GHIT Fund Product Development Proposal Form-Diagnostics
Reference Number: GHIT-RFP-PD-2026-001

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0. Instructions

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

- [Required] Product Development Proposal (this document): 30 pages or less
- [Optional] Supporting Documents related to Proposal: 20 pages or less

Supporting documents refer to pertinent data/reports from previous studies/research and development work related to this intervention's (product's) concept and research reports, feasibility study reports, verification reports, validation (clinical) reports, transfer to manufacturing reports (IQ/OP/PQ reports). The GHIT Fund reserves the right to request additional supporting documents as needed. However, any relevant data submitted after the submission deadline may not have sufficient time to be reviewed, which could impact the final decision of the award.

Please refer to "Appendix 1-Application Guidance-GHIT Fund PD Proposal" for additional guidance when completing the proposal.

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 project ID **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 G201X-10X (Awarded) and resubmission of G202X-10X (not awarded)*

1-4. Executive Summary Including To-be-developed Product and Project Overview (250-word limit)

This summary should be self-explanatory, providing clear details about key information on the product and project's goals for the duration of the project.

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.

	Designated Development Partner / 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	☐ Japanese ☐ Non-Japanese Please specify the country below. _____	☐ Japanese ☐ Non-Japanese Please specify the country below. _____	☐ Japanese ☐ 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			

	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	☐ Japanese ☐ Non-Japanese Please specify the country below.	☐ Japanese ☐ Non-Japanese Please specify the country below.	☐ Japanese ☐ 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.

Insert Partner History Here

2-2. Contractual Relationship

The GHIT Fund requires a formal contractual relationship amongst collaborating partners before distributing the awarded funds. Describe your partnership's existing or intended contractual relationship.

Insert Contractual Relationship Here

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 and Responsibilities Here

3. To-be-developed Product Diagnostic

3-1. Target Product Profiles

Complete the table with information on the target product profile (TPP) and references related to optimal and minimal TPP. The TPP should describe what *your* product is designed to achieve. In the reference columns, provide information that supports the description of the characteristics. If references are not

available, please justify the characteristics given, as appropriate. Please modify or add characteristics as needed to adequately describe your target product profiles.
The proposal (and the eventual product output) should align with WHO target product profiles (TPPs) and product profile characteristics (PPCs).

Diagnostics Characteristics	Optimal requirements	Minimal requirements	Reference/ Annotation
Scope			
Intended use[1]			
Target analyte (s)			
Method to detect and/or measure target analyte (s)			
Test outcome			
Target population			
Target user of test			
Setting (level of healthcare system)			
Performance characteristics			
Analytical sensitivity			
Analytical specificity			
Diagnostic sensitivity			
Diagnostic specificity			
Repeatability (inter-operator)			
Repeatability (inter-laboratory)			

[1] *"What's the difference between intended use and indications for use?"*
Ref; https://www.greenlight.guru/blog/intended-use-and-indications-of-use
Intended use is what you claim on your label that the device does. It is the purpose of your device.
Indications for use are the circumstances or conditions under which the device will be used. These are the reasons you would use the device.

Accuracy (if applicable)			
Operational characteristics			
Sample type			
Sample volume			
Sample preparation			
Overall test preparation			
Time to result			
Assay throughput (tests/time period)			
Assay packing			
Required supplies			
Operation conditions			
Transportation and storage stability			
In use stability			
Reagent reconstitution / preparation			
Instrument and power requirements (size & weight)			
Maintenance and calibration			
Internal quality control[2]			
External quality control[3]			
Assay interpretation			

[2] *Control of individual functionality, positive and negative controls for batch testing, possibly for kit testing*

[3] *A proficiency panel would be useful.*

Data capture/Data transfer			
Training			
Pricing			
Target cost of goods[4]			
Regulatory strategy			
Regulatory approvals and standards (key dates for registration and initial licensure by country or area)[5]			

4. Product Development Project

4-1. Goal of the Project

Describe the ultimate goal of your project and provide an overview of the product's characteristics including the "target indications and usage" and "intended use/intention for use".

In your answer, please also provide a brief explanation of how well the product focuses on the specific needs and challenges of neglected or vulnerable patient populations. (see Appendix 1 Section1.6).

Insert Goal of the Project Here

4-2. Scientific Rationale

Describe the scientific rationale that supports the pursuit of the project objectives. Please explain how your proposal aligns with and addresses key elements of the "Product Scope" (p.4-p.11 of the RFP document). https://www.ghitfund.org/assets/attach/GHIT-RFP-PD-2026-001.pdf

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

Insert Scientific Rationale Here

[4] *Price of an individual test; costs of reagents and consumables only; offer scale-up; ex-works, manufacturing costs only, excluding shipping. Also consider price/affordability in LMICs and include references. Please see more information in the "7-3. Global Access Adherence and Path to Successful Market Adoption" section*

[5] *For example, CE marking (compliant with European Directive 98/79/EC (IVDD 98/79/EC), QMS ISO13485:2016, Quality management system should be defined. Regulatory pathways/quality requirements may vary country-to-country.*

4-3. Accomplishments to Date

Summarize the project's history, major milestones, and achievements to date. Include peer reviewed publications and patents, if any. **If available, please provide key reports (including data summary, tables, and figures)** as supporting documents.

