GHIT Fund Product Development Platform
Request for Proposals
Reference Number: GHIT-RFP-PD-2024-001

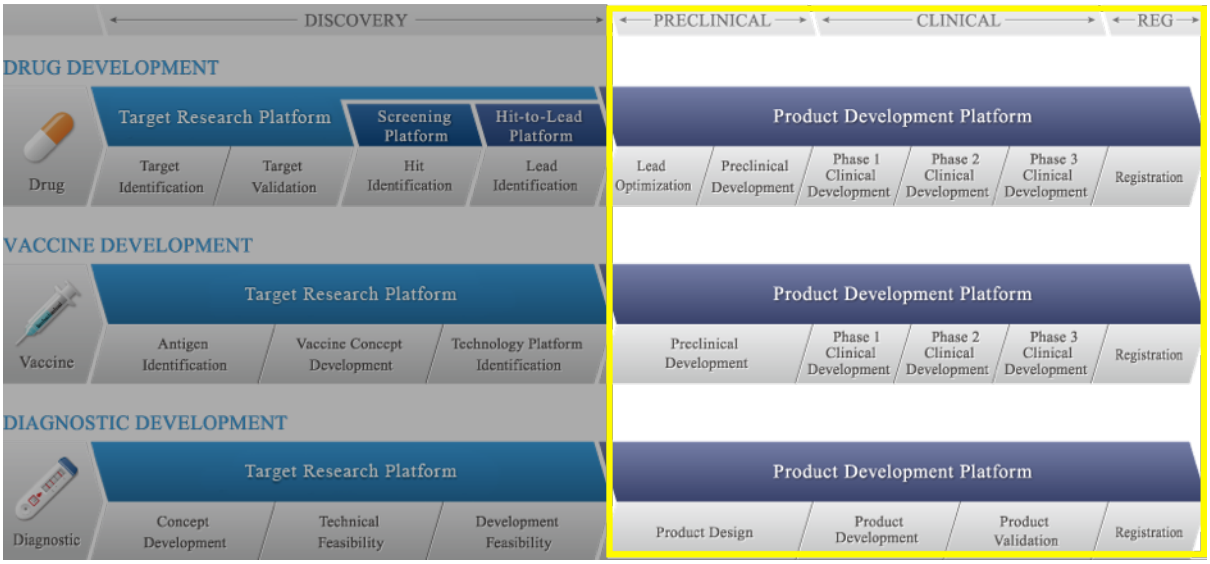
GHIT Fund Background

Over a billion people in the world suffer from infectious diseases, especially those in LICs/LMICs and settings, creating a need for new low-cost, high-impact health technologies. Response to this need in recent years has resulted in the development of new products, many of which have been the result of partnerships between pharmaceutical companies, academic 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 GHIT Fund aims to advance Japan's wealth of health technology innovation for the discovery and development of new technologies for developing world patients and populations affected by infectious disease. To this end, the GHIT Fund will catalyze **R&D partnerships between Japanese and non-Japanese organizations** and support these partnerships through GHIT Fund investments.

Funding Opportunity

The Product Development Platform (PD) 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. GHIT funding period is two-years at maximum for proposed collaboration project that focus on R&D activities within the following development stage including:

- Lead optimization
- Preclinical Development (*in vivo* studies, formulation development, chemistry and process validation)
- Clinical Development (Phase 1, 2, or 3 studies, manufacturing scale-up)

- Activities to support licensure and WHO prequalification

Please note that projects have to cover the Product Development Platform stages as illustrated above for Vaccines, Diagnostics and Therapeutics.

Investment Eligibility

Japanese Organizations	Non-Japanese Organizations
• Japanese corporations (with a research facility in Japan) • Not-for-profit research organizations and foundations • Government research institutions • Academic institutions	• Life Science/Healthcare companies • Not-for-profit research organizations and foundations • Product Development Partnerships • Government research institutions • Academic institutions

GHIT Fund investments can be awarded to existing or new partnerships between Japanese and non-Japanese organizations. Each partner should have a history of health intervention R&D and have the expertise to know which projects represent potentially substantial additions to the field. **The GHIT Fund requires each investment to have at least one eligible Japanese and one eligible non-Japanese organization as partners in order to be considered eligible.** The following table gives guidelines to the types of organizations expected to form GHIT Fund eligible partnerships.

