GHIT Fund Product Development Platform
Request for Proposals
Reference Number: GHIT-RFP-PD-2015-001

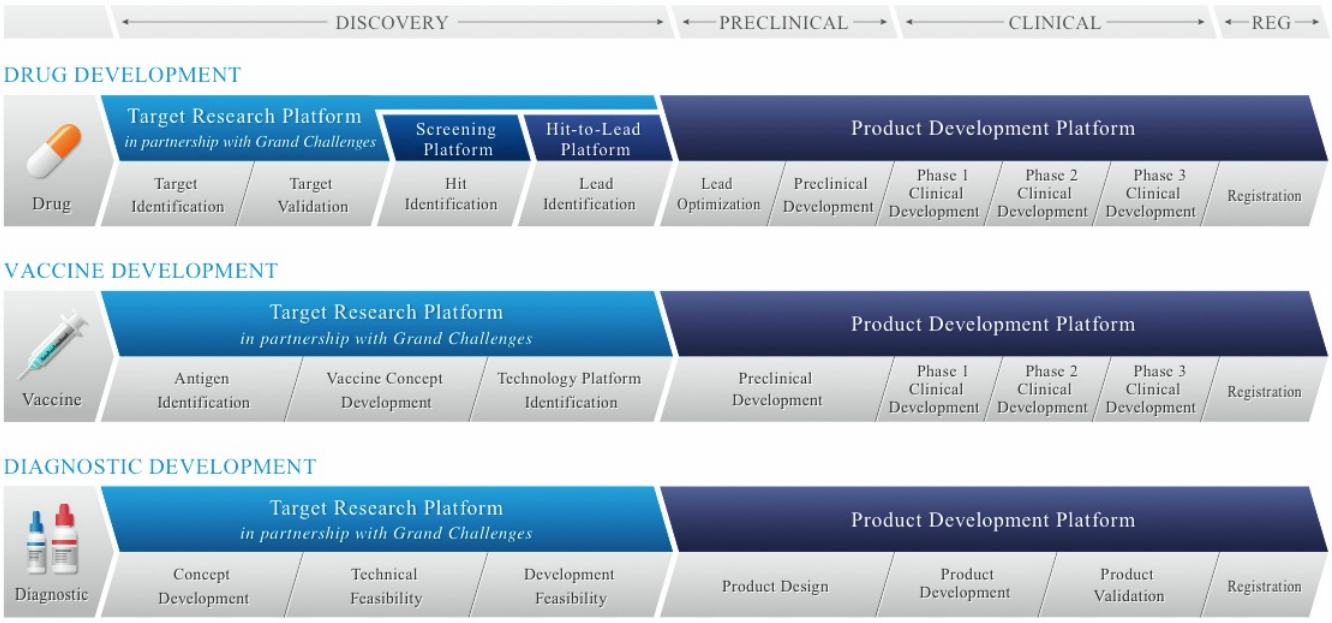
GHIT Fund Background

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 first fund of its kind in Japan, the GHIT Fund is supported by the Japanese Government, Japanese pharmaceutical companies, and the Bill & Melinda Gates Foundation. 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 may focus on a broad array of R&D activities, 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

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 following table specifies the types of organizations expected to form GHIT Fund eligible partnerships.

Japanese Organizations	Non-Japanese Organizations
• Companies with a research facility in Japan • Not-for-profit research organizations • Government research institutions • Academic institutions	• Product Development Partnerships (PDPs) and their network of partners including the following: – Life Science Companies – Not-for-profit research organizations – Government research institutions – Academic institutions

Both parties to 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 http://www.ghitfund.org/afag/policies/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 Proof of Concept (POC) activities and beyond, collaboration should include at least one commercial partner.

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 12 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.

