GHIT Fund

Global Health Innovative Technology Fund

GHIT Fund Product Development Platform (PD) Request for Proposals

Reference Number: GHIT-RFP-PD-2027-001

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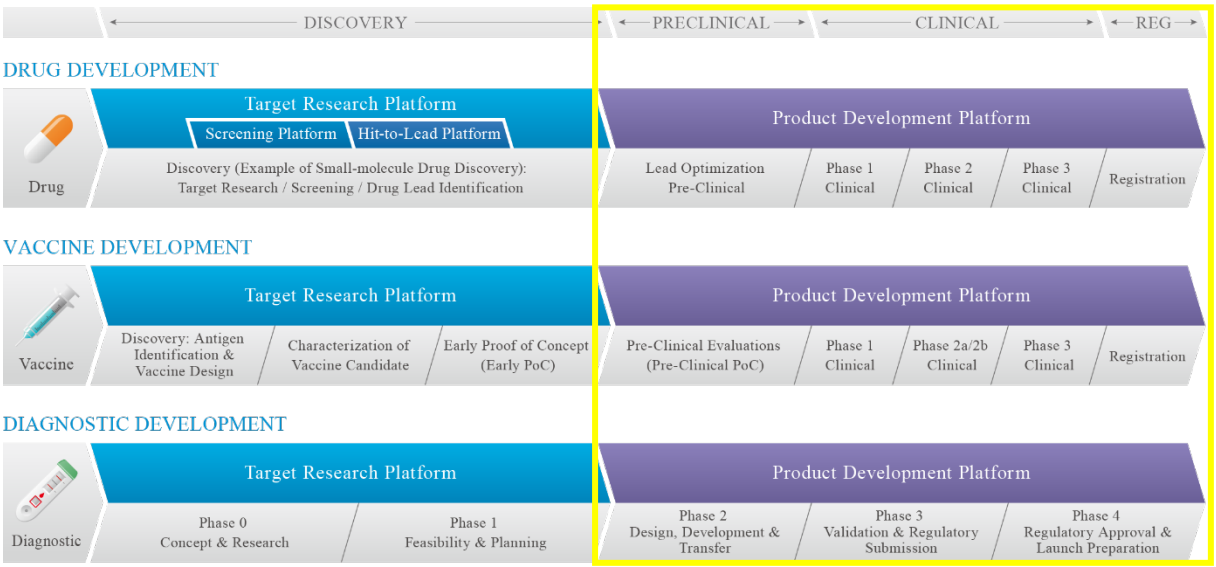
1. GHIT Fund Background

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 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 with a particular focus on innovations which can be launched within the current GHIT timeframe. Activities include

- Activities to support licensure and WHO prequalification. (Up to 5,000,000 JPY can be included in the budget for projects in Phase 2 or later, for launch readiness support to assist with the planning for successful implementation of products.)
- 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)
- Clinical Development (both clinical studies and manufacturing scale-up)
- Preclinical Development (safety and toxicity studies, formulation development, chemistry and process validation)
- Lead optimization

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3. Eligibility

- **Project:**

The proposal must align with the Project Scope, Disease Scope, Project Duration, and Budget of each Award 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 an 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 (US Subsidiary), where the subsidiary will still be considered a Japanese organization for the purposes of the project, even if only the US Subsidiary participates.

✓ 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 market access and launch planning from at least Phase 2 (Phase 1 preferred) as well as at least one commercial partner that can execute on launch, commercialization and access activities needed to successfully introduce the product in target geographies.
  - 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 launch and access strategy in the full proposal aimed at securing a commercial partner that can execute on said strategy 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, government market access personnel such as payers), 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.

- **Organizational Restrictions:**

The proposal will be considered ineligible if any Collaboration Partner or subcontractor falls under the following categories:

- Organizations headquartered or operating in countries subject to international trade or economic sanctions
- Organizations based in jurisdictions where local regulations prohibit or restrict the receipt of international funds.

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- **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 and Universities, our funding partners (including the Gates Foundation and Wellcome Trust) and with international public health leaders including the World Health Organization (WHO). The scope has also been reviewed by GHIT portfolio advisors and approved by the GHIT Board. GHIT reserves the right to update the scope periodically based on the changing global health landscape.

Funding may also be awarded for the development of innovative drugs, vaccines and diagnostics for other WHO-listed NTDs (https://www.who.int/health-topics/neglected-tropical-diseases#tab=tab_1) on a case-by-case basis with clear justifications of the needs.

Successful completion of an award does NOT guarantee GHIT funding for continuation of programs.

Requirements:

- The proposed project must demonstrate its competitive advantage over current standard of care, and other therapies likely to be launched in the next decade, and thus how it can address the identified public health need.
- Product Development programs should be clearly aligned with internationally accepted (WHO) or published Target Product Profiles. Where no such TPP exists, the project should clearly state its own proposed profile and justification. A clear definition of the final product, value proposition and use case is important. Preliminary timelines and roadmaps for implementation should be included for any product that is within 10 years from launch.
- Applicants should ensure that the project team includes an appropriate mix of technical and public health expertise, including knowledge of the needs of target populations and intended use settings.
- Any product development program is strongly encouraged to have market access and launch plans that include product value proposition based on health economics and outcomes research (relative to standard of care, if applicable), fit-for-purpose pricing strategies, product introduction and commercialization plan and, if necessary, identified funding and financing mechanisms to allow for market introduction.
- A clear understanding of the positioning of the current product in the landscape of alternative products (either those launched or those at an equivalent stage of clinical development) should be included – ideally as a figure.

