Fight Neglected Diseases through Partnerships

GHIT Fund

Global Health Innovative Technology Fund

Press Release

Total Investment of Approx. USD 11.6 Million in TB and NTD R&D projects with Partners including FUJIFILM, Stop TB Partnership, and the Ohio State University

TOKYO, JAPAN (October 29, 2025) — The Global Health Innovative Technology (GHIT) Fund announced today a total investment of approximately JPY 1.73 billion (USD 11.6 million[1]) in four R&D projects for the development of diagnostics and a vaccine for tuberculosis (TB), neglected tropical diseases (NTDs), and malaria.[2]

Investment of JPY 390 Million (USD 2.6 million[1]) to Advance a Novel Rapid Diagnostic for Tuberculosis

Tuberculosis (TB) remains one of the world's most devastating infectious diseases, affecting over 10 million people and causing 1.3 million deaths annually[3]. In resource-limited settings, over 3 million people go undiagnosed each year due to the lack of suitable, accessible diagnostic tools[4]—particularly at the point of first contact with the healthcare system. Severely ill patients and children, who often struggle to produce sputum, are especially at risk of being missed by routine diagnostics. To help address this gap, the GHIT Fund is investing JPY 390 million (USD 2.6 million[1]) in a global partnership aimed at assessing and introducing an innovative TB diagnostic. This project is being led by the United Nations Office for Project Services (UNOPS) hosted organization Stop TB Partnership, in collaboration with FUJIFILM Corporation, the Liverpool School of Tropical Medicine, and research institutions in Cameroon, Nigeria, and Germany. The investment builds on a prior GHIT-supported project that received approximately JPY 600 million (USD 4.0 million[1]) between 2016 and 2023, and seeks to bring a highly sensitive urine-based rapid test progressing toward implementation.

The project will evaluate the performance and feasibility of FUJIFILM SILVAMP TB LAM II, a rapid test developed by Fujifilm to detect urinary LAM antigens, along with a urine concentration device (UCD). This innovative diagnostic approach eliminates the need for sputum collection and has the potential to significantly improve diagnostic accuracy for a broad range of people—including those living with or without HIV, severely ill individuals, and children. By enabling earlier and more accessible diagnosis, particularly in underserved settings, this project aims to reduce diagnostic delays and disparities, help limit the spread of TB, and ultimately support global efforts to end the disease.

JPY 681 million (USD 4.5 million[1]) Investment in a Phase I Clinical Study of a Leishmaniasis Vaccine

Leishmaniasis is a parasitic disease transmitted by sandflies and is recognized by the World Health Organization (WHO) as an NTD. The GHIT Fund will invest JPY 681 million (USD 4.5 million[1]) in Phase I clinical trials of this promising vaccine, in a project jointly conducted by the Ohio State University and Nagasaki University. The project will evaluate the safety and immunogenicity of the investigational vaccine in healthy adults living in endemic regions of Brazil and Kenya. In addition, on July 25, 2025, the U.S. Food and Drug Administration (FDA) approved the Investigational New Drug

Application (IND) to initiate human clinical trials. This milestone represents a significant step forward in the fight against leishmaniasis and will accelerate product development and early access.

In addition, the GHIT Fund will invest a total of approximately JPY 666 million (USD 4.4 million[1]) in the following two R&D projects:
(1) Product development project for new rapid diagnostic test for strongyloidiasis by Drugs & Diagnostics for Tropical Diseases (DDTD), Medical & Biological Laboratories Co., Ltd. (MBL), IRCCS Sacro Cuore Don Calabria Hospital, QIMR Berghofer Medical Research Institute, Fundacion Mundo Sano, and Big Eye Diagnostics, Inc. (BEDx)
(2) Target research project for malaria diagnostics by Ehime University, Institute of Tropical Medicine (NEKKEN) Nagasaki University, and Universiti Malaysia Sabah

Please refer to Appendix 1 for detailed descriptions on these projects and their development stages.
The four projects funded in this round bring together partners from a total of 11 countries. Since its inception, the GHIT Fund has worked with more than 190 research and development partners, including more than 130 overseas institutions. The GHIT Fund serves as a bridge connecting pharmaceutical companies, universities, and research institutes in Japan with their counterparts around the world.

