

GHIT Fund Product Development (PD) Request for Proposals

Reference Number: GHIT-RFP-PD-2026-001

Table of Contents

1. GHIT Fund Background	2
2. Funding Opportunity	2
3. Eligibility	3
4. Project Scope	4
5. Partnership Roles	11
5.1. Roles and Responsibilities of the Designated Development Partner (DDP)	11
5.2. Roles and Responsibilities of the Collaboration Partners (CPs)	12
6. Applicant Instructions	12
7. Full Proposal Evaluation	13
7.1. Preliminary Screening	13
7.2. Technical Evaluation	14
7.3. Due Diligence	14
8. Award Administration and Conditions	14
9. Access Policy	15
10. Privacy Policy	15
11. Disclaimer	15
12. Key RFP Milestone Dates	16
13. Inquiries	16

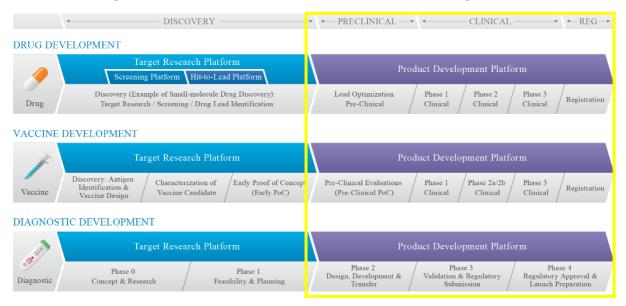
1. GHIT Fund Background

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 healthcare companies, academia and research institutions, and Product Development Partnerships (PDPs). These partnerships have proved 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 research and development of new health technologies, including drugs, vaccines and diagnostics for infectious diseases prevalent in LICs and LMICs. 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 Japanese innovation for the research and development of new technologies for vulnerable 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 investments.

2. Funding Opportunity

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



The PD offers support for innovative global health R&D, 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 (Up to 5,000,000 JPY can be included in the budget for projects reaching Phase 1 or later, for launch readiness support to assist with the planning for successful implementation of products.)

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 at least one Japanese organization and one non-Japanese organization.

Notes:

- ✓ All organizations in the partnership must be legally registered.
- Whether the organization is Japanese or non-Japanese is defined by the location of its headquarters. e.g., Example Corp. is headquartered in Japan and has a subsidiary in the United States, Example Corp. U.S. Even if only Example Corp. U.S. participates in the project, it will be considered a Japanese organization.
- ✓ Group companies are considered a single organization.
 - e.g., If Example Corp. has a subsidiary, Example Corp. Technologies, and employees from both companies participate in the project, register one of the organizations as the representative.
- ✓ 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)
- ✓ For projects covering clinical trials and beyond for drugs and vaccines, or Phase 2 "Design, Development & Transfer" and beyond for diagnostics, the partnership must include at least one commercial partner.
 - Exceptions may be made for applications involving clinical investigations of registered compounds for new indications or new combinations.
 - In such cases, applicants must provide a credible strategy in the full proposal to secure a commercial partner during or after the funding period.
- ✓ For projects in Phase 2b and beyond, applicants are strongly encouraged to seek external input on their development and launch strategy from an independent advisory body (e.g., WHO-Coordinated Scientific Advice or equivalent group of experts in the field), and to provide evidence of such review, where available.

Organizational Information:

Each organization must submit a certified copy of its registration and financial statements (audited by an independent auditor) from the most recent three fiscal years.

If the organization is less than three years from establishment, it must submit the financial statements that are available at the time of application .

• Co-funding:

For projects that cover Proof of Concept (POC) or Phase 2b activities and beyond, the investment amount from the GHIT Fund must be less than 50% of the total budget for the project.

For diagnostics projects reaching Phase 3 "Validation & Regulatory Submission" 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.

