

**GHIT Fund Discovery Investment  
Target Research Platform  
Request for Proposals  
Reference Number: GHIT-RFP-TRP-2024-002**

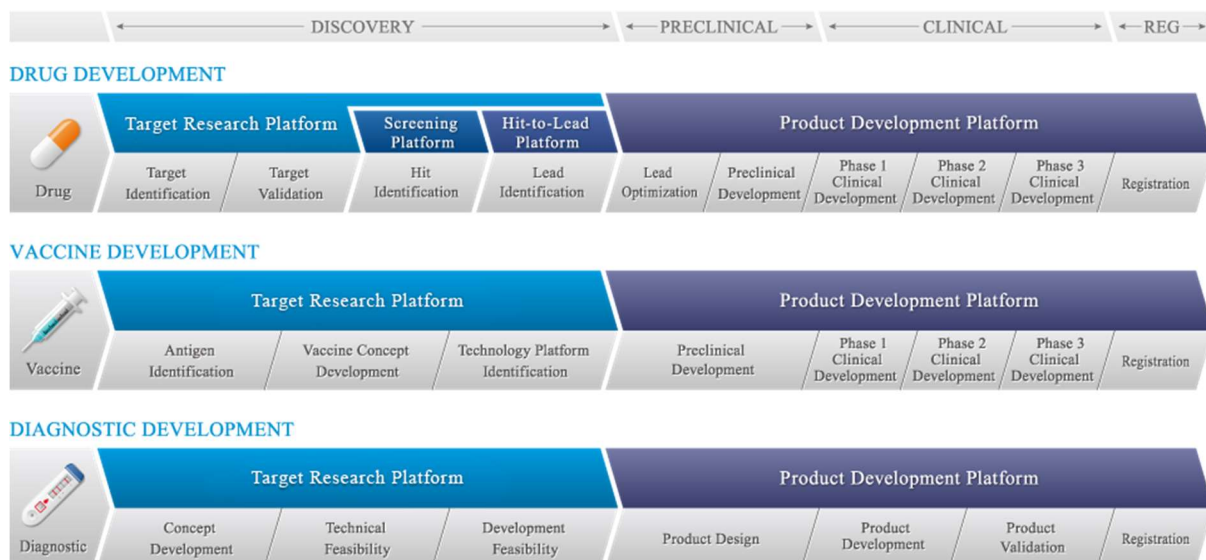
### **GHIT Fund Background**

With over a billion people in the world suffering from infectious diseases, especially in low income countries (LICs) and lower middle income countries (LMICs), there is a need for new low-cost, high-impact health technologies. Responses to this need in recent years have led to the development of new products, mostly as a result of partnerships between pharmaceutical companies, academia 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 patients and populations affected by neglected infectious diseases. 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 the crucial, earlier phase of R&D discovery of new approaches, concepts, constructs and solutions to fight neglected infectious diseases. To be considered eligible for TRP, **proposals should primarily originate from or materially involve Japanese science, technology and/or know-how.**



## Project Scope and Eligibility

TRP investments are intentionally broad in potential scope and target new technologies and novel approaches. Limited funding is also available for proposals that focus on innovative repurposing of existing technologies for use in different therapeutics/diagnostics/preventive areas 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 (TB) and Neglected Tropical Diseases (NTDs) listed in the GHIT *Intent to Apply* form.**

*However, funding may be considered for the development of improved drugs, vaccines and diagnostics for other WHO-listed NTDs on a case-by-case basis with clear justifications of the needs (and clear indication of the technological 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
- Components of pathogens implicated in diseases rather than infections
- Novel vaccine concepts, targets and constructs
- New and improved approaches to diagnostic assays
- Pharmacogenomics studies to assist in understanding the metabolism and disposition of drugs for malaria, TB and NTDs
- Repurposing of existing health technologies (including approved drugs, medical devices, diagnostic tests and 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
- Disease/market landscape and technology landscape work to address unmet and/or priority needs as a part of concept development that leads to product development (research duration should not exceed six months)
- Appropriate research with the aim of creating and publishing the Target Product Profile (TPP) for disease/intervention/modality, where the TPP is not available or needs to be updated

- Bridging activities to plan the transition of a project to the Product Development Platform. The budget for translational science and capacity building (such as developing a product development plan, finding a product development partner, consultation to regulatory bodies, etc.) for a budget at maximum of ¥5,000,000 (the budget for bridging activities can be added to the total requested budget).

Proposals aimed at developing platform technologies for pandemic preparedness should provide a justification of how the target disease is considered to be one with pandemic potential. Due to limited funds available, proposed research for repurposing technologies is expected to be awarded through a highly competitive process.