As of September 30, 2025, the GHIT Fund has invested in 42 projects, including 17 discovery projects, 14 preclinical projects, and 11 clinical trials.[6] The total amount of investments since 2013 is JPY 41.0 billion (USD 275 million[1]) (Appendix 2).

[1] USD1 = JPY148.81, the approximate exchange rate on September 30, 2025.
[2] These awarded projects were selected and approved as new investments from among proposals to RFP2023-002, RFP2024-001, and RFP2025-001 for the Product Development Platform and the Target Research Platform, which were open for applications from June 2023 to July 2025.
[3] WHO: https://www.who.int/news-room/fact-sheets/detail/tuberculosis
[4] Stop TB Partnership https://www.stoptb.org/missing-tb-millions
[5] WHO: https://www.who.int/news-room/fact-sheets/detail/leishmaniasis
[6] This number includes projects in the registration phase.

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The GHIT Fund is a Japan-based international public-private partnership (PPP) fund that was formed between the Government of Japan, multiple pharmaceutical companies, the Gates Foundation, Wellcome, and the United Nations Development Programme (UNDP). The GHIT Fund invests in and manages an R&D portfolio of development partnerships aimed at addressing neglected diseases, such as malaria, tuberculosis, and neglected tropical diseases, which afflict the world's vulnerable and underserved populations. In collaboration with global partners, the GHIT Fund mobilizes Japanese industry, academia, and research institutes to create new drugs, vaccines, and diagnostics for malaria, tuberculosis, and neglected tropical diseases.
https://www.ghitfund.org/en

Appendix 1. Project Details

ID: G2023-212

Project Title	Multi-site field trial of the FUJIFILM SILVAMP TB LAM II including the diagnostic accuracy of a urine concentration device
Collaboration Partners	1. Stop TB Partnership (Switzerland) 2. FUJIFILM Corporation (Japan) 3. Liverpool School of Tropical Medicine (LSTM) (UK) 4. Center for Health Promotion and Research (CHPR) (Cameroon) 5. Friends for International TB Relief (FIT) (Germany) 6. Zankli Research Centre, Bingham University Nigeria (ZRC) (Nigeria)
Disease	Tuberculosis
Intervention	Diagnostics
Stage	Product Validation
Awarded Amount	JPY 390,000,000 (USD 2.6 million)
Status	Continued project
Summary	[Project objective] The primary objective of the project is to provide evidence on the performance of Fujifilm's redesigned SILVAMP TB LAM II assay as well as a urine concentration device (UCD) which is expected to further increase sensitivity especially in HIV-negative individuals to obtain a WHO policy recommendation with strengthened evidence based on the operationalization, costing and feasibility studies to be conducted on this project. [Project design] The project team will prospectively evaluate the performance of the SILVAMP TB LAM II assay as well as a urine concentration device across multiple sites in Cameroon, Nigeria and Vietnam. The project team will evaluate test performance among PLHIV and HIV-negative adults as well as children irrespective of HIV co-infection. Operationalization, costing and feasibility of the assay will also be addressed.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/246/en

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ID: G2024-101

Project Title	Evaluation of the Safety and Immunogenicity of the cGMP LmCen-/- Vaccine in Phase I Clinical Trials
Collaboration Partners	1. The Ohio State University (USA) 2. Nagasaki University (Japan)
Disease	Leishmaniasis
Intervention	Vaccines
Stage	Clinical Phase I
Awarded Amount	JPY 681,063,113 (USD 4.5 million)
Status	Continued project
Summary	[Project objective] **Objective 1:** Conduct a Phase I clinical trial to evaluate the safety and immunogenicity of the *LmCen-/-* vaccine in healthy volunteers in Brazil (New World) **Objective 2:** Conduct a Phase I clinical trial to evaluate the safety and immunogenicity of the *LmCen-/-* vaccine in healthy volunteers in Kenya (Old World) [Project design] This project is a continuation of the GHIT-funded project G2018-201 to advance clinical development of the *LmCen-/-* vaccine. During the previous funding period, the project team successfully accomplished the goals of the project by: 1) Validate the safety and efficacy of a GLP-grade *LmCen-/-* vaccine produced by Gennova Biopharmaceuticals under cGMP conditions using preclinical animal models, 2) Produce a GMP master cell bank (MCB) and a GMP working cell bank (WCB) of *LmCen-/-* parasites, 3) Establish cGMP manufacturing of the *LmCen-/-* vaccine, 4) Complete preclinical toxicology studies in accordance with regulatory guidelines using a GLP *LmCen-/-* vaccine produced from an engineering run of the cGMP cell bank, and 5) Finalize the IND package for the *LmCen-/-* product for submission to regulatory authorities. In the current project, the project team proposes to evaluate the safety of the *LmCen-/-* vaccine in healthy volunteers living in leishmaniasis-endemic countries, Brazil and Kenya, where other factors such as subclinical nutritional deficiencies and co-infections, such as diarrhea, malaria, Chagas disease (in Brazil) and helminth infections, are common and have been documented to impact vaccine safety and immunogenicity.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/247/en

