GHIT Fund Product Development Platform (PD)
Request for Proposals

Reference Number: GHIT-RFP-PD-2025-002

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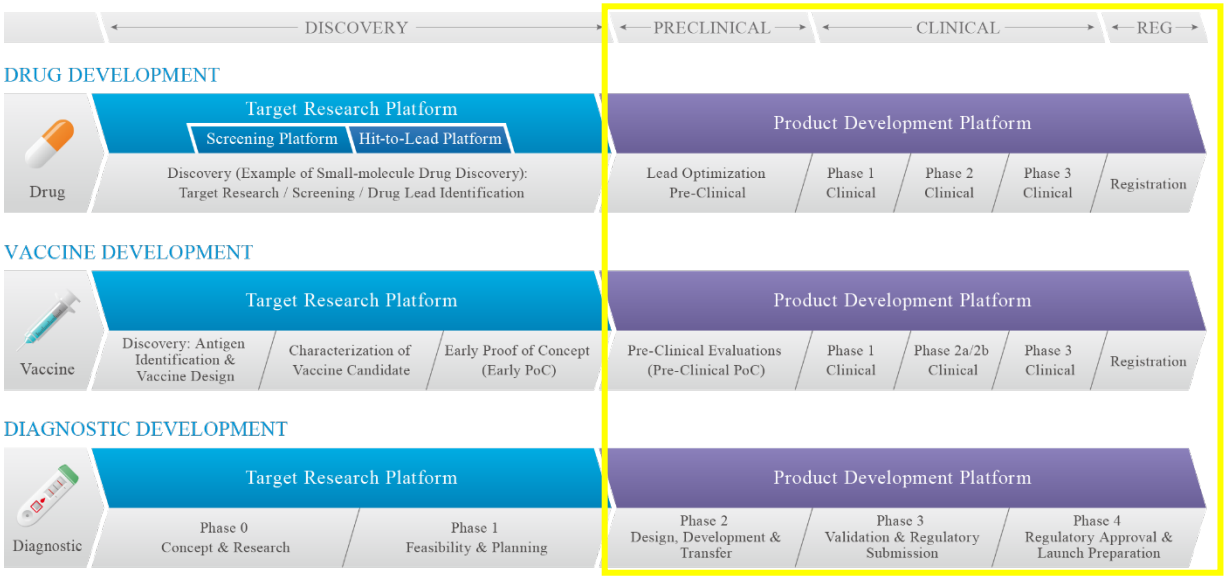
1. GHIT Fund Background

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, healthcare enterprises, the Wellcome Trust and the 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.

2. 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 development stages illustrated above and including:

- 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 assist with the planning for successful implementation of products. This funding is to be incorporated into the funding request.

3. Eligibility

- **Project:**
  The proposal must align with the Project Scope, Disease Scope, Project Duration, and Budget as outlined in this document.

- **Partnership:**
  Each proposal must have <u>at least one Japanese organization and one non-Japanese organization</u>
  Notes:
  - ✓ Whether the organization is Japanese or non-Japanese is defined by the location of its headquarters.
  - ✓ A multinational group of companies will be considered as a single Japanese/non-Japanese organization.
  - ✓ The following table presents examples of organization types.

Organization Types (examples)
● Life science/healthcare companies ● Academic institutions ● Non-profit research organizations and foundations ● Government research institutions ● Product Development Partnerships (PDPs)

- **Organizational information:**

  Each organization must submit a certified copy of its registration and financial statements (audited by an independent auditor) from the most recent 3 fiscal years.
  In the case that the organization is less than 3 years old, the financial statements that are available at the time of the application to GHIT should be submitted.

  For projects that cover Proof of Concept (POC) or Phase 2b activities and beyond, the collaboration should include at least one commercial partner and, if awarded, the investment amount from the GHIT Fund shall be less than 50% of the total requested budget for the project. For diagnostics programs reaching Product Validation stages and beyond, co-funding of over 25% is highly encouraged. Projects that demonstrate a high degree of external leverage, particularly in later stages, are preferred, provided all other factors are comparable. Exceptions for applications without a commercial partner may apply to clinical investigations of registered compounds for new indications or new combinations. In such cases, a credible strategy to secure a commercial partner during or after the funding period must be in place.

  <u>Especially for late-stage programs (Phase 2b and beyond)</u>, applicants are encouraged to seek external input on their development and launch strategy from an independent advisory body (e.g., WHO-Coordinated Scientific Advice or equivalent), and to provide evidence of such review, where available.

