

**GHIT Fund Discovery Investment
Target Research Platform in Partnership with Grand Challenges
Request for Proposals
Reference Number: GHIT-RFP-TRP-2016-002**

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.

Grand Challenges Background

First launched by the Bill & Melinda Gates Foundation and partners in 2003, the Grand Challenges program was created to foster creative and daring breakthroughs to help solve the world's most pressing global health and development problems. Since then, more than 2,000 grants have been awarded in some 80 countries with many organizations and nations, from India to Brazil to Canada, modeling their own Grand Challenges on the same ideal. Grand Challenges initiatives have ranged from reformulating a tuberculosis vaccine into an inhalable aerosol spray to a new method for controlling malaria: giving humans a drug that makes their blood poisonous to the mosquitoes that carry the disease. The Grand Challenges family of programs adhere to a common set of principles, including defining challenges whose solution would unleash progress in key areas; engaging the world's most innovative researchers; focusing research on making an impact for those most in need; building collaboration among researchers and funders to accelerate impact; and building an expanding global network of programs and partners.

Funding Opportunity

The GHIT Fund endeavors to facilitate collaboration and funding of global health technology R&D originating from Japan, 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. The Grand Challenges platform is intended to support a crucial, earlier phase of R&D—discovery of new approaches, concepts, constructs and solutions to fight neglected infectious disease. To that end, **proposals to the Grand Challenges Target Research Platform should be innovative in nature and focused on early-stage discovery**. Product development ideas appropriate for the Product Development Platform will not be considered.



Project Scope and Eligibility

TRP investments are intentionally broad in potential scope and focus on new technologies and novel approaches. **Proposals must be within the project scope and investment eligibility below to be eligible for consideration.**

The TRP is currently focused on technologies and approaches that address unmet or priority needs within malaria, tuberculosis, Chagas disease and leishmaniasis. For this RFP, the disease scope is expanded to also include Buruli ulcer, *Cryptosporidium*, lymphatic filariasis, mycetoma (non pathogen-specific solution) and schistosomiasis.

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

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

	<ul style="list-style-type: none"> • 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

Investment Eligibility

One of the main goals of the Grand Challenges platform is to harness Japanese innovation and global collaboration to target malaria, tuberculosis, and selected neglected tropical diseases (NTDs) that sicken and kill the poorest people in the world.

GHIT Fund investments can be awarded to existing or new **partnerships between Japanese and non-Japanese organizations**. **The GHIT Fund requires each investment to have at least one eligible Japanese and one eligible non-Japanese organization as partners in order to be considered eligible**. The following table specifies the types of organizations expected to form GHIT Fund eligible partnerships. **For TRP, the project should primarily originate from and be led by the Japanese organizations**. Partnerships with other non-Japanese organizations that add to the expertise and potentially success of the project are required.

Japanese Organizations	Non-Japanese Organizations
<ul style="list-style-type: none"> • Japanese corporations (with a research facility in Japan) • Not-for-profit research organizations and foundations • Government research institutions • Academic institutions 	<ul style="list-style-type: none"> • Life Science/Healthcare companies • Not-for-profit research organizations and foundations • Product Development Partnerships • 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.

To receive and manage applications, the GHIT Fund uses **Editorial Manager® for Target Research Platform** (http://www.editorialmanager.com/ghitfund_trp), an online document submission system dedicated for this funding program. Please note that Intent to Apply documents or Proposals that are not submitted through the above mentioned system will not be accepted.

Intent to Apply

Interested applicants must complete the *Intent to Apply* form (**GHIT-RFP-TRP-2016-002_IntentToApply.docx**) and submit this to the GHIT Fund via Editorial Manager® no later than **10:00 am Tokyo time on September 14, 2016**. The *Intent to Apply* form is available on the GHIT Fund website (<https://www.ghitfund.org/afag/trp/en>). Any application not using the designated *Intent to Apply* form for this RFP will not be accepted. Please do not attach any documents to the *Intent to Apply* form.

When submitting your *Intent to Apply* form on the Editorial Manager®, please list all the collaboration partners participating in the project; the name and details (including e-mail address) of at least one representative from each organization must be indicated.

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. **Only eligible applicants will be invited to submit the full proposal and will receive the proposal templates from the GHIT Fund.**

Proposal Submission

Applicants are required to submit their completed proposals to the GHIT Fund via Editorial Manager® no later than **10:00 am Tokyo time on October 11, 2016**. Applicants who successfully submit their proposal document will receive a confirmation email. Proposals may not be modified after the submission due date.

Proposals must be reviewed and approved by all the collaboration partners who are participating in the project prior to submission. The *Collaboration Partners' Approval* form (**Collaboration_Partners'_Approval.docx**) must be signed by all the collaboration partners and a PDF copy must be submitted along with other proposal documents. Also, on the Editorial Manager®, please list all the collaboration partners; the name and details (including e-mail address) of at least one representative from each organization must be indicated.

The GHIT Fund may, at its own discretion, extend the closing date by notifying applicants. 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.

RFP Questions

Prospective applicants may also submit RFP questions to TRPResponse@ghitfund.org no later than **10:00 am Tokyo time on October 7, 2016** (please use email subject line: **GHIT Fund-RFP-TRP-2016-002_Questions**). Please note that it may take time for the GHIT Fund Management Team to respond to your inquiries, so make sure to address your questions well in advance of the submission deadlines.

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

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 (ER). The aggregated External Reviewer results and the proposals will then be shared with the GHIT Fund Selection Committee (SC) for evaluation. After the evaluation process, GHIT Fund will invite selected proposals for an in-person interview with the SC. **Selected proposals for the SC interview will be notified of the interview invitation about a month prior to the scheduled interview date and time.**

Once all information has been considered after the interview, the SC will make funding recommendations to the GHIT Board. The GHIT Board will discuss the SC recommendations and will make the final approval as to which proposals will receive GHIT Fund investment. Please note that the GHIT Fund Management Team does not have influence, authority, or decision power on the review and evaluation, funding recommendations, and award or non-award decisions of submitted proposals by the External Reviewers, Selection Committee, and the Board of Directors. In addition, submission of the Intent to Apply form and proposal documents to the GHIT Fund and participation by proposal partners in the Selection Committee interview do not guarantee an automatic funding approval for your proposal.

Award Administration and Conditions

After the GHIT Board approval, the GHIT Fund will notify applicants of the award decision by email. **Please note that GHIT Fund is not able to provide formal feedback to applicants receiving a non-award decision.**

If the proposal is selected and the applicant receives an award notification, all partners are required to sign the Investment Agreement with the GHIT Fund and also submit a collaboration partners' contractual agreement which clearly defines the roles and responsibilities of all collaboration partners, **within one month from award notification**. Please be aware that the award may be void if this condition is not met.

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	August 22, 2016
Intent to Apply Due	No later than 10:00 am Tokyo time on September 14, 2016 Submit via Editorial Manager® for Target Research Platform (http://www.editorialmanager.com/ghitfund_trp/)
Q&A regarding the RFP and proposal	No later than 10:00 am Tokyo time on October 7, 2016 Submit any RFP and application questions to TRPResponse@ghitfund.org Email Subject Line: GHIT Fund-RFP-TRP-2016-002_Questions
Full Proposal Due	No later than 10:00 am Tokyo time on October 11, 2016 Submit via Editorial Manager® for Target Research Platform (http://www.editorialmanager.com/ghitfund_trp/)
Proposals Evaluation and Interview Processes	September 2016 - February 2017
Award Notification to All Applicants	No later than February 10, 2017
Investment Agreement Fully Executed (Awarded Proposals)	No later than March 31, 2017

End of Document