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

A collaboration project will be eligible if it addresses a priority need for the prevention, diagnosis or treatment of infectious diseases in developing countries within the boundary conditions outlined below. For projects that cover First in Human (FIH) and beyond, if awarded, an investment amount from GHIT shall be less than 75% of the total project during the funding period. **For projects that cover Proof of Concept (POC) or Phase 2b activities and beyond, collaboration should include at least one commercial partner and, if awarded, an investment amount from GHIT shall be less than 50% of the total project during the funding period. For diagnostics programs reaching Product Validation stages and beyond, co-funding of over 25% is highly encouraged.**

Product Scope

The GHIT Fund focuses on leveraging Japanese innovation and expertise to develop innovative drugs, vaccines, and diagnostics that are affordable and accessible to endemic populations. A high-level summary of needs associated with NTDs, TB and Malaria included in this RFP is provided below. This needs summary was developed through consultation with our partner organizations, PDPs, foundations (e.g., the Bill & Melinda Gates Foundation, Wellcome Trust), and international organizations such as the World Health Organization (WHO). The needs summary has also been reviewed by the GHIT Strategy Committee and has received approval from the GHIT Board. **Proposals must focus exclusively on addressing one or more of these needs to be eligible for consideration; any product development programme should be aligned with profiles and priorities identified in, for example, WHO (or other public health focused) developed target product profiles (TPP), and have a clear value proposition and a timeline roadmap for their implementation at the country level once it has been developed. Funding may also be awarded for the development of innovative drugs, vaccines, and diagnostics for other WHO-listed NTDs (e.g. https://www.who.int/neglected_diseases/diseases/en/), on case-by-case basis with clear justifications of the needs.**

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

Indication	Drugs	Vaccines	Diagnostics
Buruli ulcer	● Out of scope	● Out of scope	● Out of scope, with the exception of continuation of previously GHIT-funded projects
Chagas disease	● Out of scope, with the exception of continuation of previously GHIT-funded projects	● Out of scope, with exception of continuation of previously GHIT-funded projects	● Out of scope, with the exception of continuation of previously GHIT-funded projects
Chikungunya	● Out of scope. Limited investment may be available for pan-antivirals against alphaviruses/ flavivirus if the approach displays significant competitive advantage over the existing approaches.	● Out of scope	● More sensitive and specific diagnostic tests ● 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
Echinococcosis	● Out of scope	● Out of scope	● POC test or high sensitivity (Se) and specificity (Sp) serological test for diagnosis of echinococcosis in human ● Accurate, sensitive POC RDTs that can detect inactive cysts ● Confirmatory diagnostic test for cure
Foodborne Trematodiases	● Development of safe and effective drugs that can be given in mass treatments	● Therapeutic and preventative 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 techniques for Fasciola ● POC tests for potentially infected individuals ● High Se/Sp serological test for diagnosis of liver fluke and fascioliasis
Leishmaniasis	● 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	● Accurate, sensitive POC RDTs for species identification in cutaneous leishmaniasis and for disease diagnosis in visceral leishmaniasis (including for asymptomatic infections) ● Confirmatory POC RDT for post kala-azar dermal leishmaniasis (PKDL)
Leprosy	● More effective drugs, or combinations of such, with shorter treatment durations	● Vaccines which confer both pre- and post-exposure immuno-prophylaxis against leprosy without exacerbating	● POC test with high specificity to confirm diagnosis and detect infection in the population at risk

