

GHIT Fund Target Research Platform Proposal Form for Standard TRP Award

Reference Number: GHIT-RFP-TRP-2026-001

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0. Instructions

Proposals must address all sections (including attachments) within the following page limits:

- [Required] Target Research Proposal: **20 pages** or less
- [Optional] Supporting documents: **20 pages** or less

1. Overview

1-1. Project ID

Insert Project ID Here

1-2. Project Title

Insert Project Title Here

1-3. History of applying for GHIT Funding

Provide the project IDs **related to this application**.

Please specify if this is a new application or a continuation of a project previously funded by the GHIT Fund.

Insert Project ID Here

**Example: Continuation of T201X-10X (Awarded) and resubmission of T202X-10X (not awarded)*

1-4. Executive Summary (250-word limit)

Outline the project's main goals and expected outcomes over its duration.

This summary should be self-explanatory, providing key information on the target product.

Insert Executive Summary Here

2. Partnerships - Roles and Responsibilities

Complete the following table detailing partner information.

If there are more than six partners, provide additional information by adding columns to the table.

Please refer to the RFP for the roles and responsibilities of the Designated Development Partner and Collaboration Partner.

| | <u>Designated Development Partner</u> / Collaboration Partner 1 | Collaboration Partner 2 | Collaboration Partner 3 |
|--|---|---|---|
| Organization Name | | | |
| Name of Authorizing Body, if different from above | | | |
| Organization Type (e.g., PDP, pharma company, academic institution) | | | |
| Organization Status | <input type="checkbox"/> Japanese <input type="checkbox"/> Non-Japanese Please specify the country below. _____ | <input type="checkbox"/> Japanese <input type="checkbox"/> Non-Japanese Please specify the country below. _____ | <input type="checkbox"/> Japanese <input type="checkbox"/> Non-Japanese Please specify the country below. _____ |
| Organization Address and Phone Number | | | |
| Department Name, Address and Phone Number (if different from above) | | | |
| Organization Webpage | | | |
| Lead PI (name and title) | | | |
| Contact Details (e-mail and phone) | | | |
| Role and Responsibility | | | |

| | Collaboration Partner 4 | Collaboration Partner 5 | Collaboration Partner 6 |
|---|---|---|---|
| Organization Name | | | |
| Name of Authorizing Body, if different from above | | | |
| Organization Type (e.g., PDP, pharma company, academic institution) | | | |
| Organization Status | <input type="checkbox"/> Japanese <input type="checkbox"/> Non-Japanese Please specify the country below. | <input type="checkbox"/> Japanese <input type="checkbox"/> Non-Japanese Please specify the country below. | <input type="checkbox"/> Japanese <input type="checkbox"/> Non-Japanese Please specify the country below. |
| Organization Address and Phone Number | | | |
| Department Name, Address and Phone Number (if different from above) | | | |
| Organization Webpage | | | |
| Lead PI (name and job title) | | | |
| Contact Details (e-mail and phone) | | | |
| Role and Responsibility | | | |

2-1. Partner History

If the partners have previously worked together, provide a brief description of their history.

| |
|------------------------------------|
| <i>Insert Partner History Here</i> |
|------------------------------------|

2-2. Contractual Relationship

The GHIT Fund requires a formal contractual relationship amongst the Collaboration Partners before distributing the awarded funds.

Describe your partnership's existing or intended contractual relationship.

| |
|---|
| <i>Insert Contractual Relationship Here</i> |
|---|

2-3. Project Management Partner Roles & Responsibilities

Outline the roles and responsibilities of each partner within the project.

Include details such as specific contributions of each partner related to the milestones and activities.

You MUST provide a detailed description of how the project will be managed and how decisions will be made.

Insert Project Management Partner Roles & Responsibilities Here

2-4. Roles of the Japanese Organization(s)

Describe how the leadership and proposed activities by the Japanese organization play a critical role in the innovation/technology/know-how related to the project.

