**GHIT Fund Product Development Platform**

**RFP Intent to Apply Form**

**Reference Number: GHIT-RFP-PD-2024-002**

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| **Please submit the Intent to Apply (ITA) form via Editorial Manager® for the Product Development Platform (**[**https://www.editorialmanager.com/ghitfund/**](https://www.editorialmanager.com/ghitfund/)**) by 10:00am JST on July 11, 2024.** Please do not submit documents other than the ITA form to the GHIT Fund. Applicants who submit the ITA document will receive a confirmation e-mail. The GHIT Fund Management Team will then perform an initial partnership and scope eligibility assessment. **Only eligible applicants will be invited to submit a full proposal and will receive instructions to access the proposal template.**  Should applicants have RFP-related questions, please send an e-mail to [RFPResponse@ghitfund.org](mailto:RFPResponse@ghitfund.org).  Please also refer to the Frequently Asked Questions (FAQ) page on the GHIT website: <https://www.ghitfund.org/applyforfunding/investmentfaq/en>. |

***Table of contents***

[1. History of Applying for Funding to the GHIT Fund 1](#_Toc168480190)

[2. Project Title 2](#_Toc168480191)

[3. Intervention Focus 2](#_Toc168480192)

[4. Development Phase 2](#_Toc168480193)

[*4.1. Drug 2*](#_Toc168480194)

[*4.2. Vaccine 2*](#_Toc168480195)

[*4.3. Diagnostic 2*](#_Toc168480196)

[5. Target Disease 3](#_Toc168480197)

[6. Partnership and Role/Responsibility 3](#_Toc168480198)

[7. Product/Project Summary 4](#_Toc168480199)

[*7.1. Goal of the Project (200-word limit) 4*](#_Toc168480200)

[*7.2. Project Overview (200-word limit) 4*](#_Toc168480201)

[*7.3 Global Health Need and Impact and Competitive Advantage (300-word limit) 4*](#_Toc168480202)

[8. Project Budget 5](#_Toc168480203)

[9. Compliance Checklist 5](#_Toc168480204)

[10. Agreement/Signature 6](#_Toc168480205)

# 1. History of Applying for Funding to the GHIT Fund

Please provide the project ID number for programs **related to this application,** if you applied for GHIT funding before.

*Insert Project ID Here*

*\*\*G201X-10X previous proposal decision (i.e. Awarded)\*\**

*\*\*Please specify if this new application is a continuation[[1]](#footnote-1) of a project previously funded by the GHIT Fund\*\**

# 2. Project Title

*Insert Project Title Here*

# 3. Intervention Focus

|  |  |  |
| --- | --- | --- |
| ☐ Drug | ☐ Vaccine | ☐ Diagnostic |

# 4. Development Phase[[2]](#footnote-2)

## 4.1. Drug

|  |  |  |  |
| --- | --- | --- | --- |
| ☐ Lead Optimization | ☐ Pre-Clinical Development | ☐ Clinical Phase I | ☐ Clinical Phase II |
| ☐ Clinical Phase III | ☐ Registration |

## 4.2. Vaccine

|  |  |  |  |
| --- | --- | --- | --- |
| ☐ Lead Optimization | ☐ Pre-Clinical Development | ☐ Clinical Phase I | ☐ Clinical Phase II |
| ☐ Clinical Phase III | ☐ Registration |

## 4.3. Diagnostic

|  |  |  |  |
| --- | --- | --- | --- |
| ☐ Product Design  (Product Feasibility Design Lock) | ☐ Product Development  (Verification/Transfer to Manufacturing) | ☐ Product Validation  (Analytical Evaluation and Manufacturing Validation (IQ/OQ/PQ)) | ☐ Product Validation 2  (Diagnostic Evaluation) |
| ☐ Registration |

# 5. Target Disease[[3]](#footnote-3)

|  |  |  |
| --- | --- | --- |
| ☐ Buruli ulcer | ☐ Chagas Disease | ☐ Chikungunya |
| ☐ Dengue | ☐ Echinococcosis | ☐ Foodborne Trematodiases |
| ☐ Leishmaniasis | ☐ Leprosy | ☐ Lymphatic Filariasis |
| ☐ Malaria | ☐ Mycetoma | ☐ Onchocerciasis |
| ☐ Rabies | ☐ Scabies | ☐ Schistosomiasis |
| ☐ Soil-transmitted Helminthiases | ☐ Taeniasis-Cysticercosis | ☐ Tuberculosis |

# 6. Partnership and Role/Responsibility

**The partnership is comprised of the following organizations** (please add columns if your partnership consists of more than six organizations). **Please note that the GHIT Fund requires each partnership to have at least one eligible Japanese and one eligible non-Japanese organization as partners in order to be considered eligible.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Designated Development Partner[[4]](#footnote-4)  Collaboration Partner 1 | Collaboration Partner 2 | Collaboration Partner 3 |
| Organization Name |  |  |  |
| 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 |  |  |  |
| 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 |  |  |  |
| 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 |  |  |  |
| Organization Website |  |  |  |
| Lead PI (name and job title) |  |  |  |
| Contact Details  (e-mail and phone) |  |  |  |
| Role and Responsibility |  |  |  |

# 7. Product/Project Summary

## 7.1. Goal of the Project (200-word limit)

Describe the ultimate goal of your project and provide an overview of the **product** characteristics, including “target indications and usage” and “intended use/intention for use”.

