GHIT Fund

Global Health Innovative Technology Fund

GHIT Fund Hit-to-Lead Platform (HTLP)
Request for Proposals

Reference Number: GHIT-RFP-HTLP-2026-002

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1. GHIT Fund Background

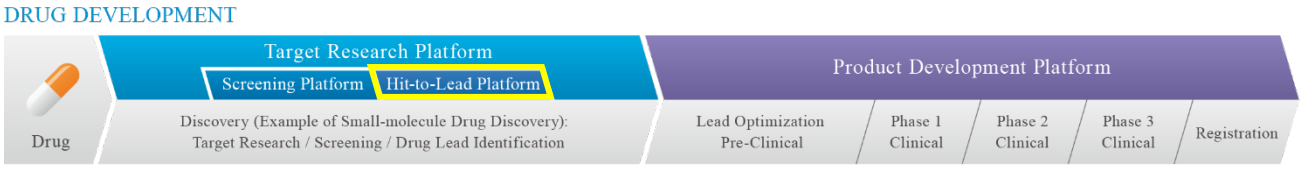
With over a billion people in the world suffering from infectious diseases, especially in low-income countries (LICs) and lower-middle-income countries (LMICs), there is a need for new low-cost, high-impact health technologies. Responses to this need in recent years have led to the development of new products, mostly as a result of partnerships between healthcare companies, academia and research institutions, and Product Development Partnerships (PDPs). These partnerships have proved 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 research and development of new health technologies, including drugs, vaccines and diagnostics for infectious diseases prevalent in LICs and LMICs. The first fund of its kind in Japan, the GHIT Fund is supported by the Japanese Government, healthcare enterprises, the Wellcome Trust and the Gates Foundation. The GHIT Fund aims to advance Japanese innovation for the research and development of new technologies for vulnerable patients and populations affected by neglected infectious diseases. To this end, the GHIT Fund will catalyze R&D partnerships between Japanese and non-Japanese organizations and support these partnerships through investments.

2. Funding Opportunity

The Hit-to-Lead Platform (HTLP) leverages the medicinal chemistry expertise in Japan and facilitate access to relevant and diverse compounds to address the unmet needs of malaria, tuberculosis, Chagas disease, Schistosomiasis, and viral infectious diseases with pandemic potential.

HTLP focuses on the aspect of the drug discovery and development process that advances hits, identified through compound library screening, into lead compounds that can then be optimized into drug candidates. This platform will provide a bridge from early drug discovery to GHIT's Product Development Platform that begins with the lead-optimization step.



The aim of HTLP is to convert drug hits derived from Japanese compound libraries or identified using innovative Japanese technologies into lead series. This is achieved through a comprehensive assessment of chemical integrity, synthetic accessibility, scalability and novelty, functional behavior, and structure-activity relationships (SAR), as well as bio-physiochemical and ADME (absorption, distribution, metabolism and excretion) properties.

This lead-generation step is critical as it represents the earliest point where knowledge-based decisions can be made about compounds. Rigorous early assessment helps concentrate resources on the most promising lead series. To address the high attrition rate in the early stages of drug discovery, applications are encouraged to include multiple hit series.

3. Eligibility

- **Project:**

Qualified drug hits that meet the eligibility criteria outlined in the "Project Scope" section will be considered for HTLP funding.

- **Partnership:**

Each proposal must have **at least one Japanese organization and one non-Japanese organization.**

Notes:

✓ All organizations in the partnership must be legally registered.

✓ Whether an organization is Japanese or non-Japanese is defined by the location of its headquarters.
e.g., Example Corp. is headquartered in Japan and has a subsidiary in the United States (US Subsidiary), where the subsidiary will still be considered a Japanese organization for the purposes of the project, even if only the US Subsidiary participates.

✓ Group companies are considered a single organization.
e.g., If Example Corp. has a subsidiary, Example Corp. Technologies, and employees from both companies participate in the project, register one of the organizations as the representative.

✓ The following table presents examples of organization types.

