

## GHIT Fund Product Development Platform Request for Proposals Reference Number: GHIT-RFP-PD-2024-002

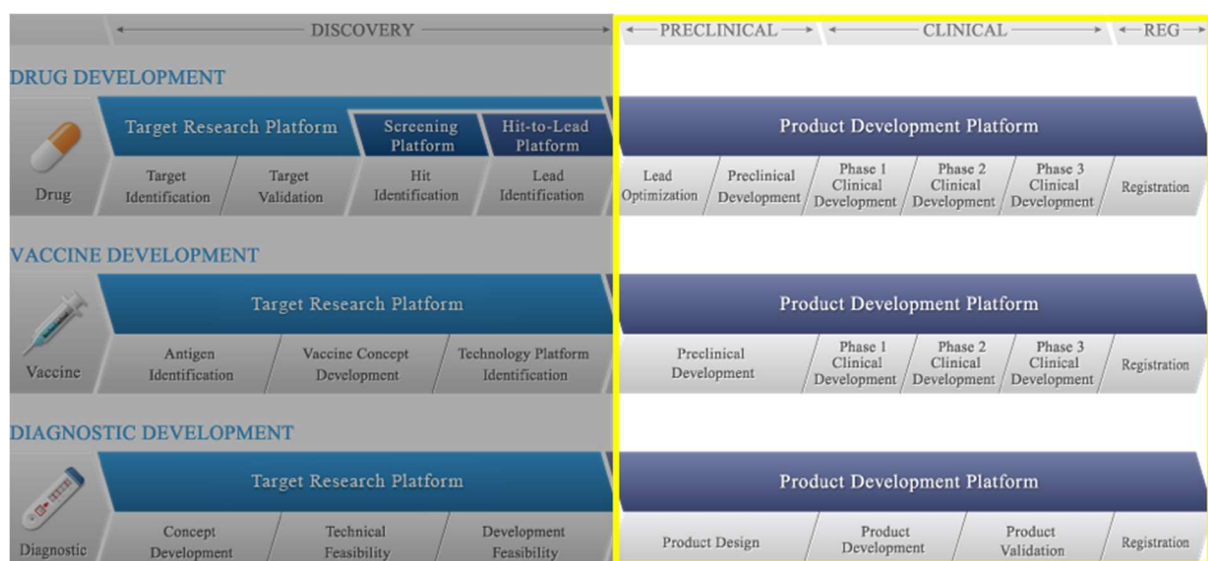
### GHIT Fund Background

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 in 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 Product Development (PD) Platform is one of four GHIT Fund investment platforms.



The GHIT Fund is pleased to announce a product development investment opportunity for the development of new drugs, vaccines or diagnostics for infectious diseases that are prevalent in the developing world. The funding period is up to two years for a proposed collaboration project that focuses on R&D activities in the following development stages:

- Lead optimization
- Preclinical Development (*in vivo* studies, formulation development, chemistry and process validation)
- Clinical Development (Phase 1, 2, and 3 studies, manufacturing scale-up)
- Parallel or concurrent development of multiple interventions (e.g., development of new drugs alongside improved diagnostic tools for disease control, advancing multiple promising drug candidates concurrently)
- Activities to support licensure and WHO prequalification

Additional funding (up to 5,000,000 JPY) will also be available for programs reaching Phase 1 or later, for launch readiness support to ensure implementation of products.

Please note that projects must cover the PD Platform stages illustrated above for vaccines, diagnostics and therapeutics.

### Investment Eligibility

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>

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 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 gives guidelines for the types of organizations expected to form GHIT Fund eligible partnerships.

All partners within the partnership will also be required to sign Global Access Agreements to provide access to relevant data, intellectual property and product use. The GHIT Fund’s access policies can be viewed at <https://www.ghitfund.org/applyforfunding/accesspolicy/en>.