4. Project Scope

Background:

The project scope below 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 scope has also been reviewed by GHIT portfolio advisors and approved by the GHIT Board. Note that the scope is subject to adjustments periodically based on the changing global health landscape.

Requirements:

- The proposed project must demonstrate its competitive advantage and how it can potentially address the identified public health need.
- Proposals must focus exclusively on addressing one or more of these needs to be eligible for consideration.
- Any product development program should ideally be aligned with profiles and priorities identified in, for example, WHO-developed (or other public health-focused) target product profiles (TPPs; provided these are up to date and appropriate), 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.
- The criteria for funding include clearly meeting TPP (if available)¹; if not, the project must instead demonstrate a strong clinical rationale, feasibility, potential affordability and deployability, as well as a thin global pipeline, clear indication of needs, and lack of alternatives.
- Successful completion of an award does NOT guarantee GHIT funding for continuation of programs.
- 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.

Notes for disease with pandemic potential and public health emergency:

- Interested parties are encouraged to contact us at RFPResponse@ghitfund.org to share their concepts and ideas, which will help inform the design of our next RFP.
- There is limited funding availability for diseases with pandemic potential and public health emergency.
- For diseases with pandemic potential, we particularly welcome proposals that address one or more virus families with epidemic or pandemic potential, excluding **COVID-19-specific** approaches and on HIV. Clear justification with relevant references is required for consideration.
- For diseases with public health emergency, the disease has to be declared as public health emergency in at least one country, excluding COVID-19-specific approaches.
- Funding is intended to be catalytic; therefore, wherever possible, proposals may build on collaborations with established leaders in pandemic preparedness.
- For vaccine development, applicants are strongly encouraged to seek parallel funding from other agencies across all development phases.

Notes for Intervention Scope:

For all interventions:

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

Proposals that conduct research on improving methods of assessment are within scope, as such research will facilitate the development and responsible use of new products in global health.

For **drugs**.

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

For 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.

For 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. 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.

Indication	Drugs	Vaccines	Diagnostics
Buruli ulcer	New drugs or combination of existing drugs with shorter treatment durations (<8 weeks)	• Out of scope	PoC diagnostic to enable early diagnosis and to confirm cases 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 ³
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

² 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)

³ 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	Highly sensitive, specific and validated RDTs that allow for early detection of cases and outbreaks, and for use in rural settings RT-PCR tests that are crosssensitive and specific across lineages/clades Field-deployable PoC without cross-reactivity with Dengue High-performance mixed antigen and antibody based RDTs 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
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 <i>Fasciola</i> 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

Indication	Drugs	Vaccines	Diagnostics
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 ⁴ 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)
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 populations⁵ Diagnostics capable of detecting leprosy infection (latent leprosy) among asymptomatic contacts⁶ 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^{7 8} 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 <i>W. bancrofti</i> Ag-based RDT for detection of infection with <i>Brugia</i> spp. AI technology to assist with accurate quantification of microfilaria in microscopy

 $^{^{4}\} WHO\ TPPs\ for\ dermal\ leish maniasis\ (both\ CL\ and\ PKDL): \underline{https://www.who.int/publications/i/item/9789240045224}$

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

⁶ 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

⁷ Diagnostic test for surveillance of lymphatic filariasis: TPP: https://www.who.int/publications/i/item/9789240018648

⁸ 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	Triple artemisinin-based combination therapies (TACTs) to counter artemisinin resistance Other Priorities: New molecules for the treatment of uncomplicated malaria that are in late preclinical or early development, overcoming current resistance: 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 (parasite clearance (parasite 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:	RDTs (with an additional band) to detect high Pf parasite densities and thus allow identification of patients at higher risk of severe malaria and who require longer ACT treatment courses to prevent recrudescence 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 preelimination evaluations POC diagnostics to detect parasite resistance

 $^{^9}$ Malaria vaccines: preferred product characteristics and clinical development considerations: $\underline{\text{https://www.who.int/publications/i/item/9789240057463}}$

