Eligible	<ul style="list-style-type: none"> • Novel mechanisms of action, for example targeting critical host components essential to infection and disease with little or no toxic effect on the host • Targeting components of the pathogen that are implicated in disease rather than infection, or that are so highly constrained that resistant variants cannot be easily selected
Ineligible	<ul style="list-style-type: none"> • Mathematical analysis, modeling and prediction of the evolution, spread, and fitness of resistant mutants during drug treatment, both within a single individual and within an epidemiological context • Conventional drug discovery approaches (e.g., standard high-throughput screens against pathogens, optimization of known drugs, hybrid-drug approaches, target-based drug development, drug combinations or formulations) • General testing of compounds against currently drug-resistant pathogens without a clear hypothesis as to why the compound may be less likely to generate resistance • Specific targeting of pathogens that cause diseases not on the GHIT's priority disease list. • Community-based interventions aimed at improving adherence to drug treatment regimens.
Vaccine Intervention Investment Scope Examples	
Eligible	<ul style="list-style-type: none"> • Novel vaccine concepts, targets, and constructs inspired by new observations or understanding about the nature of the targeted organism or the human response to that organism • New vaccine constructs that target specific tissue or cell types for appropriate induction of local and systemic immunity. • Applications of radically new technologies for disease protection, such as production of immunogens using synthetic biology or radical genetic engineering approaches
Ineligible	<ul style="list-style-type: none"> • Identification of malaria or TB antigens without ways to radically and reproducibly improve their effectiveness or efficiency • Projects targeting molecular pathways already targeted by antigens or adjuvants currently in clinical development or in market • Approaches that represent incremental improvements to conventional solutions • Basic studies of pathogen or human biology

Diagnostic Intervention Investment Scope Examples	
Eligible	<ul style="list-style-type: none"> Radically new and improved approaches to traditional immune and molecular assay methods Biochemical amplification or analysis of non-invasive samples such as urine, saliva, sweat or other excreted fluids
Ineligible	<ul style="list-style-type: none"> Technical improvement of a diagnostic with little apparent relevance or impact to a global health problem Diagnostics focused on cancer or non-infectious chronic diseases such as asthma, diabetes, allergies Improvements solely in microfluidics architecture or detection signal transduction or other elements of platform technologies without a clear path to a product of relevance to one or more GHIT priority diseases

A maximum budget per proposal is set at ¥100,000,000. The duration of the project shall not exceed two years.

Investment Eligibility

GHIT Fund investments can be awarded to existing or new partnerships between Japanese and non-Japanese organizations. Each partner should have a history of health intervention R&D and have the expertise to know which projects represent potentially substantial additions to the field. The following table specifies the types of organizations expected to form GHIT Fund eligible partnerships.

Japanese Organizations	Non-Japanese Organizations
<ul style="list-style-type: none"> Companies with a research facility in Japan Not-for-profit research organizations Government research institutions Academic institutions 	<ul style="list-style-type: none"> Product Development Partnerships (PDPs) and their network of partners including the following: <ul style="list-style-type: none"> Life Science Companies Not-for-profit research organizations Government research institutions Academic institutions

Both parties to the partnership will also be required to sign Global Access Agreements to provide access to relevant data, intellectual property, and product use. GHIT Fund's access policies can be viewed at <http://www.ghitfund.org/afag/policies/en>.

Applicant Instructions

All correspondence and documents relating to this RFP shall be written in English. The applicant shall bear all costs associated with the preparation and submission of the proposal, including costs associated with proposal presentation and contract negotiation.

Intent to Apply

Interested applicants must complete the *GHIT-RFP-TRP-2015-001_IntentToApply.docx* document and submit to the GHIT Fund via its online document submission system (http://www.editorialmanager.com/ghitfund_trp/) no later than 10:00 am Tokyo time on **March 13, 2015**.

Applicants who submit the *Intent to Apply* document will receive a confirmation email. GHIT Fund staff will then perform an initial partnership and scope eligibility assessment. Eligible applicants will receive a full GHIT Fund proposal template to support proposal development.

RFP Questions

Prospective applicants may also submit RFP questions to TRPResponse@ghitfund.org no later than 10:00 am Tokyo time on **March 30, 2015**, (please use email subject line: GHIT Fund-RFP-TRP-2015-001_Questions).

A Frequently Asked Questions (FAQ) page is available on the GHIT Fund website (<https://www.ghitfund.org/afag/seekersfaq/en>).

Proposal Submission

Applicants are required to submit their completed proposal to the GHIT Fund via its online document submission system no later than 10:00 am Tokyo time on **April 3, 2015**. Applicants who successfully submit their proposal document will receive a confirmation email. Proposals may not be modified after the submission due date.

The GHIT Fund may, at its own discretion, extend the closing date by notifying applicants who have submitted an *Intent to Apply* document. Proposals received after the closing date for submission, without prior agreement, will be ineligible for consideration, but may be resubmitted in response to future RFPs.

Proposal Evaluation

Preliminary Examination of Proposals

Proposals will initially be examined to determine whether the:

- Partnership meets GHIT Fund eligibility criteria
- Project objectives are aligned with the RFP-specified scope
- Proposal is complete and addresses all required content

Applicants will be notified by email of their proposal's readiness for technical evaluation. GHIT Fund staff may ask clarifying questions or request additional information, as needed, to qualify proposals for evaluation.