A collaboration project will be eligible if it addresses a priority need for the prevention, diagnosis or treatment of infectious diseases in developing countries within the boundary conditions outlined below. **For projects that cover Proof of Concept (POC) or Phase 2b activities and beyond, collaboration should include at least one commercial partner and, if awarded, an investment amount from GHIT shall be less than 50% of the total project requested budget during the funding period. For diagnostics programs reaching Product Validation stages and beyond, co-funding of over 25% is highly encouraged.**

## Product Scope

The GHIT Fund focuses on leveraging Japanese innovation and expertise to develop innovative drugs, vaccines and diagnostics that are affordable and accessible to endemic populations. A high-level summary of needs associated with NTDs, TB and malaria included in this RFP is provided below. This needs summary was developed through consultation with our partner organizations, PDPs, foundations (e.g., the Bill & Melinda Gates Foundation, Wellcome Trust) and international organizations such as the World Health Organization (WHO). The needs summary has also been reviewed by the GHIT Strategy Committee and approved by the GHIT Board. **Proposals must focus exclusively on addressing one or more of these needs to be eligible for consideration; any product development program should be aligned with profiles and priorities identified in, for example, WHO-developed (or other public health-focused) target product profiles (TPPs), and have a clear value proposition and a timeline roadmap for their implementation at the country level once it has been developed. Funding may also be awarded for the development of innovative drugs, vaccines and diagnostics for other WHO-listed NTDs (e.g., [https://www.who.int/health-topics/neglected-tropical-diseases#tab=tab\\_1](https://www.who.int/health-topics/neglected-tropical-diseases#tab=tab_1)) on a case-by-case basis with clear justifications of the needs.** The criteria for funding include clearly meeting the TPP (if available), a thin global pipeline, clear indication of needs and lack of alternatives.

The proposed project **must** demonstrate its **competitive advantage and how it can potentially address the identified public health need**. The scope of GHIT RFP is subject to adjustments periodically based on the changing global health landscape.

Indication	Drugs	Vaccines	Diagnostics
Buruli ulcer	<ul style="list-style-type: none"> <li>New drugs with shorter treatment durations (&lt;8 weeks)</li> </ul>	<ul style="list-style-type: none"> <li>Out of scope</li> </ul>	<ul style="list-style-type: none"> <li>Rapid diagnostic tools to enable early diagnosis and to confirm cases</li> <li>Improved detection of viable <i>M. ulcerans</i> in wound samples to distinguish between treatment failures and paradoxical reactions through methods such as mycolactone detection and 16S rRNA<sup>1</sup></li> </ul>
Chagas disease	<ul style="list-style-type: none"> <li>New or repurposed drugs with novel mechanisms of action</li> </ul>	<ul style="list-style-type: none"> <li>Out of scope, with the exception of continuation of previously GHIT-funded projects</li> </ul>	<ul style="list-style-type: none"> <li>Out of scope, with the exception of continuation of previously GHIT-funded projects</li> </ul>
Chikungunya	<ul style="list-style-type: none"> <li>Out of scope. Limited investment may be available for pan-antivirals against alphaviruses/ flaviviruses if the approach demonstrates a significant competitive advantage over existing approaches.</li> </ul>	<ul style="list-style-type: none"> <li>Out of scope</li> </ul>	<ul style="list-style-type: none"> <li>High-performance and validated molecular RDTs for use in rural settings</li> <li>RT-PCR tests that are cross-sensitive and specific across lineages/clades</li> <li>Highly sensitive, specific and validated nucleic acid-based RDT that allows for early detection of cases and outbreaks</li> <li>Field-deployable PoC without cross-reactivity with Dengue</li> </ul>

<sup>1</sup>WHO TPP for a Rapid Test for Diagnosis of Buruli Ulcer at the Primary Health-Care Level: <https://www.who.int/publications/i/item/9789240043251>