You **must** explain how your proposal aligns with and addresses the needs specified in the “Product Scope” (P.2-8 of the RFP document).

|  |
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## 7.2. Project Overview (200-word limit)

Provide an overview of the **two-year project** that you are applying to the GHIT Fund for funding, including milestones and activities, and the expected outcome at the end of the project.

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|  |

## 7.3 Global Health Need and Impact and Competitive Advantage (300-word limit)

What makes this project unique in addressing global needs and creating a significant impact

in the short- or long-term? Please also describe how the product is expected to provide a competitive edge over other products currently in development in critical parameters such as safety, efficacy & affordability. Please consider the progress/state of the field and the global portfolio in your answer.

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# 8. Project Budget

Please provide the approximate amount of funding required in Japanese Yen to support the proposed project (capital costs should be excluded). Please provide the currency exchange rate used to calculate the total budget into Japanese Yen, if applicable.

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# 9. Compliance Checklist

Please answer the following questions regarding the Designated Development Partner, Collaboration Partner(s), and primary investigators who will be involved in the project proposed in this application (“Project”). Please mark ‘Yes’ or ‘No’ and provide explanations as required. Please note that your answers in this section will be taken into consideration by the GHIT Fund as it makes its decision concerning your application.

|  |  |
| --- | --- |
| 1. Are there any pending or threatened civil, criminal, administrative, or regulatory proceedings, actions, suits, or investigations (either as a claimant or a defendant) that could have any influence on the Project? | ☐ No  ☐ Yes – Please explain: |
| 1. Are sufficient measures in place to ensure that the Project will be conducted, controlled, managed, and monitored in compliance with all applicable ethical, legal, regulatory, and safety rules and requirements, including applicable international, national, local, industrial, and institutional standards? | ☐ No  ☐ Yes – Please explain: |
| 1. Are sufficient measures in place to prevent each of the following?  * Research misconduct[[5]](#footnote-5) * Misuse, misappropriation, or other inappropriate uses of grants, donations, contributions, or subsidies[[6]](#footnote-6) | ☐ No  ☐ Yes – Please explain: |
| 1. Please confirm that the Designated Development Partner, Collaboration Partner(s), and/or primary investigators have not, to the best of their knowledge, directly or indirectly supported or promoted, and will use reasonable efforts to ensure that they do not directly or indirectly support or promote, terrorist, criminal, or anti-social activities or related training, or money laundering. | ☐ Confirm  ☐ Do not confirm |
| 1. Please confirm that the Designated Development Partner, Collaboration Partner(s), and/or primary investigators have never taken any action in furtherance of an offer, payment, promise to pay, or authorization or approval of the payment or giving of money, property, gifts, or anything else of value, directly or indirectly, to any government official in Japan or in any other jurisdiction or any official of any public international organization to influence official action or secure an improper advantage. | ☐ Confirm  ☐ Do not confirm |
| 1. Please read and confirm the “Award Administration and Conditions” described in the RFP. | ☐ Confirm  ☐ Do not confirm |

# 10. Agreement/Signature

This Intent to Apply 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]

1. *“Continuation project” is a new application of extended or continued research from a project previously funded by the GHIT Fund* [↑](#footnote-ref-1)
2. *Please note that a project that does not cover development phases within the scope of the Product Development Platform as described above will not be considered eligible. Please ensure that the development phase of your project falls within the scope of this platform.* [↑](#footnote-ref-2)
3. *Refer to specific scope based on each intervention focus in the product scope section of the RFP released on June 14, 2024.* [↑](#footnote-ref-3)
4. *The designated development partner will be the funding recipient and will be responsible for the performance of its collaborating partners. A representative of the designated development partner will serve as the main point of contact with the GHIT Fund and will be responsible for all GHIT Fund discussions and negotiations.* [↑](#footnote-ref-4)
5. *In the “Guidelines for Responding to Misconduct in Research (Adopted August 26, 2014 by the Ministry of Education, Culture, Sports, Science and Technology)”, each of the following acts is defined as specific research misconduct:*

   *(1) Fabrication: making up data or research results, etc.*

   *(2) Falsification: manipulating research materials, equipment, or processes to change data or results obtained from research activities*

   *(3) Plagiarism: appropriating the ideas, analysis, analytical methods, data, research results, research paper(s), or words of other researchers without obtaining the permission of the researchers or giving appropriate credit* [↑](#footnote-ref-5)
6. *“Misuse” shall mean the use of such funds for purposes other than those originally intended or agreed upon, whether deliberate or by gross negligence.*  [↑](#footnote-ref-6)