		nerve damage (proposals should demonstrate that the use case of the vaccine has been carefully considered)	● Diagnostics capable of identifying symptomatic cases; diagnostics capable of detecting leprosy infection (latent leprosy) among asymptomatic contacts ● Diagnostics to detect biomarker to indicate resistance to MDT drugs
Lymphatic Filariasis	● Development of macrofilaricide to kill adult worm in an infected individual	● Out of scope	● Accurate, sensitive POC RDTs that meets the WHO TPP requirements (#12: on surveillance purposes; #11: on support decisions for stopping triple-therapy mass drug administration (MDA), to be used in hypo-endemic geographies.[1] ● POC diagnostics that don't 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
Malaria	● Advance the eradication agenda with novel molecules: new drugs that could be used safely and effectively in combination with the current antimalarials, with a low resistance risk, in order to prevent the spread of drug-resistant parasites (TCP-1) ● Drugs to treat severe malaria (TCP-1) - fast clearance, rapid action - Simple to administer in remote areas ● Chemoprevention (TCP-1/4) - long duration and safe ● Drugs that clear asexual blood-stage parasitemia to block transmission (TCP-5)	● Advance the eradication agenda: - more effective and long-lasting prevention vaccines (e.g., blood stage) - transmission blocking vaccines - vaccines for vivax malaria - monoclonal antibodies (im or sc delivery) with a low cost ● Projects that focus on vaccine candidates in late-stage development (those that are or can enter the clinics within 2 years are preferred).	● RDTs (2-band test) to identify high Pf parasite densities and patients who need longer ACT treatment courses ● 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 ● RDTs targeting alternative antigens (other than PfHRP2, LDH or aldolase)

[1] The WHO target product profiles (TPPs) for diagnostics dashboard are developed by the NTD Diagnostics Technical Advisory Group (DTAG) and provides an at-a-glance view of the status of TPPs for the portfolio of NTDs. TPPs outline the desired characteristics of a product that is aimed at a particular disease or diseases. It helps define the type of diagnostics that would be most supportive of the aims and targets envisaged by the road map for NTDs 2021–2030.

Please refer to the TPPs here: https://cdn.who.int/media/docs/default-source/ntds/neglected-tropical-diseases-non-disease-specific/status-target-product-profiles-for-ntds.pdf?sfvrsn=74b6c3d_4

	● New drugs that kill hypnozoites in vivax patients with G6PD deficiency (TCP-3) ● Pediatric formulation (e.g. orally dispersible) ● Improvements of current therapeutics (e.g. fixed dose triple combinations, paediatric primaquine, rectal antibiotic antimalarial combinations)		
Mycetoma	● Safe and effective oral drugs that have fewer side effects, are more effective, and more affordable than current treatments	● Out of scope	● Accurate, sensitive POC RDTs to improve early detection at the primary care level
Onchocerciasis	● Safer and more effective drugs that kill adult worms (macrofilaricides) than current treatments ● Pediatric formulations for existing drugs	● Out of scope	● Accurate (better specificity to assess low thresholds), sensitive POC RDTs that can be used in hypo-endemic geographies and/or geographies co-endemic with Loiasis. The diagnostics should meet the WHO TPP requirements (#15: on support stopping decisions for MDA.[1] ● Diagnostics that can measure infection intensity and drug resistance
Rabies	● Safe and effective drugs that would transform the existing approach	● Out of scope	● RDT to diagnose human rabies infection ● Field-deployable antemortem diagnostic test for use in primary health care facilities ● Differential diagnostics to distinguish between different strains and variants
Scabies	● Out of scope	● Out of scope	● Low-cost POC test for individual level diagnosis and management. The diagnostics should meet the WHO TPP requirements (#16-17: on support starting/ stopping decisions for MDA.[1] ● Population level diagnostics
Schistosomiasis	● Safer and more effective oral drugs than existing treatments ● Combination of drugs that better targets egg and early larval stages	● Preventative vaccines	● Accurate, sensitive POC RDTs that can be used in hypo-endemic geographies. The diagnostics should meet the WHO TPP requirements (#18: on monitoring and evaluation; #19: on transmission interruption and subsequent surveillance)[1] ● Diagnostic to detect praziquantel resistance ● Diagnostics that offer significant advantages over the current CCA test ● New imaging techniques to detect organ damage caused by schistosomiasis