4. Product Scope

A high-level summary of needs associated with NTDs, TB and malaria included in this RFP is provided below. This summary was developed through consultation with our partner organizations, PDPs, foundations (e.g., the Gates Foundation, Wellcome Trust) and international organizations such as the World Health Organization (WHO). The summary has also been reviewed by GHIT portfolio advisors and approved by the GHIT Board.

Notes:

- **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 clearly-defined, rational use case, as well as 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) on a case-by-case basis with clear justifications of the needs.**
- The criteria for funding include clearly meeting the TPP (if available)[1], 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.
- Successful completion of an award does NOT guarantee GHIT funding for continuation of programs.

Indication	Drugs	Vaccines	Diagnostics
Buruli ulcer	• New drugs or combination of existing drugs with shorter treatment durations (<8 weeks)	• Out of scope	• Rapid diagnostic tools to enable early diagnosis and to confirm cases • Improved detection of viable *M. ulcerans* in wound samples to distinguish between treatment failures and paradoxical reactions through methods such as mycolactone detection and 16S rRNA[2]
Chagas disease	• New or repurposed drugs with novel mechanisms of action (with an improved pharmacometric approach)	• Therapeutic vaccines only	• Serology or non-serological methods involving biomarkers to identify cure and to assess therapeutic efficacy • Effective method for diagnosis of congenital cases • Continuation of previously GHIT-funded projects

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[1] Links to WHO target product profiles (TPPs) and product profile characteristics (PPCs): https://www.who.int/observatories/global-observatory-on-health-research-and-development/analyses-and-syntheses/target-product-profile/links-to-who-tpps-and-ppcs

[2] 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

Indication	Drugs	Vaccines	Diagnostics
Chikungunya	• 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. Proposals are encouraged to include validated pharmacometric methods for drug assessment	• Out of scope	• High-performance and validated molecular RDTs for use in rural settings • RT-PCR tests that are cross-sensitive and specific across lineages/clades • Highly sensitive, specific and validated nucleic acid-based RDTs that allow for early detection of cases and outbreaks • Field-deployable PoC without cross-reactivity with Dengue • High-performance dual IgM+NS1 for screening & individual clinical diagnosis • Multiplexed test with Dengue
Dengue	• Out of scope, with the exception of continuation of previously GHIT-funded projects	• Out of scope, with the exception of continuation of previously GHIT-funded projects	• Multiplexed test with Chikungunya • Diagnostic tools that utilize biomarkers to assess the risk of progression to severe disease
Echinococcosis	• Out of scope. Limited investment may be available for new or repurposed drugs with novel mechanisms of action, together with an improved pharmacometric method for assessment of drug responses	• Out of scope	• POC tests or high sensitivity (Se) and specificity (Sp) serological tests for diagnosing echinococcosis in humans • Accurate, sensitive POC RDTs that can detect inactive cysts • Confirmatory diagnostic tests for cure

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Indication	Drugs	Vaccines	Diagnostics
Foodborne trematodiases	• Development of a single-dose cure that is dramatically more efficacious than existing drugs currently available	• 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)	• POC differential diagnostics for intestinal & liver flukes • Sensitive serological or biomolecular techniques for *Fasciola* • POC tests with high Se to allow for detection of low intensity infections • High Se/Sp serological tests for diagnosis of liver fluke and fascioliasis
Leishmaniasis	• Continuation of previously GHIT-funded projects. • Local treatments for cutaneous leishmaniasis (CL) (e.g., paromomycin cream, intralesional injections) • Safer, shorter treatments for visceral leishmaniasis (VL) (proposals must clearly demonstrate how the candidate contributes to the global VL treatment landscape) Applicants are encouraged to include in their proposals better methods of assessing therapeutic response in both CL and VL	• Out of scope, with the exception of continuation of previously GHIT-funded projects • Vaccines for VL (only vaccine candidates beyond preclinical stages and that offer advantages to the global pipeline)	• Accurate, sensitive POC RDTs for infection by the *Leishmania* genus (in CL) that meet the WHO TPP requirements[3] • *Leishmania* species-specific RDTs or other rapid methods for CL diagnosis • RDTs and bimolecular tests for disease diagnosis in VL (including those for asymptomatic infections) • Confirmatory POC RDTs for post kala-azar dermal leishmaniasis (PKDL)

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[3] WHO TPPs for dermal leishmaniasis (both CL and PKDL):https://www.who.int/publications/i/item/9789240045224