Organization Types (examples)
• Life science/healthcare companies • Academic institutions • Non-profit research organizations and foundations • Government research institutions • Product Development Partnerships (PDPs)

✓ **The GHIT Fund requires each HTLP project to partner with one of the three leading PDPs below.**

- Medicines for Malaria Venture (MMV)
- Drugs for Neglected Diseases initiative (DNDi)
- TB Alliance

- **Organizational Information:**

Each organization must submit a certified copy of its registration and financial statements (audited by an independent auditor) from the most recent three fiscal years.
If the organization is less than three years from establishment, it must submit the financial statements that are available at the time of application.

- **Organizational Restrictions:**

The proposal will be considered ineligible if any Collaboration Partner or subcontractor falls under the following categories:

- Organizations headquartered or operating in countries subject to international trade or economic sanctions
- Organizations based in jurisdictions where local regulations prohibit or restrict the receipt of international funds.

4. Project Scope

4.1. Criteria for Eligible Compounds/Series

Proposals must meet the criteria below in order to be eligible for consideration.

Cellular potency consistent with potential to deliver lead series (typically *Plasmodium spp.* IC50 <1µM, *T. cruzi* intracellular amastigotes IC50 <5 µM, Emax >95%, *S. mansoni*, *S. haematobium,* or *S. japonicum* IC50 <10 µM, and *M. tuberculosis* MIC <10µM, antiviral IC50 <10 µM).
Data indicates that pre-existing clinical resistance could be overcome.

- Compounds originated/derived from Japan or selected/designed using Japanese innovative technology
- Novel hit structures confirmed
- Primary results validated on hit compounds (>90% pure)
- Acceptable *in vitro* concentration-response curves
- Preliminary SAR with existing analogues
- Progressable chemotypes
- >10-fold selectivity for cytotoxicity using a mammalian cell line (e.g., HepG2)
- Adequate selectivity in counter assay(s)
- No blocking intellectual property (IP)
- No major synthesis or formulation issues anticipated
- Novel mechanism of action:
  - For *T. cruzi* avoiding CYP51, cytochrome bc1, proteasome, tRNA synthase, squalene synthase
  - For *M. tuberculosis*, targets excluding DPRE1 and MMPL3

4.2. Criteria for Project Outcomes

4.2.1. Generic Criteria

- TPP (Target Product Profile)/TCP (Target Candidate Profile) defined
- Acceptable *in vitro* potency. Oral efficacy in appropriate disease model (see below)
- Potential to deliver compounds with sufficient potency and favorable physicochemical properties (i.e., tractable SAR and structure liability relationships) with properties within the series within 10-fold of the TCP/ TPP
- Synthetic chemistry amenable to rapid series expansion preferred
- >10-fold selectivity with respect to cytotoxicity
- Acceptable physicochemical properties (typically solubility in PBS >10µM, acceptable lipophilicity)
- Manageable ADME/Toxicity profile (liver microsome stability, plasma binding, permeability, CYP inhibition, hERG inhibition and, typically, secondary pharmacology selectivity profile)
- Oral bioavailability in rodents demonstrated (> 25%)
- No known toxicophores or undesirable reactive groups and no chemical feature with a liability associated with the pharmacophore; however, if required for biological activity, some indication that its toxicity can be managed
- No acute toxicity from *in vivo* efficacy studies
- Liabilities of the series understood, and a rationale generated for why they can be overcome in the subsequent optimization phase
- No apparent IP obstacles for progression of this series

4.2.2. Criteria for Malaria

- MMVSola predicted dose (< 1000 mg) based on in vitro 3D7 potency (IC50, u < 0.01 µM) and single species rodent PK (t1/2 > 2 h)
- Low resistance risk (MIR > 9) or clear strategy to manage risk if moderate (MIR = 7-9)

- SCID study (ideally dose-response) demonstrating correlation between in vitro and in vivo efficacy
- At Early Lead, compounds will have potential for development into a drug candidate for either treatment (TPP1) or chemoprevention (TPP2)
- Potency against *P.vivax* liver hypnozoites (TCP3), *P. falciparum* liver schizonts (TCP4) or in dual gamete formation (DGFA) assay (TCP5) within 3-fold of asexual blood stage potency if series to be considered for radical cure (TCP3), liver stage chemoprevention (TCP4) or transmission blocking potential (TCP5)