For example, concept and research reports, feasibility study reports, verification reports, validation (clinical) reports, transfer to manufacturing reports (IQ/OP/PQ reports)

Insert Accomplishments to Date Here

4-4. Independent Scientific/Technical Reviews to Date

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

Reviewing Organization	Review Date

4-5. Funding History

List all 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 (incl. amounts expected to receive) (specify currency)		
Duration covered by the funding (e.g. Oct. 2024 – Sep. 2025)		
Funding focus (e.g. only for direct costs)		
Notes		

5. Project Plan

5-1. Development Plan Timeline

Please 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 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: Lead Optimization	Example: Milestone 1: Nominate preclinical candidate	Example: Confirmed MOA, safety profile, in vitro/in vivo efficacy	Example: Optimize Leads for possible candidate selection			
			Example: Evaluate one or more leads suitable for potential preclinical development			
	Milestone 2					
	Milestone 3					
	Example: Milestone 4: Short list of pre-clinical candidates	Example: Lead compounds demonstrate xyz				
Example: Gate 2 Candidates for Pre-Clinical evaluation identified						

1) While the process used by partners might vary (e.g., partners might adopt more phases by splitting some, use fewer phases by collapsing them, or use different names for the phase/activities/milestone), the key milestones and activities are also fundamental to the development of new diagnostic products targeting less-established markets in LMICs.
2) Ref: https://pubmed.ncbi.nlm.nih.gov/30498586/

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/Method Here

5-4. Risk Mitigation Plan

Identify the scientific and technical, governance, operational, and financial risks which 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)	
Governance Risks (e.g., partnership viability, IP disputes)	
Operational Risks (e.g., clinical supply availability, protocol deviations, 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, IP)	

5-5. Ethics Review Committee (ERC) requirements

The GHIT Fund and its development partners must abide by accepted international ethical guidelines. Provide partnership plans for assuring responsible conduct of research, good clinical practice, information privacy, and security, and, if applicable, protection of animal and human subjects. If the project is exempt or has already been approved by an appropriate ethics review committee (such as an Institutional Review Board), submit supporting documentation.

Insert Ethics Review Committee requirement Here

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

Please provide a narrative to describe the proposed budget, including justifications for the **overall amount** and the **costs attributed to each milestone.**

Insert Budget Narrative Here (please insert summary table as needed).

(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. Other Funding Sources (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 4-5.)

The GHIT Fund welcomes and encourages co-funding from other entities; however, the activities supported by such co-funding(s) should not overlap 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. 2026 – May. 2027)		
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. In your answer:
   - provide an estimation of the magnitude of the lives touched by the product. (see Appendix 1 Section 1.1)
   - consider how the use of the product might mitigate risks associated with transmission, reduce disease related burden, treatment related burden, and economic burden on patients. (see Appendix 1 Section 1.2-1.5)
2. What are the unique contributions this project is expected to make?
   - Considering the **current state** of the field and the global portfolio, explain how the product offers a **competitive edge** in key aspects such as safety, efficacy & affordability, when compared to other products under development.

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 Adherence and Path to Successful Market Adoption

Describe how the project is adherent to the principles and commitments outlined in GHIT Fund's Data and Product Access Policies, particularly how the product developers will ensure that the price of the product takes into consideration the socioeconomic context of the intended target population and their ability to pay.

GHIT Fund Data and Product Access Policies: https://www.ghitfund.org/applyforfunding/accesspolicy/en

Additionally, please provide an estimate of:

- The time and the additional funding required to support the project through to successful approval and launch (see Appendix 1 Section 2.1 and 3.1)
- The probability of achieving both technical & regulatory success (see Appendix 1 Section 3.2)

Elaborate your plan, if any, to address potential challenges related to access and delivery (see Appendix 1 Section 3.3)

Insert Global Access Adherence Here

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. Checklist

☐ *ProjectID-Proposal-PD-Diagnostics Form.docx*

☐ *ProjectID-Budget Form.xlsx*

☐ *ProjectID-Gantt Form.xlsx*

☐ *ProjectID-CollaborationPartnerApproval Form.docx*

☐ *ProjectID-Applicant Information Form.docx* of lead PIs of each organization

☐ Supporting documents: e.g., Institutional Review Board findings, Ethics Review Committee approval or exemption (if applicable)[6]

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

9. Agreement and signature

This Proposal form is submitted by:

Name: Title: Organization: Date:	

Agreement

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]

[6] *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. For example, concept and research reports, feasibility study reports, verification reports, validation (clinical) reports, transfer to manufacturing reports (IQ/OP/PQ reports). 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, feasibility study report, verification report, validation (Clinical) report, or transfer to manufacturing report (IQ/OP/PQ report)*