			● Confirmatory diagnostic for female genital schistosomiasis
Soil-transmitted helminthiases	● Out of scope, with exception of continuation of previously GHIT-funded projects	● Preventative vaccines	● Ag-based RDT to detect STH infection ● AI technology to assist detection of eggs in microscopy ● Multiplex diagnostics for detection of multiple STH species simultaneously
Taeniasis-Cysticercosis	● Pediatric formulations of existing drugs ● More effective drugs	● Out of scope	● Sensitive, specific, and affordable POC diagnostics ● Effective diagnostics which measure infection intensity & detect drug resistance ● POC test or high Se/Sp serological test for diagnosis of *T. solium* and human cysticercosis
Tuberculosis	● Safe and well-tolerated drugs that contribute to a treatment-shortening regimen with the goal of <2 months treatment, Such universal / pan-TB regimens that do not require drug susceptibility testing, that are affordable, convenient to take (i.e., oral, forgiving to non-adherence), safe, and well tolerated are needed. ● 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.	● Preventative vaccines and treatment vaccines that show dramatic improvement over current vaccines in the global pipeline	● Accurate, sensitive POC RDTs, specifically non-sputum sample-based TB diagnostics

**POC RDTs = Point of Care Rapid Diagnostic Tests*

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

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

Regarding the development of vaccines: new and adapted vaccines technologies including thermostability, fewer doses, and needle-free delivery would be an advantage. GHIT 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: all new tools developed would ideally have an integrated digital backend to collect, analyze and manage data; and plans should be clearly articulated in the proposal.

Applicant Instructions

All correspondence and documents relating to this RFP shall be written in English. The applicant shall bear all costs associated with the preparation and submission of the proposal, including costs associated with proposal development, presentation, and contract and agreement negotiation (unless otherwise noted by the GHIT Fund).

To receive and manage applications, the GHIT Fund uses **Editorial Manager® for Product Development Platform** (https://www.editorialmanager.com/ghitfund/), an online document submission system dedicated for this funding program. Please note that Intent to Apply documents or Proposals that are not submitted through the above-mentioned system will not be accepted.

Step 1 - Intent to Apply

Interested applicants must complete the *Intent to Apply* form (***GHIT-RFP-PD-2024-001_IntentToApply.docx***) and submit this to the GHIT Fund via Editorial Manager® no later than:

10:00 am Tokyo time on November 28, 2023

The *Intent to Apply* form is available on the GHIT website: (https://www.ghitfund.org/applyforfunding/pdp/en). Any application not using the designated *Intent to Apply* form for this RFP will not be accepted. Please do not submit any other documents to the GHIT Fund other than the *Intent to Apply* form.

When submitting your *Intent to Apply* form on the Editorial Manager®, please list all the collaboration partners participating in the project; the name and details (including e-mail address) of at least one representative from each organization must be indicated.

Applicants who successfully submit the *Intent to Apply* document will receive a confirmation email. GHIT Fund staff will then perform an initial partnership and scope eligibility assessment. **Only eligible applicants will be invited to submit the full proposal and will receive a password to access the proposal template.**

Eligibility assessment will be conducted upon receipt of the Intent to Apply form. Applicants are encouraged to submit the ITA well in advance of the Full Proposal submission deadline (10:00am Tokyo time on January 12, 2024) to secure sufficient time to prepare full proposal.

Step 2 - Proposal Submission

Applicants invited to submit a full proposal to the GHIT Fund are required to do so via Editorial Manager® no later than;

10:00 am Tokyo time on January 12, 2024

Applicants who successfully submit their proposal document will receive a confirmation email. Proposals may not be modified after the submission due date.

Proposal documents must be reviewed and approved by all the collaboration partners who are participating in the project prior to submission. The *Collaboration Partners' Approval* form (***ProjectID-CollaborationPartnerApproval.docx***) must be signed by all the collaboration partners and a PDF copy must be submitted along with other proposal documents.

The GHIT Fund may, at its own discretion, extend the closing date by notifying applicants. Proposals received after the closing date for submission without prior agreement will be ineligible for consideration, but may be resubmitted in response to future RFPs.