4.2.3. Criteria for Tuberculosis

- *In vitro* activity MIC < 2μM against replicating and preferably also non-replicating *M. tuberculosis* Bactericidal activity preferred in an acute *in vivo* model
- Preliminary indication of safety and efficacy demonstrated in mice (greater than or equal to 1 log CFU reduction at doses equal to or less than 300 mg/kg in a mouse acute infection model)
- No cross resistance with existing TB drugs

4.2.4. Criteria for Chagas Disease

- *In vitro*:
  - *T. cruzi* intracellular amastigotes IC50 <1 μM, Emax >95%; activity against trypomastigotes also desirable
  - Consistent activity (within 10-fold) against *T. cruzi* strains representative of the DTUs (Tc I, II, V, VI) and/or slow and fast replicating strains
- *In vivo*:
  - >2-log reduction of parasitemia in an acute mouse model of Chagas disease and/or absence of viable parasites in *T. cruzi in vitro* washout assay

4.2.5. Criteria for Schistosomiasis

- *In vivo*:
  - >85% reduction of juvenile worms (*schistosomulae*) after ≤ 5 days treatment in a rodent model (n≥6 to address variability)
  - Activity also on adult worms desirable

4.2.6. Criteria for Viral Infectious Diseases

- *In vitro* cellular potency IC90 < 1 μM ideally in ≥1 relevant cell line or primary cells
- *In vivo* efficacy criteria: demonstration of dose response with ≥1 log unit in viral load and no overt toxicity in relevant preclinical animal model
- If no animal infection model available, then achieving C*trough* > IC90 following 1-3 times daily oral dosing in a rodent
- For viruses involving potential CNS infections, demonstration of appropriate CNS permeability and low efflux ratio
- Preliminary evidence of having activity across viruses from the same family desirable

5. Partnership Roles

Upon applying to the GHIT Fund, each partner organization in a partnership is referred to as Collaboration Partner (CP). The partnership must nominate one CP as a Designated Development Partner (DDP), who holds primary responsibility for the execution of the project, while the other CPs support the project through compliance with their respective obligations.
The roles and responsibilities of the DDP and the CPs are summarized below. Note that DDP must comply with the roles of DDP as well as the roles of CP.

5.1. Roles and Responsibilities of the Designated Development Partner (DDP)

From Proposal Submission to Evaluation:

- Acts as primary point of contact with the GHIT Fund.
- Coordinates and submits proposals and relevant documents on behalf of all the CPs.

When Awarded:

- Primary Representative: Main liaison between the CPs and the GHIT Fund.
- Funding Recipient: Receives the funding from the GHIT Fund and is responsible for distributing funding to other CPs.
- Project Oversight: Ensures overall project performance and monitors each CP's work and compliance with the terms of the Investment Agreement.
- Investment Management: Manages the use of the investment in accordance with the approved budget; oversees audits, financial reporting, and related requests.
- Reporting: Oversees and submits the Progress Reports, including itemized expenditure reports, and ensures proper documentation and compliance with the GHIT Fund's guidelines.
- Dual Role as CP: In addition to the roles and responsibilities unique to the DDP, the DDP must adhere to the roles and responsibilities of a CP to the extent it does not interfere or conflict with its role as a DDP.

5.2. Roles and Responsibilities of the Collaboration Partners (CPs)

From Proposal Submission to Evaluation:

- Provides necessary input and information to the DDP for the proposal preparation.

When Awarded:

- Project Participation and Obligations: Each CP delivers their assigned portion of the project and complies with all the terms of the Investment Agreement.
- Collaboration Agreement: Enters into a separate contractual relationship with the other CPs, subject to the GHIT Fund's approval, to formalize their collaboration.
- Approval of Subcontractors: CPs must adhere to the limitation on the hiring of subcontractors, under which CPs may not hire subcontractors without the GHIT Fund's approval unless the subcontractors have been previously identified in the project proposal.
- Audit and Financial Compliance: Each CP maintains accurate financial records and provides access to all relevant documentation; subject to potential audits by both the DDP and the GHIT Fund.
- Legal and Ethical Compliance: CPs must comply and adhere to all applicable laws and ethical standards, including those regarding anti-corruption, anti-terrorism.
- Legal Responsibility: CPs must indemnify the GHIT Fund and its affiliates from and against any legal actions or liabilities arising out of the Investment or the project, except to the extent such action or liability is attributable to any gross negligence or willful misconduct by the GHIT Fund.