ID: G2025-101

Project Title	*Strongyloides stercoralis* Rapid Test Plus (SsRT+): A new rapid diagnostic test with improved ease of use to support WHO strongyloidiasis control programs.
Collaboration Partners	1. Drugs & Diagnostics for Tropical Diseases (DDTD) (USA) 2. Medical & Biological Laboratories Co., Ltd. (MBL) (Japan) 3. IRCCS Sacro Cuore Don Calabria Hospital (Italy) 4. QIMR Berghofer Medical Research Institute (Australia) 5. Fundacion Mundo Sano (Spain) 6. Big Eye Diagnostics, Inc. (BEDx) (USA)
Disease	Strongyloidiasis (Soil-transmitted helminth)
Intervention	Diagnostic
Stage	Product Design
Awarded Amount	JPY 566,596,199 (USD 3.8 million)
Status	New
Summary	[Project objective] The overarching goal of this project is to deliver an easy-to-use, low-cost point-of-care test to detect *S. stercoralis* infection. Our new test, termed *S. stercoralis* Rapid Test Plus (SsRT+), will be an improved version of SsRapid, which was developed and validated by our Consultant, Prof. R. Noordin, and has been shown to be 80-97% sensitive and 90-100% specific in a series of laboratory and field studies. A first SsRT+ prototype has already been generated, which showed diagnostic performance comparable to, or better than, SsRapid. SsRT+ will be fully optimized in this project to meet all key criteria of the new TPP for *S. stercoralis* diagnostics. [Project design] Objective-1: This first activity aims to review the optimal use case(s) and define the key experimental data to be generated with SsRT+ to align with the WHO strongyloidiasis control programs. We will also finalize the study plans for the field evaluations in Australia and Argentina and complete a business/commercialization plan. Objective-2: Having access to high-quality antigens and positive control antibodies is key for efficient test development, optimization, and manufacturing under ISO-13485:2016 standards. As for all our other GHIT Fund projects, MBL will be entrusted with the production of high-quality recombinant NIE and IgG4-anti-NIE. Objective-3: The SsRT+ prototype available at the outset of G2025-101 will be fully optimized, according to all key criteria listed in the TPP for *S. stercoralis* diagnostics, including sensitivity, specificity, time to result, result stability, reproducibility (CV values), and cost. Since the precursor of SsRT+, SsRapid, already meets most of the TPP criteria, we consider this a very realistic objective. Objective-4: Prof. R. Noordin of Universiti Kebangsaan Malaysia (UKM), who has developed and validated SsRapid in numerous laboratory and field studies, and Prof. D. Buonfrate of IRCCS Sacro Cuore Don Calabria Hospital, who has previously run an in-depth diagnostic accuracy study involving SsRapid, will independently evaluate

	the diagnostic performance of SsRT+ to demonstrate that it complies with the TPP and is not inferior to SsRapid. Objective-5: Once validated for TPP-compliant performance in the laboratory, SsRT+ will be evaluated in two field studies in Australia and Argentina, conducted by the groups of Prof. D. Gray of QIMR Berghofer and Prof. A. Krolewiecki of Mundo Sano, respectively. Objective-6: An ISO-13485:2016 compliant automated manufacturing process commensurate with the anticipated demand will be developed by DDTD, modeled on the one we successfully put in place for our Onchocerciasis rapid test in the GHIT Fund project G2023-111, and subsequently validated by BEDx through production of several pilot lots and quantification of inter-lot consistency.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/248/en