RFP Questions

Prospective applicants may also submit RFP questions to RFPResponse@ghitfund.org (please use email subject line: **GHIT-RFP-PD-2024-001_Questions**). no later than

10:00 am Tokyo time on January 5, 2024

Please note that it may take time for the GHIT Fund Management Team to respond to your inquiries, so make sure to address your questions well in advance of the submission deadlines.

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

Proposal Evaluation

Preliminary Examination of Proposals

Proposals will initially be examined to determine whether the:

- Partnership meets GHIT Fund eligibility criteria
- Project objectives are aligned with the RFP-specified scope
- Proposal is complete and addresses all required content

GHIT Fund staff may ask clarifying questions or request additional information, as needed, to qualify proposals for evaluation.

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 and project management (e.g., collaboration capabilities and expertise, project history and performance, risk management, budget)

If a proposal has already been deemed technically or scientifically sound and aligned with global health needs by an established independent scientific or technical advisory committee (such as those established by PDPs), the partnership is expected to include a summary of the outcome of that review in their proposal submission.

Eligible proposals will initially be reviewed by three External Reviewers (ER) including Japanese and non-Japanese reviewers. The aggregated External Reviewer results and the proposals will then be shared with the GHIT Fund Selection Committee (SC) for evaluation. ER and SC members have signed non-disclosure agreements with the GHIT Fund prior to the evaluation. After the evaluation process, GHIT Fund will invite selected proposals for an in-person interview with the SC. **Selected proposals for the SC interview will be notified of the interview invitation about a month prior to the scheduled interview date and time**.

Once all information has been considered after the interview, the SC will make funding recommendations to the GHIT Board. The GHIT Board will discuss the SC recommendations and will make the final approval as to which proposals will receive GHIT Fund investment. Please note that the GHIT Fund Management Team does not have influence, authority, or decision power on the review and evaluation, funding recommendations, and award or non-award decisions of submitted proposals by the External Reviewers, Selection Committee, 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 Selection Committee interview do not guarantee an automatic funding approval for your proposal.

(Please note that the evaluation procedures and their format may be adjusted due to unforeseen circumstances.)

Award Administration and Conditions

After the GHIT Board approval, the GHIT Fund will notify applicants of the award decision by email. **Please note that GHIT Fund is not able to provide formal feedback to applicants receiving a non-award decision.**

Please also note below:

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

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

If the proposal is selected and the applicant receives an award notification, all partners are required to sign the Investment Agreement with the GHIT Fund and also submit a collaboration partners' contractual agreement which clearly defines the roles and responsibilities of all collaboration partners, **within two weeks to one month from award notification**. Please be aware that the award may be void if this condition is not met.

Applicants are required to identify the designated development partner (investment recipient) and all other collaboration partners. The designated development partner will be responsible for the performance of all its collaborating partners. A representative of the designated development partner will serve as the main GHIT Fund point of contact and will be responsible for all GHIT Fund discussions and negotiations.

Investments will be awarded for a period of up to two years and reflecting the agreed activities and conditions based on the award notification from the GHIT Fund. **The funding allocation will be milestone-based.** The GHIT Fund has the right to terminate the Investment Agreement if, but not limited to:

- 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

If an investment contract is terminated, the GHIT Fund reserves the right to cancel future payments, reclaim paid funds, or mandate that paid funds be redirected to other charitable activities. In lieu of termination, the GHIT Fund may choose to renegotiate the terms of the existing Investment Agreement.

Access Policy

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

Key RFP Milestone Dates

RFP Release	**November 1, 2023**
Intent to Apply Due	No later than 10:00 am Tokyo time on **November 28, 2023** *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** (https://www.editorialmanager.com/ghitfund/)
Q & A	No later than 10:00 am Tokyo time on **January 5, 2024** Submit questions to RFPResponse@ghitfund.org Email Subject Line: **GHIT-RFP-PD-2024-001_Questions**
Full Proposal Due	No later than 10:00 am Tokyo time on **January 12, 2024** Submit via **Editorial Manager® for Product Development Platform** (https://www.editorialmanager.com/ghitfund/)
Proposals Evaluation and Interview Processes	January - July 2024
Award Notification to All Applicants	July 2024
Investment Agreement Fully Executed (Awarded Proposals)	August 2024

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

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