			<ul style="list-style-type: none"> <li>• High-performance dual IgM+NS1 for screening &amp; individual clinical diagnosis</li> <li>• Multiplexed test with Dengue</li> </ul>
<b>Dengue</b>	<ul style="list-style-type: none"> <li>• Out of scope, with the exception of continuation of previously GHIT-funded projects</li> </ul>	<ul style="list-style-type: none"> <li>• Out of scope, with the exception of continuation of previously GHIT-funded projects</li> </ul>	<ul style="list-style-type: none"> <li>• Multiplexed test with Chikungunya</li> </ul>
<b>Echinococcosis</b>	<ul style="list-style-type: none"> <li>• Out of scope</li> </ul>	<ul style="list-style-type: none"> <li>• Out of scope</li> </ul>	<ul style="list-style-type: none"> <li>• POC test or high sensitivity (Se) and specificity (Sp) serological test for diagnosis of echinococcosis in humans</li> <li>• Accurate, sensitive POC RDTs that can detect inactive cysts</li> <li>• Confirmatory diagnostic test for cure</li> </ul>
<b>Foodborne Trematodiasis</b>	<ul style="list-style-type: none"> <li>• Development of a single-dose cure that is dramatically more efficacious than existing drugs that are available</li> </ul>	<ul style="list-style-type: none"> <li>• Therapeutic and preventive vaccines (e.g., vaccines to prevent or minimize the associated pathology that will reduce the incidence of liver fluke infection-induced cancer)</li> </ul>	<ul style="list-style-type: none"> <li>• POC differential diagnostics for intestinal &amp; liver flukes</li> <li>• Sensitive serological techniques for <i>Fasciola</i></li> <li>• POC tests with high sensitivity to allow for detection of low intensity infections</li> <li>• High Se/Sp serological test for diagnosis of liver fluke and fascioliasis</li> </ul>
<b>Leishmaniasis</b>	<ul style="list-style-type: none"> <li>• Out of scope, with the exception of continuation of previously GHIT-funded projects</li> </ul>	<ul style="list-style-type: none"> <li>• Out of scope, with the exception of continuation of previously GHIT-funded projects</li> <li>• Vaccines for visceral leishmaniasis (VL) (only for vaccine candidates beyond preclinical stages and that offer advantages to the global pipeline)</li> </ul>	<ul style="list-style-type: none"> <li>• Accurate, sensitive POC RDTs for infection by the <i>Leishmania</i> genus (in cutaneous leishmaniasis, CL) that meet the WHO TPP requirements.<sup>2</sup></li> <li>• RDTs for disease diagnosis in VL (including those for asymptomatic infections)</li> <li>• <i>Leishmania</i> genus RDT/confirmatory POC RDT for post kala-azar dermal leishmaniasis (PKDL)</li> </ul>
<b>Leprosy</b>	<ul style="list-style-type: none"> <li>• More effective drugs, or combinations of such drugs, with shorter treatment durations</li> </ul>	<ul style="list-style-type: none"> <li>• Vaccines which confer both pre- and post-exposure immuno-prophylaxis against leprosy without exacerbating nerve damage</li> <li>• Vaccines that show potential to be therapeutic and prophylactic in action.</li> <li>• Proposals should demonstrate that the use of the vaccine has been carefully considered.</li> </ul>	<ul style="list-style-type: none"> <li>• POC test with high specificity to confirm diagnosis and detect infection in the population at risk</li> <li>• Diagnostics capable of identifying symptomatic cases; diagnostics capable of detecting leprosy infection (latent leprosy) among asymptomatic contacts</li> <li>• Diagnostics to detect a biomarker to indicate resistance to MDT drugs</li> </ul>
<b>Lymphatic Filariasis</b>	<ul style="list-style-type: none"> <li>• Development of macrofilaricide to kill adult worms in an infected individual</li> </ul>	<ul style="list-style-type: none"> <li>• Out of scope</li> </ul>	<ul style="list-style-type: none"> <li>• Accurate, sensitive POC RDTs that meet the WHO TPP requirements<sup>3,4</sup> for use in hypo-endemic areas</li> </ul>

<sup>2</sup> WHO TPPs for dermal leishmaniasis (both CL and PKDL) <https://www.who.int/publications/i/item/9789240045224>

<sup>3</sup> Diagnostic test for surveillance of lymphatic filariasis: TPP: <https://www.who.int/publications/i/item/978924001864>

<sup>4</sup> Diagnostic test for lymphatic filariasis to support decisions for stopping triple-therapy mass drug administration: TPP: <https://www.who.int/publications/i/item/9789240018624>