Insert Roles of the Japanese organization(s) Here

3. Project Scope

3-1. Intervention Focus

| | | |
|-------------------------------|----------------------------------|-------------------------------------|
| <input type="checkbox"/> Drug | <input type="checkbox"/> Vaccine | <input type="checkbox"/> Diagnostic |
|-------------------------------|----------------------------------|-------------------------------------|

3-2. Target Disease

| | | |
|--|---|--|
| <input type="checkbox"/> Buruli ulcer | <input type="checkbox"/> Chagas Disease | <input type="checkbox"/> Chikungunya |
| <input type="checkbox"/> Dengue | <input type="checkbox"/> Dracunculiasis (guinea-worm disease) | <input type="checkbox"/> Echinococcosis |
| <input type="checkbox"/> Foodborne Trematodiasis | <input type="checkbox"/> Human African trypanosomiasis | <input type="checkbox"/> Leishmaniasis |
| <input type="checkbox"/> Leprosy | <input type="checkbox"/> Lymphatic Filariasis | <input type="checkbox"/> Malaria |
| <input type="checkbox"/> Mycetoma | <input type="checkbox"/> Chromoblastomycosis and other deep mycoses | <input type="checkbox"/> Noma |
| <input type="checkbox"/> Onchocerciasis | <input type="checkbox"/> Rabies | <input type="checkbox"/> Scabies |
| <input type="checkbox"/> Schistosomiasis | <input type="checkbox"/> Soil-transmitted Helminthiasis | <input type="checkbox"/> Snakebite envenoming |
| <input type="checkbox"/> Taeniasis-Cysticercosis | <input type="checkbox"/> Trachoma | <input type="checkbox"/> Tuberculosis |
| <input type="checkbox"/> Yaws | <input type="checkbox"/> Disease with Pandemic Potential ¹ | <input type="checkbox"/> Disease with public health emergency ¹ |

3-3. Target Product Profile (For Diagnostics ONLY)

Fill in and submit the ***ProjectID-TPP Form*** for a diagnostics project.

- Must have: Phase 1 Feasibility & Planning
- Nice to have: Phase 0 Concept & Research

¹ Provide a rationale for why the target disease is classified as a disease with pandemic potential or public health emergency in Section 4: Target Research Project.

Preliminary TPP are acceptable, which would not require fully defined critical product requirements.

4. Target Research Project

4-1. Goal of the Project

Describe the ultimate goal of the project and provide an overview of the research, including, but not limited to the following points:

- Ultimate Goal: What your target product is trying to achieve to solve the global health needs.
- Project Goal: What your project is trying to achieve within the project period
- An overview of the research/assessment/novelty of the approach

Insert Goal of the Project Here

4-2. Intended Use of the Target Product

Describe the intended use of the product to be developed, including but not limited to:

- Usability: How your target product is suitable for LMICs settings in terms of usability and accessibility
- Fit to the landscape: How your target product fits into the existing global landscape.
- Regulatory strategy plan: Who will be responsible for product development/regulatory/access (If none of the project partners, describe the licensure plan etc.)

Insert Intended Use of the Target Product Here

4-3. Scientific Rationale

Describe the scientific rationale that supports the pursuit of the project objectives (such as research question, prior research conducted by other researchers, potential impact on health).

Provide sufficient evidence/preliminary data to support your rationale as supporting documents.

If your target disease is a disease with pandemic potential or a disease with public health emergency, provide the rationale and evidence here.

Insert Scientific Rationale Here

4-4. Accomplishments to Date

Summarize the project's history including achievements to date, IP landscape/freedom to operate, and techniques developed in other disease areas. Cite relevant peer-reviewed publications and patents where applicable. **If available, provide key reports (including data summary, tables, and figures) as separate supporting documents.**

Insert Accomplishments to Date Here

4-5. Independent Scientific/Technical Reviews to Date

The GHIT Fund will consider the review results by other independent committees when evaluating the proposal. If this project has been previously reviewed, specify the organization that completed the review and attach a copy of the full review as supporting documents. (Include conclusions/recommendations)

| Reviewing Organization | Review Date |
|------------------------|-------------|
| | |
| | |

4-6. Funding History

List all other funding sources for this project, **whose support period has been completed or will be completed BEFORE the start of this proposed project.**

(For other funding sources whose support period will be completed AFTER the start of this proposed project, please specify them in Section 6-2.)

