

GHIT Fund Discovery Investment Target Research Platform Request for Proposals

Reference Number: GHIT-RFP-TRP-2023-002

GHIT Fund Background

Over a billion people in the world suffer from infectious diseases, especially those in LICs/LMICs and settings, 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, the Wellcome Trust 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 originating from Japan, to build momentum, and to demonstrate action and results. The Target Research Platform (TRP) is one of three platforms within the GHIT Fund's Discovery Investment focus area. This 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 Target Research Platform should originate from Japan and 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. Limited funding is also available for proposals that focus on innovative repurposing of existing technologies for use in different therapeutic area with high unmet medical needs.

Proposals must be both within the project scope and in line with the investment eligibility criteria in order to be considered.

The TRP is currently focused on technologies and approaches that address unmet or priority needs within malaria, tuberculosis and Neglected Tropical Diseases listed in the GHIT Intent to Apply form.

However, funding may be considered for development of improved drugs, vaccines, and diagnostics for other WHO-listed NTDs, on a case-by-case basis with clear justifications of the needs (including landscape of competing interventions currently available and in development).

The duration of the project should 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
- Repurposing of existing health technologies (including approved drugs, medical devices, diagnostic tests, platform technologies) for use in new indications (malaria, TB and NTDs) and diseases with pandemic potential.
- Repurposing of technologies developed within other sectors for accelerating medical innovation

For proposals aiming at developing platform technologies to rapidly bring new pandemic products, they should provide a justification of how the target disease is considered to be one with pandemic potential. Due to the limited funds available, proposed research for repurposing technologies are expected to be awarded through a highly competitive process.

The following table provides more detailed examples of potentially eligible and ineligible TRP investments. Proposals that bridge to GHIT's Product Development (PD) Platform are encouraged.

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● Conventional drug discovery approaches (e.g., standard high-throughput screens against pathogens, hybrid-drug approaches, target-based drug development) to address potential new targets or pathways.
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● 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

	<ul style="list-style-type: none"> ● 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 ● New interventions designed to target hard-to-reach human and vector populations e.g. vaccines for neglected malaria parasites P malariae, P ovale, and P Knowle. Only transformative ideas that offer a clear rationale for outperforming those existing programs in the current GHIT portfolio will be prioritized for funding.
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 late stage 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 ● Development of cost-effective diagnostics by utilizing or repurposing off-patent/ discontinued /novel technologies that are anticipated to encounter minimal regulatory and safety barriers
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 key goals of the TRP 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. **To receive a TRP award, the project should primarily originate from or materially involve a Japanese science and technology.**

In circumstances where the underlying innovation or technology has not emerged from Japanese science, the project may still be considered for funding. However, in such circumstances, the leadership and work

carried by the Japanese organization in the proposed TRP project must be essential to the further design, improvement or refinement of the innovation or technology. In other words, TRP proposals in which the studies carried out by the Japanese partner(s) are limited to activities such as generation of supporting data and provision of control samples etc. will not be eligible for consideration.

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. 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

All partners 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 <https://www.ghitfund.org/applyforfunding/accesspolicy/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.

Step 1 - Intent to Apply

Interested applicants must complete the *Intent to Apply* form (**GHIT-RFP-TRP-2023-002_IntentToApply.docx**) and submit this to the GHIT Fund via Editorial Manager® no later than:

10:00 am Tokyo time on July 11, 2023.

The *Intent to Apply* form is available on the GHIT Fund website: (<https://www.ghitfund.org/applyforfunding/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 a password to access the proposal template.**

Eligibility assessment will be conducted upon receipt of the Intent to Apply form. Applicants are encouraged to submit the ITA well in advance of the Full Proposal submission deadline (10:00am Tokyo time on August 9, 2023.) to secure sufficient time to prepare full proposal.

Step 2 - Proposal Submission

Applicants invited to submit a full proposal to the GHIT Fund are required to do so via Editorial Manager® no later than;

10:00 am Tokyo time on August 9, 2023.

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 (**ProjectID-CollaborationPartnerApproval.docx**) must be signed by all the collaboration partners and a PDF copy must be submitted along with other proposal documents.

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 (please use email subject line: **GHIT-RFP-TRP-2023-002_Questions**). no later than

10:00 am Tokyo time August 2, 2023.

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/applyforfunding/investmentfaq/en>).

Proposal Evaluation

Preliminary Examination of Proposals

TRP proposals will initially be examined to determine whether the:

- Partnership meets GHIT Fund eligibility criteria
- Project originates from and is led by a Japanese organization
- 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 (max. ¥70,000,000))

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) including Japanese and non-Japanese reviewers. The aggregated External Reviewer results and the proposals will then be shared with the GHIT Fund Selection Committee (SC) for evaluation. ER and SC members have signed non-disclosure agreements with the GHIT Fund prior to the 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 approximately one 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 and Staff do 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.

(Please note that the evaluation procedures and their format may be adjusted due to unforeseen circumstances.)

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 two weeks to 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.

Access Policy

Details about the GHIT Access Policy can be found here:
<https://www.ghitfund.org/applyforfunding/accesspolicy/en>.

Key RFP Milestone Dates

RFP Release	June 13, 2023
Intent to Apply Due	<p>No later than 10:00 am Tokyo time on July 11, 2023</p> <p>*Applicants are encouraged to submit the ITA well in advance of the Full Proposal submission deadline shown below to secure sufficient time to prepare full proposal.</p> <p>Submit via Editorial Manager® for Target Research Platform (http://www.editorialmanager.com/ghitfund_trp/)</p>
Q&A regarding the RFP and Full proposal	<p>No later than 10:00 am Tokyo time on August 2, 2023</p> <p>Submit questions to TRPResponse@ghitfund.org Email Subject Line: GHIT-RFP-TRP-2023-002_ Questions</p>
Full Proposal Due	<p>No later than 10:00 am Tokyo time on August 9, 2023</p> <p>Submit via Editorial Manager® for Target Research Platform (http://www.editorialmanager.com/ghitfund_trp/)</p>
Proposals Evaluation and Interview Processes	August 2023- February 2024
Award Notification to All Applicants	February 2024
Investment Agreement Fully Executed (Awarded Proposals)	March 2024

(The schedule is subject to change due to unforeseen circumstances.)

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