

GLOBAL HEALTH TECHNOLOGY DISCOVERY AND DEVELOPMENT

GHIT Fund Request for Proposals

Reference Number: GHIT-RFP-2013-002

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 effective 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 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 grants.

Funding Opportunity

The GHIT Fund announces a funding award opportunity for the development of new medicines, vaccines, or diagnostics for infectious diseases that are prevalent in the developing world. Proposed projects should address health needs in the developing world or fill a gap in global health technologies for infectious diseases.

The proposed collaboration project may include R&D activities from pre-clinical research (post-lead optimization) through licensure. More specifically, we seek to fund a portfolio of innovative collaboration projects, such as:

- Pre-clinical development (e.g., lead-optimization, in-vivo studies, formulation development, chemistry and process validation)
- Clinical development (e.g., Phase 1, Phase 2, Phase 3, manufacturing scale up)
- Activities to support licensure and WHO prequalification

Please note the issuance of this RFP does not obligate the GHIT Fund to make an award.

Eligibility

GHIT Fund grants 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
<ul style="list-style-type: none"> • Companies with a research facility in Japan • Not-for-profit research organizations • Government research institutions • Academic institutions 	<ul style="list-style-type: none"> • Product Development Partnerships (PDPs) • Companies with a research facility outside of Japan • Not-for-profit research organizations • Government research institutions • Academic institutions

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 following boundary conditions.

Product Development Areas of Interest

Indication	Drug	Vaccine	Diagnostic
Malaria	●	●	●
Tuberculosis	●	●	●
Onchocerciasis	●		●
Lymphatic filariasis	●		●
Schistosomiasis	●	●	●
Visceral Leishmaniasis	●	●	●
Chagas disease	●		●
Human African Trypanosomiasis	●		●
Dengue	●	●	●

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_IntentToApply.doc* document and return it by email to RFPResponse@ghitfund.org no later than 10:00 am Tokyo time September 30, 2013, (use email subject line: GHIT-RFP-2013-002 Intent to Apply).

Applicants who submit the Intent to Apply document will receive a confirmation email and the GHIT Fund's required proposal template.

RFP Questions

Prospective applicants may submit RFP-related questions to RFPResponse@ghitfund.org no later than 10:00 am Tokyo time October 7, 2013. (use email subject line: GHIT-RFP-2013-002 Questions).

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

Proposal Submission

Applicants are required to complete the GHIT Fund's Proposal (GHIT_RFP_ProposalForm.pdf & GHIT_RFP_BudgetTemplate.pdf; Word & Excel versions will be provided with submission of Intent to Apply form) and submit it to RFPResponse@ghitfund.org no later than 10:00 am Tokyo time on October 31, 2013 (use email subject line: GHIT-RFP-2013-002 Proposal). All proposal submissions will receive an acknowledgement from GHIT Fund staff. Proposal submissions may not be modified after the submission closing 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., 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.

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 grantee and all collaboration partners. The grantee will be the funding recipient and will be responsible for the performance of its collaborating partners. A representative of the designated grantee will serve as the main GHIT Fund point of contact and will be responsible for all GHIT Fund discussions and negotiations.

Grants will be awarded for a period reflecting the expected time required to complete agreed activities. Grants will not exceed 2 years. The GHIT Fund has the right to terminate the grant agreement if:

- The partnership disbands prior to satisfying its grant 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 specified in the grant agreement.

In the event a grant is terminated, the GHIT Fund reserves the right to cancel future fund 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 grant agreement.

Data and Product Access

The aim of the GHIT Fund Data and Product Access Policies are to articulate the principles that promote the transparency of, and accessibility to, data related to the safety and efficiency of healthcare technologies. The policy and its principles apply to data or products generated through the activities funded primarily by the GHIT Fund, including but not limited to, data related to the discovery and development of healthcare technologies, and products approved for introduction by a national regulatory authority.

All data, and processes for its access, will be clearly defined by the applicant. Appropriate data and project outcomes will be disclosed in a broad and prompt manner to optimize the translation of findings in the global advancement of new healthcare technologies.

Grantees should utilize public-access repositories, whenever available; otherwise use access alternatives that ensure the transmission of new scientific findings to the global research and development community.

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 should be fully recognized when requested or when required by law or regulation.

Existing data or project outcomes owned by a grantee at the initiation of a GHIT Fund project, including but not limited to information, know-how or intellectual property, will remain the property of the original holder. The original holder may share, assign, or license their rights to this property to a third party.

Proprietorship of data and project outcomes achieved or created through activities funded by the GHIT Fund that can be considered an intellectual property right, will be negotiated prior to grant completion. All negotiated agreements should be in alignment with the following licensing and pricing principles:

- When licensing data or products developed with GHIT Fund support, grantees and/or participants will grant royalty-free licenses in Low-Income Countries, as categorized by the World Bank's country income classification.
- In Lower-Middle-Income Countries and Upper-Middle-Income Countries, as categorized by the World Bank's country income classification, grantees and/or participants will grant licenses that provide improved product access for these countries' low-income populations.
- In Low-Income, Lower-Middle-Income, and Upper-Middle-Income Countries, as categorized by the World Bank's country income classification, grantees and/or participants will set product prices based on a no gain/no loss policy so as to improve product access for these countries' low-income populations.

Key RFP Milestone Dates

RFP Release	August 12, 2013
Intent to Apply	10:00 am September 30, 2013 Submit <i>GHIT_RFP_IntentToApply.doc</i> to RFPResponse@ghitfund.org Email Subject Line: GHIT-RFP-2013-002 Intent to Apply
Q & A	Submit Questions to RFPResponse@ghitfund.org no later than 10:00 am October 7, 2013 Email Subject Line: GHIT-RFP-2013-002 Questions
Application	10:00 am Tokyo Time October 31, 2013 Submit <i>GHIT_RFP_Proposal.doc</i> to RFPResponse@ghitfund.org Email Subject Line: GHIT-RFP-2013-002 Proposal
Award Notification	No later than March 1, 2014