Indication	Drugs	Vaccines	Diagnostics
Malaria	• Advance the eradication agenda with novel molecules: - single exposure radical cure & prophylaxis - fast clearance - long duration - targeting non-dividing stage	• Advance the eradication agenda: - transmission blocking vaccines - more effective prevention vaccines	• Accurate, sensitive POC RDTs
Tuberculosis	• Safer, faster-acting drug regimens with shorter treatment courses (≤ 4 months)	• Preventative vaccines	• Accurate, sensitive POC RDTs
Onchocerciasis	• Safer and more effective drugs that kill adult worms (macrofilaricides)	• Out of scope	• Accurate, sensitive POC RDTs
Lymphatic filariasis	• Safer and more effective drugs that kill adult worms (macrofilaricides)	• Out of scope	• Accurate, sensitive POC RDTs
Schistosomiasis	• Safe and effective oral drugs and new pediatric formulations of existing drugs	• Preventative vaccines	• Accurate, sensitive POC RDTs
Leishmaniasis	• Safer and more effective oral drugs with a shorter treatment course (< 20 days)	• Therapeutic and preventative vaccines	• Accurate, sensitive POC RDTs
Chagas disease	• Safer and more effective drugs with shorter treatment courses (< 30 days) and pediatric formulations	• Therapeutic and preventative vaccine	• Accurate, sensitive POC RDTs
Dengue	• Safe and effective oral drugs	• Vaccines effective against all 4 serotypes	• Accurate, sensitive POC RDTs
Buruli ulcer	• Safer and more effective drugs with shorter treatment courses (< 2 months)	• *M. ulcerans* - specific vaccines	• Accurate, sensitive POC RDTs
Soil-transmitted helminths	• Combination treatment to optimize effectiveness across all helminthes	• Single vaccine that prevents infection with all three major soil-transmitted helminths	• Accurate, sensitive POC RDTs
Echinococcosis	• Safe and effective oral drugs	• Preventative vaccines	• Accurate, sensitive POC RDTs
Cryptosporidium	• Safe and effective oral drugs	• Preventative vaccines	• Accurate, sensitive POC RDTs

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

Regarding the development of vaccines: new and adapted vaccines technology including thermostability, fewer doses, and needle free delivery is 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 presentation and contract negotiation.

Intent to Apply

Interested applicants must complete the *GHIT-RFP-PD-2015-001_IntentToApply.docx* document and submit to the GHIT Fund via its online document submission system (http://www.editorialmanager.com/ghitfund/) no later than 10:00 am Tokyo time on **March 13, 2015**.

Applicants who submit the *Intent to Apply* document will receive a confirmation email. GHIT Fund staff will then perform an initial partnership and scope eligibility assessment. Eligible applicants will receive a full GHIT Fund proposal template to support proposal development.

RFP Questions

Prospective applicants may also submit RFP questions to RFPResponse@ghitfund.org no later than 10:00 am Tokyo time on **March 30, 2015**, (please use email subject line: GHIT-RFP-PD-2015-001_Questions).

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

Proposal Submission

Applicants are required to submit their completed proposal to the GHIT Fund via its online document submission system no later than 10:00 am Tokyo time on **April 3, 2015**. Applicants who successfully submit their proposal document will receive a confirmation email. Proposals may not be modified after the submission due date.

The GHIT Fund may, at its own discretion, extend the closing date by notifying applicants who have submitted an *Intent to Apply* document. 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.

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

Applicants will be notified by email of their proposal's readiness for technical evaluation. GHIT Fund staff may ask clarifying questions or request additional information, as needed, to qualify proposals for evaluation.

Technical Evaluation

All proposals passing the preliminary examination will be evaluated and prioritized 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. Based on the aggregated External Reviewer results and a subsequent evaluation by the GHIT Fund Selection Committee (SC), proposals will be ranked by evaluation score. Partnerships with the highest ranked proposals will be invited for an interview with the SC. Once all information has been considered, the SC will make funding recommendations to the GHIT Board. The GHIT Board will discuss the SC recommendations, taking into account the access and delivery element of each proposal, and will decide which proposals will receive GHIT Fund investment.

Award Administration and Conditions

The GHIT Fund will notify applicants of their selection status by email. The GHIT Fund will not provide formal feedback to applicants receiving a non-award decision.

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 reflecting the expected time required to complete agreed activities. **The funding allocation will be milestone based.** 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

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

RFP Release	February 6, 2015
Intent to Apply	No later than 10:00 am Tokyo time on March 13, 2015 Submit via GHIT Fund online document submission system (http://www.editorialmanager.com/ghitfund/)
Q & A	No later than 10:00 am Tokyo time on March 30, 2015 Submit questions to RFPResponse@ghitfund.org Email Subject Line: GHIT-RFP-PD-2015-001_Questions
Application	No later than 10:00 am Tokyo time on April 3, 2015 Submit via GHIT Fund online document submission system
Award Notification	No later than August 1, 2015
Investment Agreement	No later than September 1, 2015