6. Applicant Instructions

Editorial Manager®:
To receive and manage applications, the GHIT Fund uses **Editorial Manager® for Hit-to-Lead Platform** (https://www.editorialmanager.com/ghitfund/), an online document submission system dedicated to this funding platform.
Note that the *Intent to Apply* (ITA) form or the full proposal that is not submitted through the above-mentioned system will not be accepted.

Language:
All correspondence and documents relating to this RFP shall be written in English.

Associated Expenses:
The applicant shall bear all costs associated with the preparation and submission of the proposal, including costs associated with proposal presentation and contract negotiation.

Step 1 - Intent to Apply (ITA) Form Submission

Interested applicants must complete the ITA form and submit the form to the GHIT Fund via Editorial Manager® no later than:

10:00 am on August 14, 2026 (Japan Standard Time)

The ITA form is available on the GHIT Fund website:
https://www.ghitfund.org/applyforfunding/htlp/en

Notes:

- The ITA form must be reviewed and approved by all Collaboration Partners prior to submission
- Any application not using the designated ITA form for the current RFP round will not be accepted
- Do not attach any documents to the ITA form
- When submitting your ITA form on the Editorial Manager®, list all the Collaboration Partners participating in the project; the name and details (including email address) of at least one representative from each organization must be indicated
- After submitting the ITA form, you will receive a confirmation email

The GHIT Fund Management Team will then perform an initial partnership and scope eligibility assessment.
Only eligible applicants will be invited to submit the full proposal and receive access to the proposal templates.
The eligibility assessment will be conducted upon receipt of the ITA form, and applicants will be notified of the results once it is complete. Applicants are encouraged to submit the ITA form well in advance of the deadline to secure sufficient time to prepare a full proposal.

Step 2 – Full Proposal Submission

Applicants invited to submit a full proposal are required to do so via Editorial Manager® no later than:

10:00 am on September 18, 2026 (Japan Standard Time)

Notes:

- Proposals must be reviewed and approved by all Collaboration Partners prior to submission
- The *Collaboration Partners' Approval* form must be signed by all Collaboration Partners, and a PDF copy must be submitted along with other proposal documents (Electronic signatures are acceptable)
- Each organization must submit a certified copy of its registration and financial statements audited by an independent auditor from the most recent three fiscal years, as an attachment to *Exhibit A* form
- Applicants who successfully submit their proposal documents will receive a confirmation email.

- Proposals may not be modified after submission. Incomplete proposal documents (such as those that do not adequately address the proposal questions or contain inconsistencies within the documents) will be deemed ineligible
- Additional documents, including additional data and/or supporting documents, cannot be accepted after the deadline
- The GHIT Fund may, at its sole discretion, extend or advance the deadline, with prior notice to applicants
- Proposals received after the closing date for submission without prior agreement will be ineligible but may be resubmitted in future RFPs

7. Full Proposal Evaluation

The following evaluations will be conducted for the submitted full proposal.

7.1. Preliminary Screening

Proposals will initially be examined to determine or evaluate:

- whether the partnership meets GHIT Fund eligibility criteria stated in the current RFP
- whether the project objectives are aligned with the scope stated in the current RFP
- whether the proposal is complete and addresses all required content
- that the required organizational documents have been submitted for each organization

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

7.2. Technical Evaluation

All eligible proposals will be evaluated based on the following criteria:

- Scientific and technical merit
- Potential impact
- Partnership
- Project management

Evaluation Process:

- The evaluation will be conducted by the External Panel, which is comprised of several experts in the research and development of global health technologies, each of whom possesses the experience to objectively evaluate the proposal content.
- After the review process, the External Panel will provide funding recommendations to the HTLP Subcommittee, which is comprised of selected GHIT Fund Selection Committee (SC) members, who review and make the funding decisions with appropriate conditions. The decisions will be reported to the GHIT Fund Board.
- Evaluation procedures and their format may be adjusted due to unforeseen circumstances.

7.3. Due Diligence

Due diligence (compliance and credit check) will be conducted for all the CPs in detail according to the following criteria:

- Detailed budget for each category provided by each CP is reasonable and appropriate to address the project's R&D activities to be conducted by each CP by phase/activity/milestone
- Results of the compliance and credit check reveal no significant issues or concerns

Depending on the outcome of the due diligence process, the GHIT Fund may impose funding conditions (e.g., milestone-based payments, deliverable-based payments, or other installment-based payments) or determine that the proposal is not fundable.

