

GHIT Fund Product Development Platform Request for Proposals Reference Number: GHIT-RFP-PD-2023-002

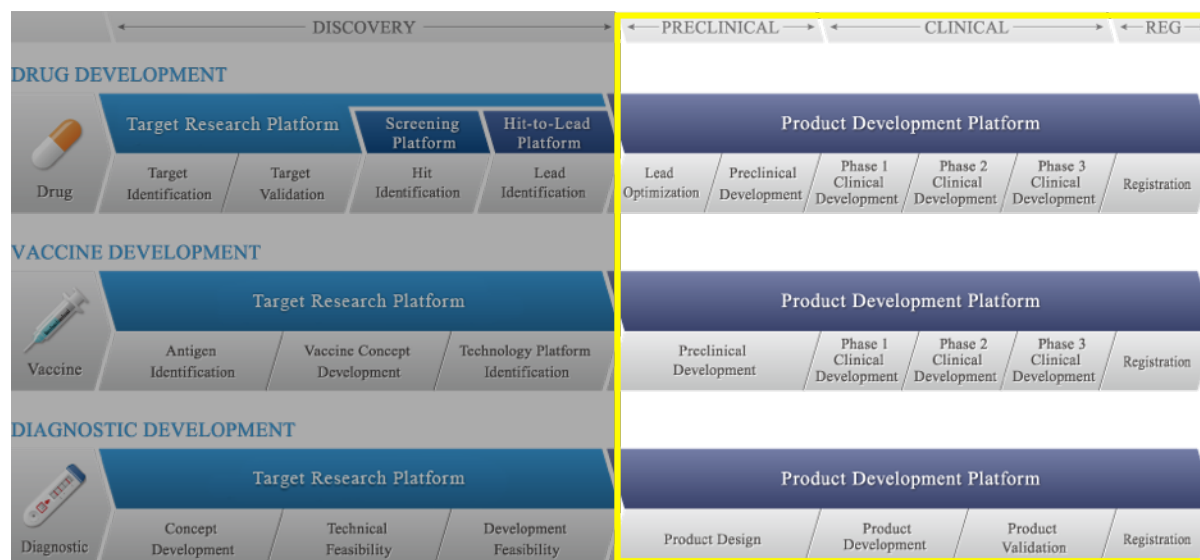
GHIT Fund Background

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
<ul style="list-style-type: none"> • Japanese corporations (with a research facility in Japan) • Not-for-profit research organizations and foundations • Government research institutions • Academic institutions 	<ul style="list-style-type: none"> • 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 each of the 18 diseases included in this RFP is provided below. This needs summary was developed through consultation with our partner organizations, PDPs, foundations (e.g., the Bill and 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 profile (TPP), and have a clear value proposition and roadmap up to their implementation in countries once it has been developed. However, funding may be awarded for 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 the competitive positioning in the global pipeline.