			<ul style="list-style-type: none"> <li>• POC diagnostics that do not cross-react with Loa loa</li> <li>• Diagnostics that can measure infection intensity and drug resistance</li> <li>• Alternative Ag-based RDT for detection of infection with <i>W. bancrofti</i></li> <li>• Ag-based RDT for detection of infection with <i>Brugia</i> spp.</li> <li>• AI technology to assist with accurate quantification of microfilaria in microscopy</li> </ul>
<b>Malaria</b>	<ul style="list-style-type: none"> <li>• New drugs for severe malaria (TCP-1) that demonstrate rapid action and fast clearance and are simple to administer in remote areas</li> <li>• New drugs that advance the eradication agenda for safe and effective use in combination with current antimalarial drugs. Must have a low resistance frequency to prevent the spread of drug resistant parasites (TCP-1). Including: <ul style="list-style-type: none"> <li>• long-acting chemopreventive agents with good safety profiles (TCP-1/4)</li> <li>• that clear asexual blood-stage parasitemia to block transmission (TCP-5)</li> <li>• that clear <i>P. vivax</i> hypnozoites in patients with G6PD deficiency (TCP-3)</li> </ul> </li> <li>• Novel pediatric formulation (e.g., orally dispersible)</li> <li>• New combinations/formulations of existing therapies (e.g., fixed dose triple combinations, pediatric primaquine, rectal antibiotic antimalarial combinations)</li> </ul> <p>*Drug candidates presumed to operate through the same mechanism as existing therapies, or advanced competitive compounds, must demonstrate clear superiority and a lack of cross resistance to be considered for funding</p>	<ul style="list-style-type: none"> <li>• Advance the eradication agenda: <ul style="list-style-type: none"> <li>- more effective and long-lasting preventive vaccines (e.g., blood stage)</li> <li>- transmission blocking vaccines</li> <li>- vaccines for vivax malaria</li> <li>- low-cost monoclonal antibodies (im or sc delivery)</li> </ul> </li> <li>• Projects that focus on vaccine candidates in late-stage development (those that are or can enter clinics within 2 years are preferred) that aligns with the WHO PPC.<sup>5</sup></li> </ul>	<ul style="list-style-type: none"> <li>• RDTs (2-band tests) to identify high Pf parasite densities and patients who need longer ACT treatment courses</li> <li>• Accurate, sensitive POC RDTs for better diagnosis of sub microscopic parasitemia in pregnant women and in pre-elimination evaluations</li> <li>• POC diagnostics to detect parasite resistance</li> <li>• RDTs targeting alternative antigens (other than PfHRP2, LDH or aldolase)</li> </ul>
<b>Mycetoma</b>	<ul style="list-style-type: none"> <li>• Safe and effective oral drugs that have fewer side effects, are more effective and more affordable than current treatments</li> </ul>	<ul style="list-style-type: none"> <li>• Out of scope</li> </ul>	<ul style="list-style-type: none"> <li>• Accurate, sensitive POC RDTs to improve early detection at the primary care level</li> </ul> <p>Diagnostics should meet the WHO TPP requirements.<sup>6</sup></p>
<b>Onchocerciasis</b>	<ul style="list-style-type: none"> <li>• Development of macrofilaricides to kill adult worms in an infected individual</li> </ul>	<ul style="list-style-type: none"> <li>• Out of scope</li> </ul>	<ul style="list-style-type: none"> <li>• Accurate (improved specificity to assess at low thresholds) and sensitive POC RDTs that can be used in hypo-endemic</li> </ul>

<sup>5</sup> Malaria vaccines: preferred product characteristics and clinical development considerations: <https://www.who.int/publications/i/item/9789240057463>

<sup>6</sup> TPP for a rapid test for diagnosis of mycetoma at primary health care level: <https://www.who.int/publications/i/item/9789240047075>