8. Award Administration and Conditions

Notification of Results:

- Following the funding decision, applicants will receive the award decision by email, with a notification letter attached.
- **Note that the GHIT Fund is not able to provide additional feedback to applicants receiving a non-award decision beyond what is stated in the notification letter.**

Agreements:

- If the applicant receives an award notification, all CPs are required to sign an Investment Agreement with the GHIT Fund and put in place a contractual agreement among the CPs, which clearly defines the roles and responsibilities of all CPs **within two weeks to one month from the award notification**
- The Investment Agreement template will be shared with the applicants who are invited to submit the full proposal
- The award may be revoked or considered void if any of the conditions are not met
- Please note that (1) the GHIT Fund may update the Investment Agreement template from time to time, and (2) while the GHIT Fund is open to discuss the terms of the Investment Agreement on a case-by-case basis, the template represents the GHIT Fund's positions generally except in certain circumstances where the CPs can present reasonable grounds for exceptions or modifications (such as undue burdens). 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.

9. Access Policy

The applicants are required to agree to the Access Policy of the GHIT Fund to ensure that GHIT's objectives of providing equitable and affordable access are met.
Details about the GHIT Access Policy can be found here:
https://www.ghitfund.org/applyforfunding/accesspolicy/en.

10. Privacy Policy

Details about the GHIT Fund Privacy Policy can be found here:
https://www.ghitfund.org/general/privacypolicy/en.

11. Applicant Responsibility

Applicants are responsible for ensuring that all proposed project activities, funding flows, participating organizations, and subcontracting arrangements comply with all applicable laws and regulations. This includes relevant ethical, legal, regulatory, safety, and data protection requirements in the relevant jurisdictions.

Specific obligations include, but are not limited to:

- Compliance with requirements relating to foreign funding, local registration, approvals, reporting, recordkeeping, audits, and fund transfers.
- Obtaining and maintaining all necessary approvals, consents, and reviews required for the project.
- Ensuring the project is structured and managed in a manner consistent with the GHIT Fund Access Policy, where applicable.

12. Disclaimer

The GHIT Fund Management Team does not have any influence, authority or decision-making power with respect to: (i) review and evaluation, (ii) funding recommendations and (iii) funding decisions of submitted proposals by the Expert Panel, HTLP Subcommittee and the Board of Directors.
In addition, submission of the ITA form or the full proposal does not guarantee funding of your proposal.

Submitted documents will be shared with GHIT Fund reviewers and external consultants for the purpose of review and evaluation.

GHIT Fund will treat application materials as if they are confidential and use them only for evaluation and internal purposes. If applicants submit any information on not publicly available sensitive intellectual property and essential for the review, the applicants should contact the GHIT Fund Management Team before submission.

13. Key RFP Milestone Dates

RFP Release	**June 15, 2026**
Intent to Apply Due	No later than **10:00 am on August 14, 2026 (Japan Standard Time)** *Applicants are encouraged to submit the *Intent to Apply* (ITA) form well in advance of the full proposal submission deadline shown below to secure sufficient time to prepare the full proposal Submit via **Editorial Manager® for Hit-to-Lead Platform** (https://www.editorialmanager.com/ghitfund/)
Full Proposal Due	No later than **10:00 am on September 18, 2026 (Japan Standard Time)** Submit via **Editorial Manager® for Hit-to-Lead Platform** (https://www.editorialmanager.com/ghitfund/)
Proposals Evaluation and Interview Processes	**September 2026 - January 2027**
Notification of Results	**January 2027**
Investment Agreement Fully Executed (Awarded Proposals)	**March 2027**

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

For proposals addressing diseases with Pandemic Potentials and diseases with public health emergency, proposals may be submitted outside the above-mentioned timeline. Please contact the GHIT Fund for more details.

14. Inquiries

For any inquiries, please contact RFPresponse@ghitfund.org (please use the email subject line: **GHIT-RFP-HTLP-2026-002_Questions**)
A Frequently Asked Questions (FAQ) page is available on the GHIT Fund website:
(https://www.ghitfund.org/applyforfunding/investmentfaq/en).

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