Notes for diseases 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 available specifically 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. This excludes approaches to SARS-CoV-2

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/COVID-19 and AIDS/HIV. A clear product justification and landscape analysis with relevant references should be included.

- For diseases with public health emergency, the disease has to be declared as public health emergency in at least one country by a competent national authority, but excludes SARS-CoV-2/COVID-19 and AIDS/HIV.
- Funding is intended to be catalytic, and therefore leverage of existing in-kind and financial contributions will be important, as well as proposals should be building on existing networks and collaborations with established leaders in pandemic preparedness.

Notes for Intervention Scope:

*For **all interventions**:*

Priority will be given to programs where a market access plan has been initiated that can be used and/or expanded to fit our scope. 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. Discovery and development strategies should prioritize medicines which have an acceptable benefit-risk balance for use during pregnancy and lactation. Where relevant, development programmes should intentionally address the needs of pregnant and lactating women by generating appropriate evidence from pre-clinical development, e.g., reprotox studies and modelling approaches, to inform appropriate use and regulatory labelling.

Additionally, we seek opportunities to repurpose existing drugs or amend drugs already in development (e.g., expand indications, reformulation) to benefit our target populations across the diseases in scope.

*For **vaccines**:*

New and adapted vaccine technologies that improve product characteristics, such as thermostability, fewer doses, needle-free delivery, simplified manufacturing, or reduced production costs, would be an advantage. AI-enabled approaches may also be considered where they directly support the development of a specific vaccine candidate for eligible indications, including antigen or immunogen design, RNA or protein engineering, immune analytics, manufacturing optimisation, or R&D decision support.

*For **diagnostics**:*

New tools developed would ideally have an integrated digital backend to collect, analyze and manage data, where appropriate to the setting and/or use cases/s defined in available TPP, 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.[1] The development of multiplex diagnostics for different NTDs is encouraged, given the increasing availability of theoretical and technical platforms for rapid, point-of-care (POC) multiplex diagnostics. Multiplex differential diagnostics that distinguish between disease stages of the same pathogen, where different interventions are required, are also encouraged. Applicants should provide a clear rationale for the intended use case.

[1] 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)

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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 • Development and validation of improved methods for detecting viable *Mycobacterium ulcerans* in Buruli ulcer wound samples, including mycolactone detection, RNA synthesis ratio-based assays, and 16S rRNA-based approaches[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
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 cross-sensitive 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	• Evaluation of small molecule direct-acting antivirals or immune modulators with potential for low Cost of Goods in a therapeutic clinical design setting. • 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

[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

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Indication	Drugs	Vaccines	Diagnostics
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 *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, especially to East Africa, VL treatment landscape) • Treatment for PKDL that demonstrates novelty and/or higher efficiency compared to SoC.	• Vaccines for VL (only vaccine candidates beyond preclinical stages and that offer advantages to the global pipeline) • Continuation of previously GHIT-funded projects	• 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 and diagnosis of relapse or treatment failure)[4, 5] • Confirmatory POC RDTs for post kala-azar dermal leishmaniasis (PKDL)

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

[4] WHO TPPs for confirmation VL: https://www.who.int/publications/i/item/9789240098718

[5] WHO TPPs for confirm cure VL: https://www.who.int/publications/i/item/9789240091818

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Indication	Drugs	Vaccines	Diagnostics
Leprosy	• More effective and safer drugs, or drug combinations, with shorter treatment durations, than the current MDT regimen.	• 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[6] • Diagnostics capable of detecting leprosy infection (latent leprosy) among asymptomatic contacts[7] • 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[8] [9] 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

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

[7] 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

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

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

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Indication	Drugs	Vaccines	Diagnostics
Malaria	***Top Priority:*** • **Triple artemisinin-based combination therapies (TACTs)** to counter the spread of artemisinin resistance. New combinations which address transmission blocking are particularly welcome • **New non-artemisinin containing combinations** prioritizing those which can be used against all plasmodial species, with a priority for Africa. ***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 in all populations (including small children and pregnant/lactating women) • **Drugs to treat severe malaria:** - Rapid action, fast clearance (parasite clearance <72 hours) and refractory to resistance selection. - Simple to administer in remote areas • **Chemoprevention:** - Long duration of efficacy with acceptable safety profiles - Injectable combinations which provide coverage for 3-6 months or oral combinations with monthly dosing. • Suitable for use during pregnancy and lactation are particularly encouraged, where relevant **(Continuation projects only) Liver stage 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 significantly 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. A plan for how the cost of the monoclonal antibodies will be addressed will need to be included. • 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[10]	• 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 and development of drug resistance • RDTs targeting alternative antigens (other than PfHRP2, LDH or aldolase) • RDTs that can detect all malaria species • Accurate, sensitive POC RDTs for better diagnosis of sub microscopic parasitemia in pregnant women and in pre-elimination evaluations • POC diagnostics to detect parasite antimalarial drug resistance