Add additional column(s) in the table if there are more than two sources.

| | Source 1 | Source 2 |
|---|----------|----------|
| Name of funding source | | |
| Total amount (specify currency) | | |
| Duration covered by the funding (e.g., Apr. 2024 – Mar. 2025) | | |
| Funding focus (e.g., only for direct costs) | | |
| Notes | | |

5. Project Plan

5-1. Development Plan Timeline

Submit your development plan timeline using the **ProjectID-Gantt Form**. Make sure that the duration of the Activities and Milestones matches the Milestones and Activities Table in the section below.

Your proposed project should be **no more than two years in duration**. For this RFP, assume the project will start in October 2026 and to be completed no later than September 2028.

5-2. GHIT-Monitored Project Milestones and Activities

Complete the Milestone and Activity Table by following these steps with the insertion of additional rows as appropriate. (You may also describe the details of the criteria in the Project Approach/Methods section below.) *Guidance: Appendix 2-GHIT Phases-Milestones-Activities-Gates Definitions.*

- **Select GHIT Phase:** Choose the phase that reflects your proposal scope (e.g., Lead Optimization, Pre-Clinical, Clinical).
- **Define Project Milestones:** Identify key events that demonstrate progress toward project objectives
- **List Project Activities:** Describe the specific steps required to achieve each milestone.

- **Set Go/No-Go Criteria:** Define clear, measurable, if applicable quantitative criteria that will determine whether the project has completed a milestone
- **Provide Timelines:** Include the expected start and completion dates for the activities.
- **(if applicable) Target a GHIT Gate:** The final milestone should align with a GHIT Gate to enable transition to the next phase.

These GHIT-monitored project milestones and activities should reflect those milestones and activities best able to demonstrate progress against project objectives and completion of the project scope, and to be reported in your semi-annual progress reports.

| GHIT Phase | Milestone | Go/No-Go Criteria | Key Activities | Key Deliverable | Start date | Completion date |
|---|--|--|--|-----------------|------------|-----------------|
| Example: Feasibility & Planning | Example: Milestone 1: Nominate preclinical candidate | Example: Feasibility demonstrated as XYZ | Example: Define product requirements | | | |
| | | | Example: Evaluate technical feasibility against target specs | | | |
| | Milestone 2 | | | | | |
| | Milestone 3 | | | | | |
| | Milestone 4: | | | | | |
| Example: Gate 2 Candidate Feasibility Confirmed | | | | | | |

5-3. Project Approach/Methods

Describe the processes or methods that will be leveraged to conduct each Activity and the criteria mentioned in the GHIT-Monitored Milestones & Activities Table above, as well as the expected outcome of each Milestone during the 2-year project and include the rationale for selecting these approaches. Describe which partner/partners will be responsible for conducting each activity.

Insert Project Approach/Methods Here

5-4. Risk Mitigation Plan

Identify the scientific and technical, governance, operational, financial, and regulatory/access risks that may affect the successful completion of the project and outline the corresponding risk mitigation strategy.

| Potential Risk | Mitigation Plan |
|--|-----------------|
| Scientific and Technical Risks (e.g., non-standardized assays, not meeting the pre-defined specification, usability in LMICs setting) | |
| | |
| | |
| | |
| Governance Risks (e.g., partnership viability, licensing, IP disputes) | |
| | |
| | |
| | |
| Operational Risks (e.g., insufficient facility, personnel, time delays) | |

| | |
|---|--|
| | |
| | |
| | |
| Financial Risks (e.g., insufficient funding, cost overruns) | |
| | |
| | |
| | |
| Regulatory/Access Risks (e.g., lack of product development partner, regulatory hurdles, lack of regulatory experts, high COGs for LMICs) | |
| | |
| | |
| | |
| Other Risks (e.g., personnel) | |
| | |
| | |
| | |

6. Project Budget

All applicants must submit their project budget using the **ProjectID-Budget Form**. Please note that the GHIT Fund does not support capital costs.

6-1. Funding Request from the GHIT Fund

Provide a narrative to describe the proposed project budget, including justifications for the **overall amount and the costs associated with each milestone (max. JPY 100,000,000)**.

Insert Budget Narrative Here

(Example)

Milestone 1: budget and justification

Personnel Salaries: e.g., breakdown and/or %FTE spent by each PI and staff.