The table below provides more detailed examples of potentially eligible and ineligible TRP investments. Proposals that bridge a project to GHIT’s Product Development Platform are encouraged.

<b>Drug Intervention Investment Scope</b>	
Examples of Eligible Projects	<ul style="list-style-type: none"> <li>● Novel mechanisms of action, e.g., targeting critical host components essential for infection and disease with little or no toxic effect on the host</li> <li>● Project targeting components of pathogens that are implicated in diseases rather than infections, or that are so highly constrained that resistant variants cannot be easily selected</li> <li>● Conventional drug discovery approaches (e.g., standard high-throughput screening against pathogens, hybrid-drug approaches, target-based drug development) to address potential new targets or pathways</li> <li>● Disease/market landscape and technology landscape work to address unmet and/or priority needs as a part of concept development, eventually leading to technology development, and to identify technologies/platforms/solutions, etc. for which Japan can significantly contribute to fight against malaria, TB, NTDs and diseases with pandemic potential</li> <li>● Novel drug delivery modality/system modality</li> <li>● Appropriate research with the aim of creating and publishing the TPP for disease and intervention/modality, where the TPP is not available or needs to be updated.</li> </ul>
Ineligible	<ul style="list-style-type: none"> <li>● Mathematical analysis, modeling and prediction of the evolution, spread and fitness of resistant mutants during drug treatment, both within a single individual and in an epidemiological context</li> <li>● 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</li> <li>● Project that specifically targets pathogens that cause diseases not on the GHIT’s priority disease list</li> <li>● Community-based interventions aimed at improving adherence to drug treatment regimens</li> </ul>
<b>Vaccine Intervention Investment Scope</b>	
Examples of Eligible Projects	<ul style="list-style-type: none"> <li>● Novel vaccine concepts, targets and constructs inspired by new observations or understanding about the nature of the targeted organism or human response to that organism</li> <li>● New vaccine constructs that target specific tissue or cell types for appropriate induction of local and systemic immunity</li> <li>● Applications of radically new technologies for disease protection, such as production of immunogens using synthetic biology or radical genetic engineering approaches</li> <li>● New interventions designed to target hard-to-reach human and vector populations, e.g., vaccines for neglected malaria parasites <i>P. malariae</i>, <i>P. ovale</i> and <i>P. knowlesi</i>. Only transformative ideas that offer a clear rationale for</li> </ul>

	<p>outperforming the existing programs in the current GHIT portfolio will be prioritized for funding.</p> <ul style="list-style-type: none"> <li>● Disease/market landscape and technology landscape work to address unmet and/or priority needs as a part of concept development, eventually leading to technology development, and to identify technologies/platforms/solutions, etc., for which Japan can significantly contribute to fight against malaria, TB, NTDs and disease with pandemic potential</li> <li>● Appropriate research with the aim of creating and publishing the TPP for disease and intervention/modality where the TPP is not available or needs to be updated</li> </ul>
Ineligible	<ul style="list-style-type: none"> <li>● Identification of malaria or TB antigens without ways to radically and reproducibly improve their effectiveness or efficiency</li> <li>● Projects targeting molecular pathways already targeted by antigens or adjuvants currently in late-stage clinical development or in market</li> <li>● Approaches that represent incremental improvements to conventional solutions</li> <li>● Basic studies of pathogens or human biology</li> </ul>
<b>Diagnostic Intervention Investment Scope</b>	
Examples of Eligible Projects	<ul style="list-style-type: none"> <li>● Radically new and improved approaches to traditional immune and molecular assay methods</li> <li>● Biochemical amplification or analysis of non-invasive samples such as urine, saliva, sweat or other excreted fluids</li> <li>● Development of cost-effective diagnostics by utilizing or repurposing off-patent/discontinued/novel technologies that are anticipated to encounter minimal regulatory and safety barriers</li> <li>● Technology and market assessment/landscaping research to address unmet and/or priority needs as a part of concept development for malaria, TB, NTDs and diseases with pandemic potential (intended use, intention for use, method, target analyte, specimens, instrument, etc.)</li> <li>● Creating and publishing the TPP for disease and intervention/modality where the TPP is not available</li> <li>● Technology and market assessment/landscaping research for medical devices (e.g., portable X-ray system) to address unmet and/or priority needs as a part of concept development for malaria, TB, NTDs and diseases with pandemic potential</li> <li>● Technology and market assessment/landscaping research for digital health solution (image analysis artificial intelligence (AI) for X-ray system, microscopy, AI-based diagnosis of skin-related NTDs, etc.) to address unmet and/or priority needs as a part of concept development for malaria, TB, NTDs and diseases with pandemic potential</li> <li>● Novel assay technologies that can address therapeutic screening of viral families</li> <li>● Innovative design for customizable multiplexing which can be delivered to endemic regions</li> </ul>
Ineligible	<ul style="list-style-type: none"> <li>● Technical improvement of a diagnostic with little or no apparent relevance to or impact on a global health problem</li> <li>● Diagnostics focused on cancer or non-infectious chronic diseases such as asthma, diabetes and allergies</li> <li>● Improvements solely in the microfluidic architecture, 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</li> </ul>

