

GHIT Fund Product Development Platform Request for Proposals Reference Number: GHIT-RFP-PD-2019-002

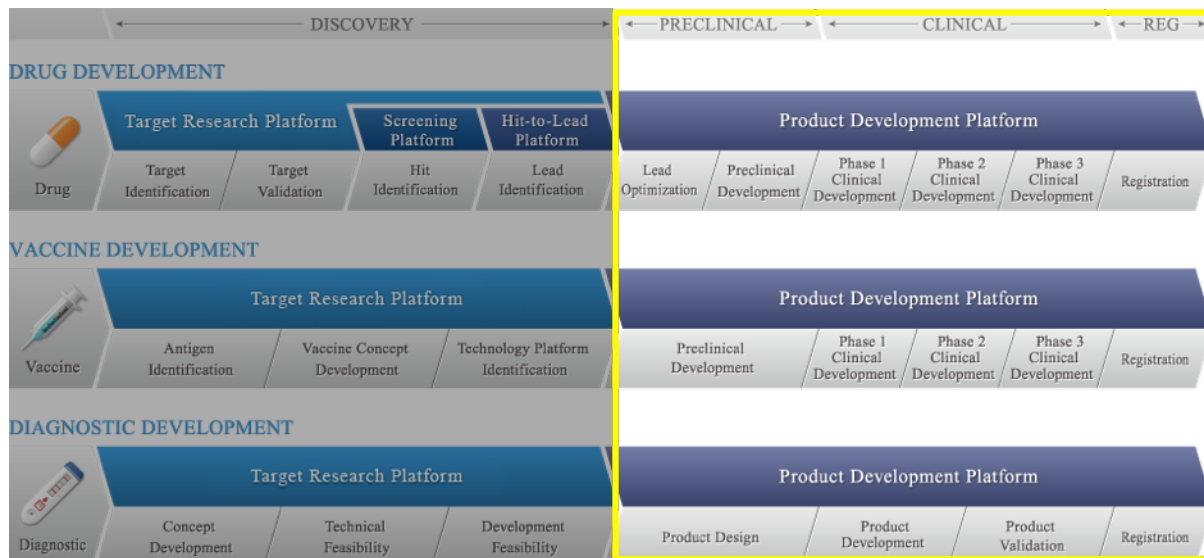
GHIT Fund Background

Over a billion people in the developing world suffer from infectious diseases, 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. Proposed collaboration projects should be **no more than two years in duration** and focus on R&D activities within the following development stages, 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 a project that does not cover development stages within the scope of Product Development Platform as described above will not be considered eligible. Please ensure that development stages of your project fall into the scope of this platform.

Investment Eligibility

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.

| 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 |

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 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.**

Product Scope

The GHIT Fund focuses on leveraging Japanese innovation and expertise to develop improved drugs, vaccines, and diagnostics that are affordable and accessible to endemic populations. A high-level summary of needs associated with each of the 13 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.**

Scope for the RFP-PD-2019-002 is primarily focused on continuation projects, diagnostics projects, and late stage projects (e.g. FIH and POC).

- **New project: eligible for late stage (e.g. FIH and POC)**
- **Continuation project: eligible for diseases described below**
- **Diagnostics project: eligible for diseases described below**