Indication	Drugs	Vaccines	Diagnostics
Buruli ulcer	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● Out of scope, with the exception of continuation of previously GHIT-funded projects
Chagas disease	<ul style="list-style-type: none"> ● Out of scope, with the exception of continuation of previously GHIT-funded projects 	<ul style="list-style-type: none"> ● Out of scope, with exception of continuation of previously GHIT-funded projects 	<ul style="list-style-type: none"> ● Out of scope, with the exception of continuation of previously GHIT-funded projects
Chikungunya	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● 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	<ul style="list-style-type: none"> ● Out of scope, with the exception of continuation of previously GHIT-funded projects 	<ul style="list-style-type: none"> ● Out of scope, with the exception of continuation of previously GHIT-funded projects 	<ul style="list-style-type: none"> ● Multiplexed test with Chikungunya
Echinococcosis	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● 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 Trematodiasis	<ul style="list-style-type: none"> ● Safe and effective drugs (e.g. through the use of genomics to find key targets that can confer anti-cancer protection) 	<ul style="list-style-type: none"> ● 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) 	<ul style="list-style-type: none"> ● 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	<ul style="list-style-type: none"> ● Out of scope, with the exception of continuation of previously GHIT-funded projects 	<ul style="list-style-type: none"> ● Out of scope, with the exception of continuation of previously GHIT-funded projects 	<ul style="list-style-type: none"> ● Accurate, sensitive POC RDTs (including for asymptomatic infections)
Leprosy	<ul style="list-style-type: none"> ● More effective drugs, or combinations of such, with shorter treatment durations ● Treatments which provide nerve function improvement 	<ul style="list-style-type: none"> ● Vaccines which confer both pre- and post-exposure immuno-prophylaxis against leprosy without exacerbating nerve damage (proposals should demonstrate that the use case of the vaccine has been carefully considered) 	<ul style="list-style-type: none"> ● POC test to confirm diagnosis and detect infection in the population at risk ● 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	<ul style="list-style-type: none"> ● Out of scope, with the exception of continuation of previously GHIT-funded projects ● Adulticide to kill adult worm in an infected individual 	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● Accurate, sensitive POC RDTs that can be used in hypo-endemic geographies ● POC diagnostics that don't cross-react with <i>Loa loa</i> ● 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 detection of microfilaria in microscopy
Malaria	<ul style="list-style-type: none"> ● Advance the eradication agenda with novel molecules <ul style="list-style-type: none"> - single exposure radical cure & prophylaxis and/or new drugs that could be used in combination that could address resistance issues - fast clearance - long duration - targeting non-dividing stage ● Drugs to treat severe malaria ● Drugs that clear asexual blood-stage parasitemia 	<ul style="list-style-type: none"> ● Advance the eradication agenda: <ul style="list-style-type: none"> - more effective prevention vaccines - transmission blocking vaccines (showing better promise than the existing program in GHIT portfolio) 	<ul style="list-style-type: none"> ● Accurate, sensitive POC RDTs, specifically for asymptomatic carrier ● RDT for <i>P. falciparum</i> and/or <i>vivax</i> with 2 logs better sensitivity and accuracy compared to current RDT ● RDTs to detect and distinguish <i>P. falciparum</i> vs. <i>P. vivax</i> ● Diagnostics to detect parasite resistance ● Diagnostics to distinguish between current and past infection
Mycetoma	<ul style="list-style-type: none"> ● Safe and effective oral drugs that have fewer side effects, are more effective, and more affordable 	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● Accurate, sensitive POC RDTs to improve early detection at the primary care level
Onchocerciasis	<ul style="list-style-type: none"> ● Safer and more effective drugs that kill adult worms (macrofilaricides) ● Pediatric formulations for existing drugs 	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● 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 ● Diagnostics that can measure infection intensity and drug resistance
Rabies	<ul style="list-style-type: none"> ● Safe and effective drugs 	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● RDT to diagnose human rabies infection ● Field-deployable antemortem diagnostic test for use in primary health care facilities
Scabies	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● Low-cost POC test for individual level diagnosis and management ● Population level diagnostics
Schistosomiasis	<ul style="list-style-type: none"> ● Safer and more effective oral drugs ● Pediatric formulations of existing drugs ● New drugs to mitigate resistance to existing treatments 	<ul style="list-style-type: none"> ● Preventative vaccines 	<ul style="list-style-type: none"> ● Accurate, sensitive POC RDTs that can be used in hypo-endemic geographies ● Diagnostic to detect praziquantel resistance ● Diagnostics that offer significant advantages over the current CCA test

	<ul style="list-style-type: none"> ● Drug/ Drug combination that better targets egg and early larval stages 		
Soil-transmitted helminthiases	<ul style="list-style-type: none"> ● Out of scope, with exception of continuation of previously GHIT-funded projects 	<ul style="list-style-type: none"> ● Preventative vaccines 	<ul style="list-style-type: none"> ● Ag-based RDT to detect STH infection ● AI technology to assist detection of eggs in microscopy
Taeniasis-Cysticercosis	<ul style="list-style-type: none"> ● Pediatric formulations of existing drugs ● More effective drugs 	<ul style="list-style-type: none"> ● Out of scope 	<ul style="list-style-type: none"> ● 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 <i>T. solium</i> and human cysticercosis
Tuberculosis	<ul style="list-style-type: none"> ● Safe and well-tolerated drugs that contribute to a treatment-shortening regimen with the goal of <2 months treatment ● Universal / pan-TB regimens are needed that do not require drug susceptibility testing, are affordable, convenient to take (i.e., oral, forgiving to non-adherence), safe, and well tolerated and that significantly shorten the duration of treatment 	<ul style="list-style-type: none"> ● Preventative vaccines and treatment vaccines that show dramatic improvement over current vaccines in the global pipeline 	<ul style="list-style-type: none"> ● Accurate, sensitive POC RDTs, specifically non-sputum 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.

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

Applicant Instructions

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

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

Step 1 - Intent to Apply

Interested applicants must complete the *Intent to Apply* form (***GHIT-RFP-PD-2023-002_IntentToApply.docx***) and submit this to the GHIT Fund via Editorial Manager® no later than:

10:00 am Tokyo time on July 11, 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 August 9, 2023) 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 August 9, 2023
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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-2023-002_Questions**). no later than

10:00 am Tokyo time on August 2, 2023
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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	June 13, 2023
Intent to Apply Due	<p>No later than 10:00 am Tokyo time on July 11, 2023</p> <p>*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</p> <p>Submit via Editorial Manager® for Product Development Platform (http://www.editorialmanager.com/ghitfund/)</p>
Q & A	<p>No later than 10:00 am Tokyo time on August 2, 2023</p> <p>Submit questions to RFPResponse@ghitfund.org Email Subject Line: GHIT-RFP-PD-2023-002_Questions</p>
Full Proposal Due	<p>No later than 10:00 am Tokyo time on August 9, 2023</p> <p>Submit via Editorial Manager® for Product Development Platform (http://www.editorialmanager.com/ghitfund/)</p>
Proposals Evaluation and Interview Processes	August 2023- February 2024
Award Notification to All Applicants	February 2024
Investment Agreement Fully Executed (Awarded Proposals)	March 2024

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

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