## Investment Eligibility

One of key goals of the TRP platform is to harness Japanese innovation and global collaboration to fight against malaria, tuberculosis and selected 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 Japanese science, technology and/or know-how.**

A project may still be considered for funding even if the underlying innovation or technology has emerged from science/know-how outside Japan; however, in such circumstances, the leadership and work carried out 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 eligible GHIT Fund partnerships.

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

## 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** ([https://www.editorialmanager.com/ghitfund\\_trp](https://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-2024-002\_IntentToApply.docx***) and submit the form to the GHIT Fund via Editorial Manager® no later than:

**10:00 am Tokyo time on July 11, 2024**

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 e-mail. The GHIT Fund Management Team will then perform an initial partnership and scope eligibility assessment. **Only eligible applicants will be invited to submit the full proposal and 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 *Intent to Apply* form well in advance of the full proposal submission deadline (10:00am Tokyo time on August 9, 2024) to secure sufficient time to prepare a 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:

<b>10:00 am Tokyo time on August 9, 2024</b>
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Applicants who successfully submit their proposal document will receive a confirmation e-mail. Proposals may not be modified after the submission due date.

Proposals must be reviewed and approved by all Collaboration Partners who are participating in the project prior to submission. The *Collaboration Partners' Approval* form (***ProjectID-CollaborationPartnerApproval.docx***) must be signed by all 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.

## **Proposal Evaluation**

### *Preliminary Examination of Proposals*

TRP proposals will initially be examined to determine or evaluate:

- whether the partnership meets GHIT Fund eligibility criteria
- whether the project primarily originates from or materially involve Japanese science, technology and/or know-how
- whether the project objectives are aligned with the RFP-specified scope
- whether the proposal is complete and addresses all required contents (within the specified budget)
- that the overall budget does not exceed max. ¥100,000,000
- that an organizational credit check of each applicant (so-called “Due Diligence”) reveals no significant issues or concerns\*

\* Each applicant should submit a certificated copy of organization registration and financial statements audited by an independent auditor from the most recent three years.

Applicants will be notified by e-mail of their proposal's readiness for technical evaluation. The GHIT Fund Management Team may ask clarifying questions or request additional information, as needed, to qualify proposals for evaluation.

### ***Technical Evaluation***

All eligible proposals will be evaluated on the basis of 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 and risk management)

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 should include a summary of the outcome of that review in their proposal submission.

Eligible proposals will initially be reviewed by three External Reviewers (ER), typically including Japanese and non-Japanese reviewers. The aggregated ER 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, the GHIT Fund will invite selected proposals for an interview with the SC. **Selected proposals will be notified of the SC interview invitation about approximately one month prior to the scheduled interview date and time.**

Following the interview, the SC will make final funding decisions with appropriate conditions and report the decisions to the GHIT Board. Please note that the GHIT Fund Management Team does not have any influence, authority or decision-making power with respect to: (i) review and evaluation, (ii) funding recommendations and (iii) funding decisions of submitted proposals by the ER, SC 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 SC interview do not guarantee an automatic funding approval for your proposal.

For TRP proposals that specifically aim to conduct disease/technology and market assessment/landscaping research to lead to product development, where limited funding opportunity is available, eligible proposals are subject to an internal review involving the SC and GHIT Fund Management Team.

*(Evaluation procedures and their format may be adjusted due to unforeseen circumstances.)*

### ***Budget evaluation, organizational credit check***

All proposals that pass the other requirements of preliminary evaluation will also be subject to evaluation of budget and an organizational credit check in detail according to the following criteria:

1. The detailed, consolidated budget for each category provided by the Designated Development Partner is reasonable and appropriate to address all contemplated R&D activities of the project by phase/activity/milestone.\*\*
2. Each detailed budget for each category provided by each collaboration partner is reasonable and appropriate to address the project's R&D activities to be conducted by each Collaboration Partner by phase/activity/milestone.\*\*\*
3. Results of the organizational credit check of each applicant reveal no significant issues or concerns.