| Indication | Drugs | Vaccines | Diagnostics |
|-----------------------------------|---|---|--|
| Malaria | <ul style="list-style-type: none"> Advance the eradication agenda with novel molecules (preferably with a novel mechanism of action): <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 | <ul style="list-style-type: none"> Advance the eradication agenda: <ul style="list-style-type: none"> - transmission blocking vaccines - more effective prevention vaccines | <ul style="list-style-type: none"> Accurate, sensitive POC RDTs (Point of Care Rapid Diagnostic Tests), specifically asymptomatic carrier. RDT for Plasmodium falciparum and/or vivax with 2 logs better sensitivity and accuracy compared to current RDT product. Diagnostics product to detect parasite resistance and diagnostics that can distinguish between current and past infection. |
| Tuberculosis | <ul style="list-style-type: none"> Drug candidates that contribute to a treatment-shortening regimen with the goal of <2 months treatment | <ul style="list-style-type: none"> Preventative vaccines | <ul style="list-style-type: none"> Accurate, sensitive POC RDTs, specifically non-sputum TB diagnostics for carrier. Universal point of care sample extraction and purification technologies. |
| Onchocerciasis | <ul style="list-style-type: none"> Safer and more effective drugs that kill adult worms (macrofilaricides) | <ul style="list-style-type: none"> Out of scope | <ul style="list-style-type: none"> Accurate, sensitive POC RDTs that can be used in hypoendemic geographies and/or geographies co-endemic with Loiasis. |
| Lymphatic filariasis | <ul style="list-style-type: none"> Safer and more effective drugs that kill adult worms (macrofilaricides) | <ul style="list-style-type: none"> Out of scope | <ul style="list-style-type: none"> Accurate, sensitive POC RDTs that can be used in hypoendemic geographies. |
| Schistosomiasis | <ul style="list-style-type: none"> Safe and effective oral drugs and new pediatric formulations of existing drugs | <ul style="list-style-type: none"> Preventative vaccines | <ul style="list-style-type: none"> Accurate, sensitive POC RDTs that can be used in hypoendemic geographies. |
| Leishmaniasis | <ul style="list-style-type: none"> Safer and more effective oral drugs with a shorter treatment course (< 20 days) | <ul style="list-style-type: none"> Therapeutic and preventative vaccines | <ul style="list-style-type: none"> Accurate, sensitive POC RDTs (including for asymptomatic infections) |
| Chagas disease | <ul style="list-style-type: none"> Safer and more effective drugs with shorter treatment courses (< 30 days) and pediatric formulations | <ul style="list-style-type: none"> Therapeutic and preventative vaccine | <ul style="list-style-type: none"> Accurate, sensitive POC RDTs (including both acute and chronic phases and for congenital infections) |
| Dengue | <ul style="list-style-type: none"> Safe, effective and affordable oral drugs (support only continuation projects that are previously funded by GHIT) | <ul style="list-style-type: none"> Preventive vaccines (support only continuation projects that are previously funded by GHIT) | <ul style="list-style-type: none"> Out of scope |
| Buruli ulcer | <ul style="list-style-type: none"> Safer and more effective drugs with shorter treatment courses (< 2 months) | <ul style="list-style-type: none"> <i>M. ulcerans</i> - specific vaccines | <ul style="list-style-type: none"> Accurate, sensitive POC RDTs |
| Soil-transmitted helminths | <ul style="list-style-type: none"> Combination treatment to optimize effectiveness across all helminths (including resistant mutants) | <ul style="list-style-type: none"> Out of scope | <ul style="list-style-type: none"> Accurate, sensitive POC RDTs that replace coprological method for measuring species-specific egg-count reduction. |
| Echinococcosis | <ul style="list-style-type: none"> Safe and effective oral drugs | <ul style="list-style-type: none"> Preventative vaccines | <ul style="list-style-type: none"> Accurate, sensitive POC RDTs |
| Cryptosporidium | <ul style="list-style-type: none"> Safe and effective oral drugs (including for immunocompromised patients) | <ul style="list-style-type: none"> Preventative vaccines | <ul style="list-style-type: none"> Accurate, sensitive POC RDTs |
| Mycetoma | <ul style="list-style-type: none"> Safe and effective oral drugs | <ul style="list-style-type: none"> Out of scope | <ul style="list-style-type: none"> Accurate, sensitive POC RDTs |

*POC RDTs = Point of Care Rapid Diagnostic Tests

For LDCs, LICs, and MICs, partners/participants will set prices for products on the basis of a no gain/no loss policy to improve access to the product for patients and citizens of these LDCs, LICs, and MICs. Based on the Target Product Profiles, partners will need to provide a target price range and definitive rationale for the estimated Cost of Goods Sold (COGS) and final product price as it relates to the socio-economic benefits that the product provides. Manufacturing cost, delivery costs, etc. will need to be factored into your target price range.

Regarding the development of vaccines: new and adapted vaccines technologies including thermostability, fewer doses, and needle-free delivery are expected. GHIT also prefers 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-2019-002_IntentToApply.docx**) and submit this to the GHIT Fund via Editorial Manager® no later than:

10:00 am Tokyo time on August 27, 2019.