	<ul style="list-style-type: none"> <li>• Pediatric formulations for existing drugs</li> </ul>		<p>areas and/or areas co-endemic for Loiasis. Diagnostics should meet the WHO TPP requirements.<sup>7</sup></p> <ul style="list-style-type: none"> <li>• Diagnostics that can identify Loa loa infection intensity for use in loiasis co-endemic areas, and diagnostics that can detect drug resistance</li> </ul>
<b>Rabies</b>	<ul style="list-style-type: none"> <li>• Safe and effective drugs that would transform the existing approach</li> </ul>	<ul style="list-style-type: none"> <li>• Out of scope</li> </ul>	<ul style="list-style-type: none"> <li>• RDT to diagnose human rabies infection</li> <li>• Field-deployable antemortem diagnostic test for use in primary health care facilities</li> <li>• Differential diagnostics to distinguish between different strains and variants</li> </ul>
<b>Scabies</b>	<ul style="list-style-type: none"> <li>• Out of scope</li> </ul>	<ul style="list-style-type: none"> <li>• Out of scope</li> </ul>	<ul style="list-style-type: none"> <li>• Low-cost POC test for individual level diagnosis and management. The diagnostics should meet the WHO TPP requirements.<sup>8</sup></li> <li>• Population level diagnostics</li> </ul>
<b>Schistosomiasis</b>	<ul style="list-style-type: none"> <li>• Oral drugs that are safer and more effective than existing treatments, are more environmentally friendly to manufacture and are as safe and efficacious as PZQ.</li> <li>• Combinations of drugs that target all life stages, or with a longer duration effect.</li> </ul>	<ul style="list-style-type: none"> <li>• Preventive vaccines (proposals should focus on testing new potential vaccine antigens or using an innovative platform with the long-term aim to achieve high levels of worm reduction and transmission reduction.)</li> </ul>	<ul style="list-style-type: none"> <li>• Accurate, sensitive POC RDTs that can be used in hypo-endemic areas. Diagnostics should meet the WHO TPP requirements.<sup>9</sup></li> <li>• Diagnostics to detect praziquantel resistance/reduced praziquantel efficacy (e.g., in genetically predisposed people with slower/less efficient PZQ metabolism)</li> <li>• New imaging techniques to detect organ damage caused by schistosomiasis for use in low resource settings including portable or modular devices</li> <li>• POC multiplex diagnostics for <i>Schistosoma mansoni</i> or <i>S. haematobium</i> and other co-endemic diseases such as STH</li> <li>• Confirmatory diagnostics for female genital schistosomiasis</li> </ul>
<b>Soil-transmitted helminthiases (STH)</b>	<ul style="list-style-type: none"> <li>• Out of scope, with the exception of continuation of previously GHIT-funded projects</li> </ul>	<ul style="list-style-type: none"> <li>• Preventive vaccines</li> </ul>	<ul style="list-style-type: none"> <li>• Ag-based RDT to detect STH infection</li> <li>• AI technology to assist detection of eggs in microscopy</li> <li>• Multiplex diagnostics for simultaneous detection of multiple STH species</li> </ul>

<sup>7</sup> Onchocerciasis: diagnostic TPP to support preventive chemotherapy: <https://www.who.int/publications/i/item/9789240024496>

<sup>8</sup> Target Product Profiles (TPP) for the development of new diagnostic tools to start and stop mass drug administration for scabies: <https://www.who.int/publications/i/item/9789240045026>

<sup>9</sup> WHO schistosomiasis diagnostics for monitoring, evaluation and surveillance TPPs: <https://www.who.int/publications/i/item/9789240031104>

			Diagnostics should meet the WHO TPP requirements. <sup>10</sup>
<b>Taeniasis-Cysticercosis</b>	<ul style="list-style-type: none"> <li>● Pediatric formulations of existing drugs</li> <li>● More effective drugs</li> </ul>	<ul style="list-style-type: none"> <li>● Out of scope</li> </ul>	<ul style="list-style-type: none"> <li>● Sensitive, specific and affordable POC diagnostics</li> <li>● Effective diagnostics which measure infection intensity &amp; detect drug resistance</li> <li>● POC test or high Se/Sp serological test for diagnosis of <i>T. solium</i> and human cysticercosis</li> </ul>
<b>Tuberculosis<sup>11</sup></b>	<ul style="list-style-type: none"> <li>● Safe and well-tolerated drugs that contribute to a treatment-shortening regimen with the goal of &lt;2 months of treatment, universal/pan-TB regimens that do not require drug susceptibility testing, those that are affordable, convenient to take (i.e., oral, forgiving to non-adherence), safe and well-tolerated</li> <li>● Long-acting injectable (LAI) formulations of TB drugs that are components of potential oral, shorter pan-TB regimens. Cost-effective, scalable, safe and well-tolerated LAIs that provide at least 2 months of effective drug coverage.</li> </ul>	<ul style="list-style-type: none"> <li>● Preventive vaccines and treatment vaccines that show dramatic improvement over current vaccines in the global pipeline</li> </ul>	<ul style="list-style-type: none"> <li>● Accurate, sensitive POC RDTs, specifically non-sputum sample-based TB diagnostics</li> <li>● Development of rapid and scalable targeted next-generation sequencing (tNGS) or phenotypic drug susceptibility testing platforms for available and emerging TB drugs</li> </ul>

\*POC RDTs = Point of Care Rapid Diagnostic Tests

\*In principle, the proposal needs to be focused on the Product Scope in the table.