\*\* The Designated Development Partner should submit a detailed, consolidated budget for each category outlining the project's expenditures as a part of the Project Full Proposal.

\*\*\* Each Collaboration Partner should submit a detailed budget for each category outlining the expenditures for the project to be conducted by each collaboration partner as a part of the Project Full Proposal.

### *Award Administration and Conditions*

After GHIT Board approval, the GHIT Fund will notify applicants of the award decision by e-mail. **Please note that the 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 an Investment Agreement with the GHIT Fund and also submit a contractual agreement among the collaboration partners 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 revoked or considered 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.

### **The GHIT Fund has the right to revoke the award if the following conditions are not agreed upon:**

#### 1. Funding and Use of the Investment

The funding granted by the GHIT Fund (Investment) may be used by the collaboration partners solely for the project in accordance with the Budget (as defined below). Any portion of the Investment unused or uncommitted at the end of the period for the Investment must be promptly returned to the GHIT Fund; and the return of any such portion of the Investment upon an early termination of the period for the Investment will be made in accordance with the termination clause of the relevant Investment Agreement. Any amounts not used properly in accordance with the Budget for the project shall be reimbursed to the GHIT Fund upon its written request.

The designated development partner and the collaboration partners for each project should submit a detailed, categorized budget outlining the projected expenditures for the project as a part of the Project Proposal (such budget as approved by the GHIT Fund, the "Budget"). Only immaterial changes may be made to the projected expenditures for any Budget category without the GHIT Fund's approval, and under all circumstances, changes of ten percent (10%) or more or amounting to more than JPY500,000, whichever is larger, to the projected expenditures for any budget category must be approved in writing by the GHIT Fund in advance of such expenditures. The designated development partner and the collaboration partners may not use the Investment to reimburse expenses incurred prior to the effective date of the Investment Agreement.

The designated development partners shall ensure that the collaboration partners use the Investment strictly in accordance with the preceding two paragraphs.

#### 2. Reporting Procedures

The designated development partner is required to submit bi-annual reports, in accordance with the reporting and payment schedule regarding the expenditure of Investment funds and the progress on the project to be attached to the Investment Agreement. The report templates and submission guidelines will be provided by the GHIT Fund. These templates and guidelines are subject to change upon confirmation by the GHIT Fund. The reports should be submitted electronically to the GHIT Fund in accordance with the instructions shown in each template. The Designated Development Partner also agrees to submit such



other reports as the GHIT Fund may reasonably request. The GHIT Fund reserves the right to demand interim status and other reports at any time.

### 3. Survival

Each Collaboration Partner's obligations will be continuous and survive expiration or termination of the project or the Investment Agreement as expressly provided in the Investment Agreement or otherwise required by law or intended by their nature.

Investments will be awarded for a period reflecting the expected time required to complete agreed activities. **The funding allocation/disbursement will be “by milestone/deliverable” or “on an annual basis”, or in the form of “disbursement in advance”, “deferred disbursement/disbursement after confirmation of delivery of deliverable” or “disbursement by installments (in advance disbursement and deferred disbursement) based on the risk of project.** 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 Agreement 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 or terminate participation in the project or the existing Investment Agreement by one or multiple collaboration partners.

### Access Policy

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

## Key RFP Milestone Dates

<b>RFP Release</b>	<b>June 14, 2024</b>
<b>Intent to Apply Due</b>	No later than 10:00 am Tokyo time on <b>July 11, 2024</b>  *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.  Submit via <b>Editorial Manager® for Target Research Platform</b> ( <a href="https://www.editorialmanager.com/ghitfund_trp/">https://www.editorialmanager.com/ghitfund_trp/</a> )
<b>Full Proposal Due</b>	No later than 10:00 am Tokyo time on <b>August 9, 2024</b>  Submit via <b>Editorial Manager® for Target Research Platform</b> ( <a href="https://www.editorialmanager.com/ghitfund_trp/">https://www.editorialmanager.com/ghitfund_trp/</a> )
<b>Proposals Evaluation and Interview Processes</b>	August 2024 - February 2025 (August 2024 - September 2024*)
<b>Award Notification to All Applicants</b>	February 2025 (Not before September 2024*)
<b>Investment Agreement Fully Executed (Awarded Proposals)</b>	March 2025 (Not before September 2024*)

\*For Technology and Market assessment/landscaping research  
(The schedule is subject to change due to unforeseen circumstances.)

## Inquiries

For any inquiries, please contact [RFPresponse@ghitfund.org](mailto:RFPresponse@ghitfund.org) (please use the e-mail subject line: **GHIT-RFP-TRP-2024-002\_Questions**)

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

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