Indication	Drugs	Vaccines	Diagnostics
Leprosy	• More effective drugs, or drug combinations, with shorter treatment durations	• Vaccines which confer both pre- and post-exposure immuno-prophylaxis against leprosy without exacerbating nerve damage • Vaccines that show potential to be therapeutic and prophylactic in action • Proposals should demonstrate that the use of the vaccine has been carefully considered	• POC tests with high Sp to confirm diagnosis of borderline and tuberculoid leprosy and detect infection in at-risk populations[4] • Diagnostics capable of detecting leprosy infection (latent leprosy) among asymptomatic contacts[5] • Diagnostics to detect a biomarker to indicate resistance to MDT drugs
Lymphatic Filariasis	• Development of macrofilaricide to kill adult worms in an infected individual	• Out of scope	• Accurate, sensitive POC RDTs that meet the WHO TPP requirements[6, 7] for use in hypo-endemic areas • POC diagnostics that do not cross-react with Loa loa • Diagnostics that can measure infection intensity and drug resistance • Alternative Ag-based RDT for detection of infection with *W. bancrofti* • Ag-based RDT for detection of infection with *Brugia* spp. • AI technology to assist with accurate quantification of microfilaria in microscopy

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[4] TPP for a diagnostic test to confirm leprosy in individuals with clinical signs and symptoms: https://iris.who.int/handle/10665/371647

[5] TPP for a diagnostic test to detect Mycobacterium leprae infection among asymptomatic household and familial contacts of leprosy patients: https://www.who.int/publications/i/item/9789240074231

[6] Diagnostic test for surveillance of lymphatic filariasis: TPP: https://www.who.int/publications/i/item/9789240018648

[7] Diagnostic test for lymphatic filariasis to support decisions for stopping triple-therapy mass drug administration: TPP: https://www.who.int/publications/i/item/9789240018624

Indication	Drugs	Vaccines	Diagnostics
Malaria	***Top Priority:*** • **Triple artemisinin-based combination therapies (TACTs)** to counter artemisinin resistance ***Other Priorities:*** • **New molecules for the treatment of uncomplicated malaria, overcoming current resistance and offering the potential for treatment shortening:** - To be used safely and effectively in combination with current antimalarials - Low risk of emergence of drug-resistant parasites • **Drugs to treat severe malaria:** - Rapid action, fast clearance (parasite clearance <72 hours) - Simple to administer in remote areas • **Pediatric formulations:** - Child friendly versions of current therapeutics (e.g., fixed dose triple combinations, pediatric primaquine, rectal antibiotic antimalarial combinations) • **Chemoprevention:** - Long duration of efficacy with acceptable safety profiles - For use in endemic areas - Improved methods of assessment • **Transmission blocking drugs:** - Drugs that clear both asexual and sexual blood stage parasitemia and/or prevent viable transmission in the mosquito • **Liver stage drugs:** - Drugs that clear *P. vivax* hypnozoites with an improved safety profile over primaquine/tafenoquine with respect to G6PD deficient patients	• Advance the eradication agenda: - More effective and long-lasting, multistage falciparum vaccines (e.g., sporozoite, liver stage, blood stage, and/or transmission-blocking stages), with protective efficacy in malaria-exposed adults in areas of high malaria endemicity - Important that vaccines have promise for outperforming current candidates in the global pipeline and provide a path for benchmarking against such candidates - Vaccines for vivax malaria - Low-cost monoclonal antibodies (im or sc delivery) that provide cover for a season (4–6 months) from a single injection, with minimal heat stability and shelf-life issues • Projects that focus on vaccine candidates in late-stage development (those that have entered or can enter clinics within 2 years are preferred) that align with the WHO PPC[8]	• RDTs (with an additional band) to detect high Pf parasite densities and thus allow identification of patients at higher risk of severe malaria requiring longer ACT treatment courses • RDTs targeting alternative antigens (other than PfHRP2, LDH or aldolase) • Accurate, sensitive POC RDTs for better diagnosis of sub microscopic parasitemia in pregnant women and in pre-elimination evaluations • POC diagnostics to detect parasite resistance

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[8] Malaria vaccines: preferred product characteristics and clinical development considerations: https://www.who.int/publications/i/item/9789240057463