Please note that successful completion of an award does NOT guarantee GHIT funding for continuation of programs.

Regarding the development of vaccines: new and adapted vaccine technologies including thermostability, fewer doses and needle-free delivery would be an advantage. The GHIT Fund also prioritizes collaborations that aim to simplify the production of complex vaccines in order to help reduce vaccine costs and increase availability.

Regarding the development of diagnostics: new tools developed would ideally have an integrated digital backend to collect, analyze and manage data, where appropriate to the setting, and plans should be clearly articulated in the proposal. Additionally, the REASSURED criteria should be considered as the guiding framework for the development of POC tests.<sup>12</sup>

We are also seeking proposals that will allow for rapid activation of R&D activities during epidemics, with the goal of fast-tracking the availability of effective diagnostics, vaccines and medicines for

<sup>10</sup> Diagnostic target product profile for monitoring and evaluation of soil-transmitted helminth control programmes: <https://www.who.int/publications/i/item/9789240031227>

<sup>11</sup> Please refer to all TB-related WHO TPP here: <https://www.who.int/observatories/global-observatory-on-health-research-and-development/analyses-and-syntheses/target-product-profile/links-to-who-tpps-and-ppcs>

<sup>12</sup> Land, K.J.et. al., REASSURED diagnostics to inform disease control strategies, strengthen health systems and improve patient outcomes. *Nat. Microbiol.* **2019**, *4*, 46–54 (<https://www.nature.com/articles/s41564-018-0295-3>)

priority pathogens. We would be particularly interested in concepts that are aligned with the *WHO list of priority pathogens of epidemic and pandemic threat* (<https://www.who.int/teams/blueprint/who-r-and-d-blueprint-for-epidemics>). Subject to funding availability, proposals SHOULD leverage collaborations with key partners that are already leaders in the field of pandemic preparedness. **Interested parties are invited to e-mail us directly at [RFPResponse@ghitfund.org](mailto:RFPResponse@ghitfund.org) to discuss their concepts.**

## 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 development, presentation, and contract and agreement negotiation (unless otherwise noted by the GHIT Fund).

To receive and manage applications, the GHIT Fund uses **Editorial Manager® for Product Development Platform** (<http://www.editorialmanager.com/ghitfund/>), 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-PD-2024-002\_IntentToApply.docx***) and submit the form to the GHIT Fund via Editorial Manager® no later than:

<b>10:00 am Tokyo time on July 11, 2024</b>
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The *Intent to Apply* form is available on the GHIT website: (<https://www.ghitfund.org/applyforfunding/pdp/en>). Any application not using the designated *Intent to Apply* form for this RFP will not be accepted. Please do not submit any other documents to the GHIT Fund other than 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 Evaluation of Proposals*

Proposals will initially be examined to determine or evaluate:

- whether the partnership meets GHIT Fund eligibility criteria
- whether the project objectives are aligned with the RFP-specified scope
- whether the proposal is complete and addresses all required content
- that an organizational credit check of each applicant (so-called “Due Diligence”) reveals no significant issues or concerns\*

\* Each applicant should submit the certificated copy of organization registration and the financial statement that was 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 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), 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.**

After the interview, the SC will make funding recommendations to the GHIT Board. The GHIT Board will discuss the SC's recommendations and make the final approval as to which proposals will receive GHIT Fund investment. 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.

*(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.**

Please also note:

• Investments will be executed subject to the condition that our funding partners contribute funds to the GHIT Fund in a sufficient amount to support such investments.

• By submitting an application, applicants agree that the GHIT Fund may rescind any awarded investment in its sole discretion at any time.

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 Product Development Platform</b> ( <a href="http://www.editorialmanager.com/ghitfund/">http://www.editorialmanager.com/ghitfund/</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 Product Development Platform</b> ( <a href="http://www.editorialmanager.com/ghitfund/">http://www.editorialmanager.com/ghitfund/</a> )
<b>Proposals Evaluation and Interview Processes</b>	<b>August 2024 – February 2025</b>
<b>Award Notification to All Applicants</b>	<b>February 2025</b>
<b>Investment Agreement Fully Executed (Awarded Proposals)</b>	<b>March 2025</b>

*(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-PD-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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