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

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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 [11]
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 [12] • Diagnostic tools that can detect alive adult *O. volvulus* • Diagnostics that can identify and detect drug resistance in *O. volvulus* • 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 [13] • Population level diagnostics

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

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

[13] 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

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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	***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 [14] • 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 [15]

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

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

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Indication	Drugs	Vaccines	Diagnostics
Taeniasis /Cysticercosis	• More effective drugs than current treatments	• Out of scope	• Sensitive, specific and low cost 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[16]	• 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	• Vaccine candidates in early to late-stage clinical development with clear clinical path to contribute in the overall WHO TB vaccine strategy and showing significant promise over the front-runner vaccines currently in development.	• 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 tools

5. Partnership Roles

Upon applying to the GHIT Fund, each partner organization in a partnership is referred to as Collaboration Partner (CP). 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.

[16] 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

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- 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.

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 18, 2026 (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

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- 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. Applicants are encouraged to submit the ITA form well in advance of the 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 on December 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 submission. Incomplete proposal documents (such as those that do not adequately address the proposal questions or contain inconsistencies within the documents) will be deemed ineligible
- Additional documents, including additional data and/or supporting documents, cannot be accepted after the deadline
- The GHIT Fund may, at its sole discretion, extend or advance the deadline, with prior notice to applicants
- Proposals received after the closing date for submission 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 assessed and screened by the GHIT Fund Management Team based on the following points and will be prioritized for the technical evaluation. Proposals may be considered ineligible and will not proceed to technical evaluation if they do not fulfill the following aspects.

- the partnership meets GHIT Fund eligibility criteria stated in the current RFP
- the proposals are aligned with the project scope stated in the current RFP
- the proposal is complete, consistent across all submitted documents, and addresses all required content
- the required organizational documents have been submitted for each organization

Proposals will initially be examined to determine or evaluate:

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- 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 to be submitted within a specified deadline, as needed.
Applicants will be notified by email if the preliminary screening deems the proposals ineligible.

7.2. Technical Evaluation

All proposals qualifying the preliminary screening 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, the GHIT Fund may impose funding conditions (e.g., milestone-based payments, deliverable-based payments, or other installment-based payments) or determine that the proposal is not fundable.

8. Award Administration and Conditions

Notification of Results:

- Following the funding decision, applicants will receive the notification of results by email, with a notification letter attached.
- An award notification does not by itself constitute a legally binding commitment by the GHIT Fund to provide funding.
- **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.**

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Agreements:

- The Investment Agreement template will be shared with the applicants who are invited to submit the full proposal.
- To receive funding from the GHIT Fund, all CPs are required to fulfill the following requirements after the applicant receives an award notification:
  - Fulfill all conditions specified in the award notification
  - Sign an Investment Agreement with the GHIT Fund
  - Put in place a contractual agreement among the CPs, which clearly defines the roles and responsibilities of all CPs
  - All agreements to be fully executed **within three months from the award notification** unless otherwise agreed (Award Expiration Period).
- **The award will expire if the agreements cannot be signed within the Award Expiration Period.**
- **The award may be revoked or expire if any of the requirements are not met.**
- 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. Applicant Responsibility

Applicants are responsible for ensuring that all proposed project activities, funding flows, participating organizations, and subcontracting arrangements comply with all applicable laws and regulations. This includes relevant ethical, legal, regulatory, safety, and data protection requirements in the relevant jurisdictions.

Specific obligations include, but are not limited to:

- Compliance with requirements relating to foreign funding, local registration, approvals, reporting, recordkeeping, audits, and fund transfers.
- Obtaining and maintaining all necessary approvals, consents, and reviews required for the project.
- Ensuring the project is structured and managed in a manner consistent with the GHIT Fund Access Policy, where applicable.

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12. 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.

Submitted documents will be shared with GHIT Fund reviewers and external consultants for the purpose of review and evaluation.

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

13. Key RFP Milestone Dates

RFP Release	**October 23, 2026**
Intent to Apply Due	No later than **10:00 am on November 18, 2026** **(Japan Standard Time)** *Applicants are encouraged to submit the *Intent to Apply* (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/)
Full Proposal Due	No later than **10:00 am on December 16, 2026 (Japan Standard Time)** Submit via **Editorial Manager® for Product Development Platform** (https://www.editorialmanager.com/ghitfund/)
Proposals Evaluation and Interview Processes	**December 2026 - July 2027**
Notification of Results	**July 2027**
Investment Agreement Fully Executed (Awarded Proposals)	**September 2027**

(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.

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14. Enquiries

For any inquiries, please contact RFPresponse@ghitfund.org (please use the email subject line: **GHIT-RFP-PD-2027-001_Questions**)
A Frequently Asked Questions (FAQ) page is available on the GHIT Fund website: (https://www.ghitfund.org/applyforfunding/investmentfaq/en).

[End of Document]

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