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 10
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 requirements¹¹ Diagnostic tools that can detect alive adult <i>O. volvulus</i> Diagnostics that can identify and detect drug resistance in <i>O. volvulus</i> Diagnostics that can quantify Loa loa or identify heavily 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 (to augment post exposure prophylaxis or treat rabies encephalitis without neurological deficit in survivors)	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 12 Population level diagnostics

TPP for a rapid test for diagnosis of mycetoma at primary health care level: https://www.who.int/publications/i/item/9789240047075
Onchocerciasis: diagnostic TPP to support preventive chemotherapy: https://www.who.int/publications/i/item/9789240024496

¹² 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 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	Vaccines that can contribute to elimination (interruption of transmission), ideally protective across species and >90% efficacious	 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 requirements¹³ 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 14

 $^{^{13} \} WHO \ schistosomias is \ diagnostics \ for \ monitoring, \ evaluation \ and \ surveillance \ TPPs: \\ \underline{https://www.who.int/publications/i/item/9789240031104}$

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
	More effective drugs	• Out of scope	Sensitive, specific and affordable POC diagnostics
Taeniasis /Cysticercosis			Effective diagnostics which measure infection intensity & detect drug resistance
/Cysticer cosis			• POC tests or high Se/Sp serological tests for diagnosis of <i>T. solium</i> and human cysticercosis
Tuberculosis 15	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

5. Partnership Roles

Upon applying to the GHIT Fund, each partner organization in a partnership are called Collaboration Partners (CPs). The partnership must nominate one CP as a Designated Development Partner (DDP), who holds primary responsibility for the execution of the project, while the other CPs support the project through compliance with their respective obligations.

The roles and responsibilities of the DDP and the CPs are summarized below. 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 (DDP)

From Proposal Submission to Evaluation:

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

When Awarded:

- 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.

 $^{{}^{15}\} Refer to \ all\ TB-related\ WHO\ TPP\ here:\ \underline{https://www.who.int/observatories/global-observatory-on-health-research-and-development/analyses-and-syntheses/target-product-profile/links-to-who-tpps-and-ppcs}$

- 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 (CPs)

From Proposal Submission to Evaluation:

• Provides necessary input and information to the DDP for the proposal preparation.

When Awarded:

- 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 LICs and LMICs.

6. Applicant Instructions

Editorial Manager®:

To receive and manage applications, the GHIT Fund uses **Editorial Manager® for Product Development Platform** (https://www.editorialmanager.com/ghitfund/), an online document submission system dedicated to this funding platform.

Note that the *Intent to Apply* (ITA) form or the full proposal that is 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 (ITA) Form Submission

Interested applicants must complete the ITA form and submit the form to the GHIT Fund via Editorial Manager® no later than:

10:00 am on November 27, 2025 (Japan Standard Time)

The ITA form is available on the GHIT Fund website: https://www.ghitfund.org/applyforfunding/pdp/en

Notes:

• The ITA form must be reviewed and approved by all Collaboration Partners prior to submission

- Any application not using the designated ITA form for the current RFP round will not be accepted
- Do not attach any documents to the ITA form
- When submitting your ITA form on the Editorial Manager®, list all the Collaboration Partners participating in the project; the name and details (including email address) of at least one representative from each organization must be indicated
- After submitting the ITA form, you will receive a confirmation email

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 templates.

The eligibility assessment will be conducted upon receipt of the ITA form, and applicants will be notified of the results once it is complete. <u>Applicants are encouraged to submit the ITA form well in advance of the deadline to secure sufficient time to prepare a full proposal.</u>

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 on January 16, 2026 (Japan Standard Time)

Notes:

- Proposals must be reviewed and approved by all Collaboration Partners prior to submission
- The *Collaboration Partners' Approval* form must be signed by all Collaboration Partners, and a PDF copy must be submitted along with other proposal documents (Electronic signatures are acceptable)
- Each organization must submit a certified copy of its registration and financial statements audited by an independent auditor from the most recent three fiscal years, as an attachment to *Exhibit A* form
- Applicants who successfully submit their proposal documents will receive a confirmation email.
- 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 Screening

Proposals will initially be examined to determine or evaluate:

- whether the partnership meets GHIT Fund eligibility criteria stated in the current RFP
- whether the project objectives are aligned with the scope stated in the current RFP
- 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 email 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 technical evaluation.