Indication	Drugs	Vaccines	Diagnostics
Mycetoma	• Safe and effective oral drugs that have fewer side effects and are more effective, with shorter treatment durations and more affordable than current treatments	• Out of scope	• Accurate, sensitive POC RDTs to improve early detection at the primary care level • Diagnostics that allow differentiation between actinomycetoma and eumycetoma at remote clinics • Diagnostics should meet the WHO TPP requirements[9]
Onchocerciasis	• Development of macrofilaricides to kill adult worms in an infected individual • Efficient treatment for L3 larvae • Continuation of previously GHIT-funded projects	• Out of scope	• Accurate (improved Sp to assess at low thresholds) and sensitive POC RDTs that meet the WHO TPP requirements[10] • Diagnostic tools that can detect alive adult *O. volvulus* • Diagnostics that can identify and detect drug resistance to *O. volvulus* • Diagnostics that can identify Loa loa infection intensity or highly infected subjects for use in loaiasis co-endemic areas
Rabies	• Safe drugs that can be given post-vaccine exposure or treatment drugs that provide a cure without causing long-term complications	• Out of scope	• RDTs to diagnose human rabies infection • Field-deployable ante-mortem diagnostic tests for use in primary health care facilities
Scabies	• Out of scope	• Out of scope	• Low-cost POC tests for individual level diagnosis and management. Diagnostics should meet the WHO TPP requirements[11] • Population level diagnostics

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[9] TPP for a rapid test for diagnosis of mycetoma at primary health care level: https://www.who.int/publications/i/item/9789240047075

[10] Onchocerciasis: diagnostic TPP to support preventive chemotherapy: https://www.who.int/publications/i/item/9789240024496

[11] 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

Indication	Drugs	Vaccines	Diagnostics
Schistosomiasis	• Oral drugs that target the juvenile stages of infection and thus give promise for shorter interventions for eradication • Combinations of drugs that target all life stages, or with a longer duration effect • Preventive therapeutics such as topical and barrier creams that prevent infection e.g. cancericidal creams and soaps	• Vaccines that can contribute to elimination (interruption of transmission), ideally protective across species and >90% efficacious	***Top Priority:*** • PoC tests for detection of biomarker(s) specific for current active infection of *Schistosoma mansoni* and/or *S. haematobium*, for use in endemic areas. Diagnostics should meet the WHO TPP requirements[12] • Confirmatory diagnostics for female genital schistosomiasis • Diagnostics to detect praziquantel resistance/ reduced praziquantel efficacy (e.g., in genetically predisposed people with slower/less efficient PZQ metabolism) ***Other Priorities:*** • New imaging techniques to detect organ damage caused by schistosomiasis for use in low-resource settings, including portable or modular devices • POC multiplex diagnostics for *S. mansoni* or *S. haematobium* and other co-endemic diseases such as STH
Soil-transmitted helminthiases (STH)	• Out of scope, with the exception of continuation of previously GHIT-funded projects	• Preventive vaccines	***Top Priority:*** • AI technology to assist detection of eggs in microscopy • Multiplex diagnostics for simultaneous detection of multiple STH species ***Other Priorities:*** • Ag-based RDT to detect STH infection • Semi-quantitative RDTs to estimate egg loads Diagnostics should meet the WHO TPP requirements[13]

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[12] WHO schistosomiasis diagnostics for monitoring, evaluation and surveillance TPPs: https://www.who.int/publications/i/item/9789240031104

[13] Diagnostic target product profile for monitoring and evaluation of soil-transmitted helminth control programmes: https://www.who.int/publications/i/item/9789240031227

Indication	Drugs	Vaccines	Diagnostics
Taeniasis /cysticercosis	• More effective drugs	• Out of scope	• Sensitive, specific and affordable POC diagnostics • Effective diagnostics which measure infection intensity & detect drug resistance • POC tests or high Se/Sp serological tests for diagnosis of *T. solium* and human cysticercosis
Tuberculosis[14]	• Safe and well-tolerated drugs that contribute to a treatment-shortening regimen with the goal of <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 • 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	• Preventive vaccines that show promise for outperforming current vaccines in the global pipeline and provide a path for benchmarking against such candidates	• Accurate, sensitive POC RDTs (Point-of-care rapid diagnostic tests), specifically non-sputum sample-based TB diagnostics • Development of rapid and scalable targeted next-generation sequencing (tNGS) or phenotypic drug susceptibility testing platforms for available and emerging TB drugs • AI-driven radiograph interpretation

Additional Considerations Across Product Categories:

*Regarding the development of **drugs**:*
We encourage the development of pediatric formulations for existing drugs across all areas of the scope.