Technical Evaluation

All proposals passing the preliminary examination will be evaluated and prioritized based on the following criteria:

- Scientific and technical merit (e.g., sound approach and methodology, level of innovation, overall quality and comprehensiveness)
- Potential Impact (e.g., how it will address a global health priority)
- Partnership and project management (e.g., collaboration capabilities and expertise, project history and performance, risk management, budget)

If a proposal has already been deemed technically or scientifically sound and aligned with global health needs by an established independent scientific or technical advisory committee (such as those established by PDPs), the partnership is expected to include a summary of the outcome of that review in their proposal submission.

Eligible proposals will initially be reviewed by three External Reviewers. Based on the aggregated Expert Reviewer results and a subsequent evaluation by the GHIT Fund Selection Committee (SC), proposals will be ranked by evaluation score. Partnerships with the highest ranked proposals will be invited for an interview with the SC. Once all information has been considered, the SC will make funding recommendations to the GHIT Board. The GHIT Board will discuss the SC recommendations, taking into account the access and delivery element of each proposal, and will decide which proposals will receive GHIT Fund investment.

Award Administration and Conditions

The GHIT Fund will notify applicants of their selection status by email. The GHIT Fund will not provide formal feedback to applicants receiving a non-award decision.

Applicants are required to identify the designated development partner (investment recipient) and all other collaboration partners. The designated development partner will be responsible for the performance of all its collaborating partners. A representative of the designated development partner will serve as the main GHIT Fund point of contact and will be responsible for all GHIT Fund discussions and negotiations.

Investments will be awarded for a period reflecting the expected time required to complete agreed activities. **The funding allocation will be milestone based.** The GHIT Fund has the right to terminate the investment agreement if:

- The partnership disbands prior to satisfying its investment project obligations
- The progress of work is such that the obligations undertaken by the partnership will not be fulfilled
- The partnership fails to meet the milestones or goals specified in the investment agreement

In the event an investment contract is terminated, the GHIT Fund reserves the right to cancel future payments, reclaim paid funds, or mandate that paid funds be redirected to other charitable activities. In lieu of termination, the GHIT Fund may choose to renegotiate the terms of the existing investment agreement.

Data Access Policy

The aim of our Data Access Policy is to articulate the principles that promote the transparency of and accessibility to data related to the safety and efficacy of healthcare technologies. This policy and its principles apply to data generated through activities primarily funded by the GHIT Fund, including but not limited to, those related to the discovery, development, and/or delivery of healthcare technologies.

All data and its processes for access will be transparent and clearly defined with the aim to ensure data quality, security, and equitable access. All data and findings will be disclosed in a broad and prompt manner in order to optimize prospects for the translation of findings in the global advancement of new healthcare technologies. Grantees should utilize public-access repositories and, if unavailable, should use alternatives for access that can ensure the transmission of new scientific findings to the larger research and development community globally.

Respect must be given to individuals and communities from or about whom data are collected. Respect must also be given to all matters of confidentiality and attribution as they pertain to researchers, evaluators, and their collaborators. Confidentiality and respect for such should be fully recognized where necessary or required by law or regulation.

Any and all existing data and findings owned by a grantee at the initiation of a project, including but not limited to information, know-how or intellectual property, will remain that of the original holder. The original holder may share, assign, or license their rights to a third party.

Ownership of any and all data and findings that is obtained or created through activities funded by the GHIT Fund and that can be applied for any intellectual property rights will be discussed and negotiated between participants and/or grantees of a project. All final agreements shall be in alignment with the licensing and pricing principles outlined below.

Any existing data owned by a grantee and/or any new data obtained through activities funded by the GHIT Fund may be disclosed by the GHIT Fund to a third party if such data is used in a patent application for a product which was derived from the activities funded by the GHIT Fund; provided, however: (1) that the disclosure of such data shall be limited to the proposed title of the invention, a draft of the abstract, the international non-proprietary name (INN) where applicable, and an outline of the specifications of such patent

application; and (2) such third party shall take reasonable measures to keep confidential any such data received from the GHIT Fund.

Product Access Policy

The aim of the Product Access Policy is to articulate the principles that improve access to products primarily developed with funding from the GHIT Fund, where such products refer to healthcare technologies approved for market by a national regulatory authority.

When development partners/participants are successfully granted a patent deriving from projects funded by the GHIT Fund, development partners/participants will grant royalty-free licenses to users operating in Least Developed Countries (LDCs) as categorized by the United Nations and Low-Income Countries (LICs) as categorized by the World Bank. License-related matters concerning middle income countries (MICs) will be reviewed on an individual basis with the goal of ensuring reasonable royalty licenses.

For LDCs, LICs, and MICs, partners/participants will set prices for products on the basis of a no gain/no loss policy to improve access to the product for patients and citizens of these LDCs, LICs, and MICs.

Key RFP Milestone Dates

RFP Release	February 5, 2015
Intent to Apply	No later than 10:00 am Tokyo time on March 13, 2015 Submit via GHIT Fund online document submission system (http://www.editorialmanager.com/ghitfund_trp/)
Q & A	No later than 10:00 am Tokyo time on March 30, 2015 Submit questions to TRPResponse@ghitfund.org Email Subject Line: GHIT Fund-RFP-TRP-2015-001_Questions
Application	No later than 10:00 am Tokyo time on April 3, 2015 Submit via GHIT Fund online document submission system
Award Notification	No later than August 1, 2015
Investment Agreement	No later than September 1, 2015