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 the proposal templates from the GHIT Fund.**

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 September 10, 2019) 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 September 10, 2019.

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 (**[Project ID] Collaboration Partners Approval.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-2019-002_Questions**). no later than

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|---|
| 10:00 am Tokyo time on September 6, 2019 |
|---|

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. 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.

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.**

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.

Data Access Policy

The aim of our Data Access Policy is to articulate the principles that promote the transparency of and accessibility to data related to the safety and efficacy of healthcare technologies. This policy and its principles apply to data generated through activities primarily funded by the GHIT Fund, including but not limited to, those related to the discovery, development, and/or delivery of healthcare technologies.

All data and its processes for access will be transparent and clearly defined with the aim to ensure data quality, security, and equitable access. All data and findings will be disclosed in a broad and prompt manner in order to optimize prospects for the translation of findings in the global advancement of new healthcare technologies. Grantees should utilize public-access repositories and, if unavailable, should use alternatives for access that can ensure the transmission of new scientific findings to the larger research and development community globally.

Respect must be given to individuals and communities from or about whom data are collected. Respect must also be given to all matters of confidentiality and attribution as they pertain to researchers, evaluators, and their collaborators. Confidentiality and respect for such should be fully recognized where necessary or required by law or regulation.

Any and all existing data and findings owned by a grantee at the initiation of a project, including but not limited to information, know-how or intellectual property, will remain that of the original holder. The original holder may share, assign, or license their rights to a third party.

Ownership of any and all data and findings that is obtained or created through activities funded by the GHIT Fund and that can be applied for any intellectual property rights will be discussed and negotiated between participants and/or grantees of a project. All final agreements shall be in alignment with the licensing and pricing principles outlined below.

Any existing data owned by a grantee and/or any new data obtained through activities funded by the GHIT Fund may be disclosed by the GHIT Fund to a third party if such data is used in a patent application for a product which was derived from the activities funded by the GHIT Fund; provided, however: (1) the disclosure of such data shall be limited to the proposed title of the invention, a draft of the abstract, the international non-proprietary name (INN) where applicable, and an outline of the specifications of such patent application; and (2) such third party shall take reasonable measures to keep confidential any such data received from the GHIT Fund.

Product Access Policy

The aim of the Product Access Policy is to articulate the principles that improve access to products primarily developed with funding from the GHIT Fund, where such products refer to healthcare technologies approved for market by a national regulatory authority.

When development partners/participants are successfully granted a patent deriving from projects funded by the GHIT Fund, development partners/participants will grant royalty-free licenses to users operating in Least Developed Countries (LDCs) as categorized by the United Nations and Low-Income Countries (LICs) as categorized by the World Bank. License-related matters concerning middle income countries (MICs) will be reviewed on an individual basis with the goal of ensuring reasonable royalty licenses.

For LDCs, LICs, and MICs, partners/participants will set prices for products on the basis of a no gain/no loss policy to improve access to the product for patients and citizens of these LDCs, LICs, and MICs.

Key RFP Milestone Dates

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|--|---|
| RFP Release | July 10, 2019 |
| Intent to Apply Due | No later than 10:00 am Tokyo time on August 27, 2019 *Applicants are encouraged to submit the ITA well in advance of the Full Proposal submission deadline shown below to secure sufficient time to prepare full proposal. Submit via Editorial Manager® for Product Development Platform (http://www.editorialmanager.com/ghitfund/) |
| Q & A | No later than 10:00 am Tokyo time on September 6, 2019 Submit questions to RFPResponse@ghitfund.org Email Subject Line: GHIT-RFP-PD-2019-002_Questions |
| Full Proposal Due | No later than 10:00 am Tokyo time on September 10, 2019 Submit via Editorial Manager® for Product Development Platform (http://www.editorialmanager.com/ghitfund/) |
| Proposals Evaluation and Interview Processes | September - February 2020 |
| Award Notification to All Applicants | February 2020 |
| Investment Agreement Fully Executed (Awarded Proposals) | March 2020 |

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