*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.[15]
We also encourage the development of **multiplex diagnostics for different NTDs**, as theoretical and technical platforms for rapid, point-of-care (POC) multiplex diagnostics are now available. In addition, **multiplex differential diagnostics** that can distinguish between disease stages of the same pathogen—where different interventions are required—are likewise encouraged.

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[14] 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

[15] 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)

We are also seeking proposals that will allow for rapid activation of R&D activities during epidemics, which result in the early availability of effective diagnostics, vaccines and medicines for 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), excluding approaches which are **specific only** for COVID-19. Subject to funding availability, proposals SHOULD leverage collaborations with key partners that are already leaders in the field of pandemic preparedness. Especially for vaccine development proposals for disease with pandemic potential and diseases with public health emergency, applicants are strongly encouraged to seek funding from other agencies in parallel (apply to all development phases). **Interested parties are invited to e-mail us directly at RFPResponse@ghitfund.org to discuss their concepts.**

5. Partnership Roles

Partner organizations in a partnership are called Collaboration Partners (CPs). The partnership must nominate one partner as a Designated Development Partner (DDP), who has the primary responsibility for the project's execution, while CPs support the project through compliance with their respective obligations. The roles and responsibilities of the DDP and the CPs are summarized below. Please note that DDP must comply with the roles of DDP as well as the roles of CP.

5.1 Roles and Responsibilities of the Designated Development Partner

From Proposal submission to proposal evaluation

- Act as primary point of contact with the GHIT Fund
- Coordinates and submits proposals and relevant documents on behalf of all the CPs

After Award

- Primary Representative: Main liaison between the CPs and the GHIT Fund.
- Funding Recipient: Receives the funding from the GHIT Fund and is responsible for distributing funding to other CPs.
- Project Oversight: Ensures overall project performance and monitors each CP's work and compliance with the terms of the Investment Agreement.
- Investment Management: Manages the use of the investment in accordance with the approved budget; oversees audits, financial reporting, and related requests.
- Reporting: Oversees and submits the Progress Reports, including itemized expenditure reports, and ensures proper documentation and compliance with the GHIT Fund's guidelines.
- Dual Role as CP: In addition to the roles and responsibilities unique to the DDP, the DDP must adhere to the roles and responsibilities of a CP to the extent it does not interfere or conflict with its role as a DDP.

5.2 Roles and Responsibilities of the Collaboration Partners

From Proposal submission to proposal evaluation

- Provides necessary input and information to the DDP for the proposal preparation

After Award

- Project Participation and Obligations: Each CP delivers their assigned portion of the project and complies with all the terms of the Investment Agreement.
- Collaboration Agreement: Enters into a separate contractual relationship with the other CPs, subject to the GHIT Fund's approval, to formalize their collaboration.

- Approval of Subcontractors: CPs must adhere to the limitation on the hiring of subcontractors, under which CPs may not hire subcontractors without the GHIT Fund's approval unless the subcontractors have been previously identified in the project proposal.
- Audit and Financial Compliance: Each CP maintains accurate financial records and provides access to all relevant documentation; subject to potential audits by both the DDP and the GHIT Fund.
- Legal and Ethical Compliance: CPs must comply and adhere to all applicable laws and ethical standards, including those regarding anti-corruption, anti-terrorism.
- Legal Responsibility: CPs must indemnify the GHIT Fund and its affiliates from and against any legal actions or liabilities arising out of the Investment or the project, except to the extent such action or liability is attributable to any gross negligence or willful misconduct by the GHIT Fund.
- Global Access and Product Strategy: CPs must ensure that the project meets the requirements under the GHIT Fund's global access policies, including dissemination of knowledge and accessibility of the resulting products to developing countries.

6. Applicant Instructions

Editorial Manager®

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 the *Intent to Apply* documents or Proposals that are not submitted through the above-mentioned system will not be accepted.

Language: All correspondence and documents relating to this RFP shall be written in English.

Associated Expenses: The applicant shall bear all costs associated with the preparation and submission of the proposal, including costs associated with proposal presentation and contract negotiation.

Step 1 - Intent to Apply

Interested applicants must complete the *Intent to Apply* form (***GHIT-RFP-PD-2025-002_IntentToApply.docx***) and submit the form to the GHIT Fund via Editorial Manager® no later than:

10:00 am JST on July 9, 2025

The *Intent to Apply* form is available on the GHIT Fund website:
https://www.ghitfund.org/applyforfunding/pdp/en

- *Intent to Apply* form must be reviewed and approved by all Collaboration Partners prior to submission.
- 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.
- After submitting the *Intent to Apply* form, you 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 access to 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 to secure sufficient time to prepare a full proposal.