Contractor Costs: e.g., breakdown of each CRO

Materials and Supplies: breakdown of each material and supply

Travel and Accommodations: breakdown of each Travel and Accommodation

Administrative Expenses: breakdown of each administrative expense

Milestone 2: budget and justification

Personnel Salaries: e.g., breakdown and/or %FTE spent by each PI and staff.

Contractor Costs: e.g., breakdown of each CRO

Materials and Supplies: breakdown of each material and supply

Travel and Accommodations: breakdown of each Travel and Accommodation

Administrative Expenses: breakdown of each administrative expense

Indicate the breakdown of GHIT investment (both amount and percentage) to be **distributed for each Collaboration Partner**.

Insert Budget Narrative Here

(Example: Collaboration Partner 1: JPY AA (BB%), Collaboration Partner 2: JPY CC (DD%))

6-2. Co-funding

List all funding sources for this project, **whose support period will be completed AFTER the start of this proposed project.** (including your organization's in-kind contributions)

(For funding sources whose support period has been completed or will be completed BEFORE the start of this proposed project, please specify them in Section 4-6.)

The GHIT Fund welcomes and encourages co-funding from other entities; however, the activities supported by such co-funding(s) should not overlap with those funded by the GHIT Fund.

In case other funding sources are not committed yet, please indicate the expected notification date below and inform the GHIT Fund upon approval of the funding.

Add additional column(s) in the table if there are more than two sources.

Please note that the information below including pending/requested budget must be written also in the **ProjectID-Budget Form.**

| | Source 1 | Source 2 |
|--|--|--|
| Name of funding source | | |
| Funding type | Please Select: Other funding sources | Please Select: Other funding sources |
| Status | Please Select: Committed | Please Select: Committed |
| Expected notification date (if any) | | |
| Total amount (specify currency) | | |
| Duration covered by the funding (e.g., June 2025 – May 2026) | | |
| Funding Focus (e.g., only for direct costs) | | |
| Notes | | |

6-3. Organizational Policy or Rule Related to Expenses

Is there an organizational policy or rule to ensure an appropriate and rational level of expenses for transportation, accommodation, and other indirect expenses that are necessary for this project?

☐ Yes ☐ No

If “No”, please provide your rationale for the proposed budget for such expenses.

Insert Rationale Here

7. Impact

7-1. Global Health Need and Impact

1. Describe how the project will address a specific global health need and how it will impact that need in the short- or long-term.
2. What are the unique contributions this project is expected to make? Compare with similar approaches taken by other research groups or front runners, and/or existing products.

Insert global health need and impact here

7-2. Global Strategy Alignment

Describe how the project aligns with the current global strategy for this particular disease. Include references, where appropriate.

Insert global strategy alignment here

7-3. Global Access Policies

Please confirm that all Collaboration Partners have read and agree to the GHIT Fund Data Access Policy and Product Access Policy. <https://www.ghitfund.org/applyforfunding/accesspolicy/en>

☐ Yes, all Collaboration Partners have read and agreed to the Data Access Policy and Product Access Policy.

8. Proposal Checklist

- ☐ *ProjectID-Proposal-Standard TRP Award Form.docx*
- ☐ *(diagnostics only) ProjectID-TPP Form.docx*
- ☐ *ProjectID-Gantt Form.xlsx*
- ☐ *ProjectID-Budge Form.xlsx*
- ☐ *ProjectID-CollaborationPartnerApproval Form.docx*
- ☐ *ProjectID-Applicant Information Form.docx* of lead PIs of each organization
- ☐ Supporting documents (if applicable) ²

² Supporting documents refer to pertinent data/reports from previous studies/research and development work related to this intervention's (product's) safety, efficacy, effectiveness, or feasibility. The GHIT Fund reserves the right to request additional supporting documents as needed.

☐ *Exhibit A Form.docx* **for each individual Partner**

9. Agreement and signature

This Proposal form is submitted by:

| | |
|--|--|
| Name: Title: Organization: Date: | |
| <u>Agreement</u> We hereby agree that the above information is accurate and true. We understand that any incorrect information provided could result in revocation of the proposal submitted. (Signature) | |

[End of Document]

If applicants would like to use a publication as supporting documentation, please indicate that the publication can be used as a concept and research report etc.