7.2. Technical Evaluation

All eligible proposals will be evaluated based on the following criteria:

- Scientific and technical merit
- Potential impact
- Partnership
- Project management

Evaluation Process:

- Eligible proposals will initially be reviewed by three External Reviewers (ER), typically including both Japanese and non-Japanese reviewers with expertise in the field.
- 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.
- After the interview, the SC will make funding recommendations to the GHIT Fund Board. The GHIT Fund Board will discuss the SC's recommendations and make the funding decision with appropriate conditions.
- Evaluation procedures and their format may be adjusted due to unforeseen circumstances.

7.3. Due Diligence

Due diligence (compliance and credit check) will be conducted for all the CPs in detail according to the following criteria:

- Detailed budget for each category provided by each CP is reasonable and appropriate to address the project's R&D activities to be conducted by each CP by phase/activity/milestone
- Results of the compliance and credit check reveal no significant issues or concerns

Depending on the outcome of the due diligence process, conditions may apply for the funding from the GHIT Fund (e.g., milestone-based payments, deliverable-based payments and any other installment payments etc.) or may be considered not fundable.

8. Award Administration and Conditions

Notification of Results:

- Following the funding decision, applicants will receive the award decision by email, with a notification letter attached.
- Note that the GHIT Fund is not able to provide additional feedback to applicants receiving a non-award decision beyond what is stated in the notification letter.

Agreements:

- If the applicant receives an award notification, all CPs are required to sign an Investment Agreement with the GHIT Fund and put in place a contractual agreement among the CPs, which clearly defines the roles and responsibilities of all CPs within two weeks to one month from the award notification
- The Investment Agreement template will be shared with the applicants who are invited to submit the full 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 CPs 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.

9. 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.

10. Privacy Policy

Details about the GHIT Fund Privacy Policy can be found here: https://www.ghitfund.org/general/privacypolicy/en.

11. 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 ITA form or the full proposal, or participation in the SC interview, does not guarantee funding of your proposal.

GHIT Fund will treat application materials as if they are confidential and use them only for evaluation and internal purposes. If applicants submit any sensitive information on intellectual property that is not publicly available and essential for the review, they should contact the GHIT Fund Management Team prior to submission.

12. Key RFP Milestone Dates

RFP Release	October 31, 2025
	No later than 10:00 am on November 27, 2025 (Japan Standard Time)
Intent to Apply Due	*Applicants are encouraged to submit the <i>Intent to Apply</i> (ITA) form well in advance of the full proposal submission deadline shown below to secure sufficient time to prepare the full proposal
	Submit via Editorial Manager® for Product Development Platform (https://www.editorialmanager.com/ghitfund/)
Eull Dwon ogal Duo	No later than 10:00 am on January 16, 2026 (Japan Standard Time)
Full Proposal Due	Submit via Editorial Manager® for Product Development Platform (https://www.editorialmanager.com/ghitfund/)
Proposals Evaluation and Interview Processes	January 2026 - July 2026
Award Notification to All Applicants	July 2026
Investment Agreement Fully Executed (Awarded Proposals)	September 2026

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

For proposals addressing diseases with pandemic potential or public health emergencies, enquiries regarding evaluations outside the above-mentioned timeline may be considered. Please contact the GHIT Fund for further details.

13. Inquiries

For any inquiries, please contact <u>RFP-PD-2026-001 Questions</u>)

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

[End of Document]