With the right commitment, coordination, and collaboration, the public & private sectors will work together to enable more than a billion people suffering from NTDs to lead healthier and more productive lives.

--London Declaration on NTDs (January 2012)

Combatting NTDs
GHIT Fund Request for Proposals
Reference Number: GHIT-RFP-2014-002

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 and products. 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 global health technologies and products.

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 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 neglected tropical diseases (NTDs) that are prevalent in the developing world. Proposed projects should address NTD-related health needs in the developing world or fill a gap in global health technologies focused on NTDs.

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
• 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

Disease 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 the needs for each of the 9 diseases included in this RFP is shown below. Proposals must be focused exclusively on addressing the needs listed in the table.

Indication	Drug	Vaccine	Diagnostic
Onchocerciasis	• Macrofilaricides that target adult worms • Drug that can be used in Loasis co-endemic areas without SAEs • Identification of IVM resistance markers	• *Out of scope*	• Accurate, sensitive POC RDTs • Antigen test for quantification of infection intensity • Tests to detect adult worms
Lymphatic filariasis	• Macrofilaricides that target adult worms • Long acting formulation of IVM to take advantage of endectocidal properties	• *Out of scope*	• Antibody test to detect exposure
Schistosomiasis	• Pediatric PZQ formulation • Single isomer PZQ formulation	• Preventative vaccines	• Accurate, sensitive POC RDTs • Tests with high specificity for use in low transmission areas • Tests that do not require stool

Indication	Drug	Vaccine	Diagnostic
Leishmaniasis	• Safer and more effective oral drugs with a shorter treatment course (less than 20 days) • Medicines that target the skin for PKDL	• Therapeutic and preventative vaccines	• Accurate, sensitive POC RDTs, particularly for African kala-azar • Tests to confirm clearing of infection, also for PKDL
Leprosy	• Shorter treatment course • Improved treatment for leprosy reactions • Ensuring new TB vaccines will give same protection against leprosy as BCG does	• *N/A*	• Test to detect early infection and identify household contacts to target chemo-prophylaxis initiatives
Chagas Disease	• Safer and more effective drugs with shorter treatment courses (less than 30 days) • Pediatric formulation • Drug indicated for all infection stages	• Therapeutic and preventative vaccines	• Accurate, sensitive POC RDTs • Test to confirm clearing of infection • Screening test to identify patients at risk of pathological cardiac or GIT outcomes
Human African Trypanosomiasis	• Safer and more effective drugs • Oral cure that is not stage specific	• *N/A*	• Accurate, sensitive POC RDTs and for *T.b. gambiense* • User friendly tests (1 step required) with higher

Indication	Drug	Vaccine	Diagnostic
			specificity than current rapid tests
Soil-Transmitted Helminths	• Combination treatment to optimize effectiveness across all helminthes • Back -up drug for benzamidazoles	• Single vaccine that prevents infection with all three major soil-transmitted helminths	• Accurate, sensitive POC RDTs • Test to quantify all 3 species without microscopy of stool
Trachoma	• *N/A*	• *N/A*	• Test to detect active infection and/or evidence of exposure

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

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 submit Intent to Apply document using our online submission system. Submission of Intent to Apply can be made from 10:00am Tokyo time 16th June, 2014 to no later than 10:00am Tokyo time 18th August, 2014. For details of submission procedure, see file "GHIT Fund 2014-002 Instruction For Applicants.pdf," which will be available on our website on 16th June, 2014.

Applicants who submit the Intent to Apply document will receive a confirmation email. GHIT Fund staff will perform an initial partnership and scope eligibility assessment and eligible applicants will receive GHIT Fund's full proposal templates.

RFP Questions

Prospective applicants may submit RFP-related questions to RFPResponse@ghitfund.org no later than 10:00am Tokyo time 11th September, 2014. (use email subject line: GHIT Fund-RFP-2014-002 Questions).

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

Proposal Submission

Eligible applicants who submit an Intent to Apply form will receive GHIT Fund Proposal, Timeline and Budget templates. Applicants are required to complete and submit them to the GHIT Fund using our online submission system no later than 10:00 am Tokyo Time on 18th September, 2014. The instruction of the online submission system will be sent with the templates via email by the GHIT Fund to the applicants.

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 all applicants who have submitted 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 contribute to addressing 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 by email of their selection status. 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.

The Grant Agreement and Grantee Profile templates will be sent to awarded grantees from the GHIT Fund. Awarded grantees must submit to the GHIT Fund the signed Grant Agreement, the signed collaboration partners contractual agreement as well as the completed Grantee Profile documents no later than 10:00am Tokyo time on 16th March, 2015. The grant may not be provided if this condition is not met.

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 and intellectual property 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 national regulatory authorities.

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	13th June, 2014
Intent to Apply	From 10:00am Tokyo Time on 16th June, 2014 To 10:00 am Tokyo Time on 18th August, 2014
Q & A	Submit Questions to RFPResponse@ghitfund.org no later than 11th September, 2014. Email Subject Line: GHIT Fund-RFP-2014-002 Questions
Application	No later than 10:00 am Tokyo Time on 18th September, 2014
Award Notification	No later than 16th February, 2015
Agreement	No later than 16th March, 2015