Step 2 - Full Proposal Submission

Applicants invited to submit a full proposal are required to do so via Editorial Manager® no later than:

10:00 am JST on August 7, 2025

- Proposals must be reviewed and approved by all Collaboration Partners 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.
- Applicants who successfully submit their proposal documents will receive a confirmation e-mail.
- Proposals may not be modified after the submission due date.
- Additional documents (including additional data and/or supporting documents) cannot be accepted after the deadline. 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 but may be resubmitted in future RFPs.

7. Full Proposal Evaluation

The following evaluations will be conducted for the submitted Full Proposal.

7.1 Preliminary Evaluation

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 the required organizational documents have been submitted for each organization.

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. Organizational information and financial statements will be reviewed during the Budget evaluation, organizational credit check step.

7.2 Technical Evaluation

All eligible proposals will be evaluated 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 (e.g., collaboration capabilities and expertise, project history)
- Project management (e.g., performance and risk management, decision-making process

Evaluation Process:

- Eligible proposals will initially be reviewed by three External Reviewers (ER), typically including Japanese and non-Japanese reviewers.
- The aggregated ER review results and the proposals will then be shared with the GHIT Fund Selection Committee (SC) for evaluation.
- After the evaluation, the GHIT Fund will invite selected proposals for an interview with the SC. **Selected proposals will be notified of the SC interview invitation approximately one month prior to the scheduled interview date and time.**
- ER and SC members have signed non-disclosure agreements with the GHIT Fund prior to the evaluation.
- Evaluation procedures and their format may be adjusted due to unforeseen circumstances.
- 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.

7.3 Budget evaluation, organizational credit check

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

- 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.*
- Results of the organizational compliance and credit check reveal no significant issues or concerns.**

Depending on the outcome of the organizational credit check, conditions may apply for the funding from the GHIT Fund (milestone-based payments, deliverable-based payment and any other installment payments etc.) or may be considered not fundable.

**A detailed budget for each category outlining the expenditures for the project to be conducted by each Collaboration Partner should be outlined in the budget sheet as well as the budget section of the Project Full Proposal.*
***Organizational status and adherence to relevant compliance policies should be outlined in the relevant part of the Project Full Proposal.*

For reference, the amounts of previous grant awards can be viewed at the GHIT Fund website (GHIT Investment Overview https://www.ghitfund.org/investment/overview/en) .

7.4 Award Administration and Conditions

Notification of Results

- 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 feedback to applicants receiving a non-award decision.**

Agreements

- 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 put in place 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 the award notification.

- The Investment Agreement template will be shared with the applicants who are considered eligible to submit the Proposal.
- The award may be revoked or considered void if any of the conditions are not met.
- Please note that (1) the GHIT Fund may update the Investment Agreement template from time to time, and (2) while the GHIT Fund is open to discuss the terms of the Investment Agreement on a case-by-case basis, the template represents the GHIT Fund's positions generally except in certain circumstances where the Collaboration Partners can present reasonable grounds for exceptions or modifications (such as undue burdens). 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.

7.5 Access Policy

The applicants are required to agree to the Access Policy of the GHIT Fund to ensure that GHIT's objectives of providing equitable and affordable access are met.
Details about the GHIT Access Policy can be found here:
https://www.ghitfund.org/applyforfunding/accesspolicy/en.

7.6 Disclaimer

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.

8. Key RFP Milestone Dates

RFP Release	**June 12, 2025**
Intent to Apply Due	No later than 10:00 am JST on **July 9, 2025** *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 **Editorial Manager® for Product Development Platform** (http://www.editorialmanager.com/ghitfund/)
Full Proposal Due	No later than 10:00 am JST on **August 7, 2025** Submit via **Editorial Manager® for Product Development Platform** (http://www.editorialmanager.com/ghitfund/)
Proposals Evaluation and Interview Processes	**August 2025 - February 2026**
Award Notification to All Applicants	**February 2026**
Investment Agreement Fully Executed (Awarded Proposals)	**March 2026**

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

For proposals addressing diseases with Pandemic Potentials and diseases with public health emergency, Proposals may be submitted outside the above-mentioned timeline, please contact the GHIT Fund for more details.

9. Inquiries

For any inquiries, please contact RFPresponse@ghitfund.org (please use the e-mail subject line: **GHIT-RFP-PD-2025-002_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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