ID: T2024-276

Project Title	Development of Ultrasensitive and Robust Malaria Rapid Diagnostic Tests Using *de novo* Designed Antigen Binders
Collaboration Partners	1. Ehime University (Japan) 2. Institute of Tropical Medicine (NEKKEN) Nagasaki University (Japan) 3. Universiti Malaysia Sabah (Malaysia)
Disease	Malaria
Intervention	Diagnostics
Stage	Concept Development
Awarded Amount	JPY 99,670,808 (USD 0.6 million)
Status	New
Summary	[Project objective] Current malaria Lateral Flow Assays (LFAs) use antibodies as their capture and detection reagents. The limited sensitivity of LFAs in part reflects the relativity modest affinities of typical antibodies for their target proteins. In addition, the identification of antibodies that target related proteins with high specificity is time-consuming and uncertain of success. A technology that replaces monoclonal antibodies could thus have a transformative impact on the development of new diagnostics. We propose to develop novel protein-based affinity reagents that enable the creation of rapid diagnostic tests (RDTs) that diagnose infection with *Plasmodium falciparum*, non-*falciparum* malaria parasites, and the emerging pathogen *Plasmodium knowlesi* with sensitivities that considerably exceed existing alternatives. Our work will result in affinity reagents that integrate directly into the existing infrastructure for the creation of LFAs, the technology used in rapid COVID tests. The products of this project can thus be rapidly scaled to impact malaria treatment worldwide. As part of this project, we will validate our approach using clinical samples. If successful, the diagnostics resulting from our collaboration will possess enhanced sensitivity, greater shelf stability, lower cost, and the elimination of test failure due to

	parasite mutations, four improvements that have been identified as critically important by the World Health Organization (WHO) for the management of malaria. Success in this project will establish a general-purpose platform for the rapid development of highly sensitive diagnostic assays. In addition to its impact on malaria diagnosis and treatment, this project will thus provide proof-of-concept for a novel platform technology enabling the development of rapidly scalable diagnostics for novel infectious diseases. Our overall goals are thus to develop new protein-based affinity reagents that can improve the sensitivity of malaria LFAs, and to extend malaria LFAs to include diagnosis of infection with *P. knowlesi*. [Project design] Our overall strategy is to replace the antibodies that are used in conventional LFAs with computationally designed binders based on the monobody scaffold. The nanomolar (nM) affinities of most antibodies limit the sensitivity of LFAs. To circumvent this limitation, we will use de novo protein design to identify numerous monobody binders for a target malaria antigen of interest. We will then link monobodies together to generate bivalent binders for the malaria antigens. This strategy makes use of the well-known principle of avidity, in which linear improvements in binding energy yield exponential improvements in dissociation constants: both empirical evidence and simple calculations indicate that combining monobody binders with 10-100 nM KD values should yield multivalent binders with KD values in the pM regime. Importantly, this strategy is made possible by the unique ability of computational design to deliberately target multiple, distinct sites on the target protein. We will quantify the binding affinities and cross-reactivity of bivalent monobodies and confirm that they possess the properties required for use in an LFA. Finally, we will assess the performance of the resulting capture and detection reagents in prototype LFAs.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/249/en

*All amounts are listed at an exchange rate of USD1 = JPY148.81, the approximate exchange rate on September 30, 2025.

Appendix 2. Investment Overview (as of September 30, 2025)

Investments to date
Total investments: 41.0 billion yen (USD 275 million[1])
Total invested projects: 141 (42 active projects and 99 completed projects)

To learn more about the GHIT Fund's investments, please visit
Investment Overview: https://www.ghitfund.org/investment/overview/en
Portfolio: https://www.ghitfund.org/investment/portfolio/en
Advancing Portfolio: https://www.ghitfund.org/investment/advancingportfolio/en
Clinical Candidates: https://www.ghitfund.org/investment/clinicalcandidates/en