Fight Neglected Diseases through Partnerships

GHIT Fund

Global Health Innovative Technology Fund

Press Release

Total Investment of Approx. USD 11.4 Million in Schistosomiasis Diagnostics and R&D projects for NTDs with Partners including Drugs & Diagnostics for Tropical Diseases and Medical & Biological Laboratories

TOKYO, JAPAN (March 18, 2025) — The Global Health Innovative Technology (GHIT) Fund announced today a total investment of approximately JPY 1.7 billion (USD 11.4 million[1]) in five projects for the development of schistosomiasis diagnostics and drugs for neglected tropical diseases (NTDs) [2].

Investment total of approximately JPY 780 million (USD 5.2 million[1]) for the development of diagnostics for schistosomiasis

Schistosomiasis is one of 21 NTDs that affect approximately 250 million people worldwide, with 90% of cases occurring in Africa. People become infected through contact with contaminated freshwater, allowing the parasite to penetrate their skin[3]. Among the five species of schistosomiasis causing the disease, two are widely distributed on the African continent: *Schistosoma hematobium*, which infects the urogenitary tract, and *Schistosoma mansoni*, which infects the intestine and liver. Current diagnostics face challenges such as low sensitivity and quality issues, making it difficult to accurately assess the infection status. To address this issue, the GHIT Fund had decided to invest approximately JPY 780 million (USD 5.2 million[1]) in two projects to develop new diagnostics for schistosomiasis led by Drugs & Diagnostics for Tropical Diseases, a non-profit organization based in San Diego, USA, in collaboration with Medical & Biological Laboratories Co., Ltd., a Japanese manufacturer of clinical diagnostic kits and reagents, Nagasaki University Institute of Tropical Medicine, the Kenya Medical Research Institute, and the Noguchi Memorial Institute for Medical Research.

The project will advance the development of a rapid diagnostic test (RDT) for *Schistosoma mansoni*, leveraging previous research findings and evaluating the diagnostic performance of the candidate RDT in endemic regions of Africa. In addition, the project team will develop a new serological RDT for *Schistosoma haematobium*. These tests are expected to be used as a low-cost, easy-to-use point-of-care (POC) diagnostics to support decision for Interruption of Transmission/Stopping Mass Drug Administration (MDA) and for subsequent Surveillance of the disease.

In addition, the GHIT Fund will invest in the following three R&D projects for a total amount of approximately JPY 932 million (USD 6.2 million[1]):

1) Phase I clinical trial project for dengue vaccine by VLP Therapeutics, Inc. and Nagasaki University
2) Screening project against chikungunya by Medicines for Malaria Venture (MMV) and Eisai Co., Ltd.
3) Screening project against Chagas disease by Drugs for Neglected Diseases initiative (DNDi) and Shionogi & Co., Ltd.

Please refer to Appendix 1 for detailed descriptions of these projects and their development stages.

As of March 18, 2025, the GHIT Fund has invested in 35 projects, including 14 discovery projects, 12 preclinical projects and 9 clinical trials[4]. The total amount of investments since 2013 is JPY 37.5 billion (USD 251 million[1]) (Appendix 2).

[1] USD1 = JPY149.63, the approximate exchange rate on February 28, 2025.
[2] These awarded projects were selected and approved as new investments from among proposals to RFP2023-002 and RFP2024-001 for the Product Development Platform and the Screening Platform, which were open for applications from June 2023 to July 2024.
[3] WHO: https://www.who.int/news-room/fact-sheets/detail/schistosomiasis
[4] 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: G2024-202

Project Title	In Support of WHO Schistosomiasis Control and Elimination Programs: Progressing a TPP-compliant serological test for *Schistosoma mansoni* to Field Testing and Manufacturing Process Development.
Collaboration Partners	1. Drugs & Diagnostics for Tropical Diseases (DDTD) (USA) 2. MBL, Medical & Biological Laboratories Co., Ltd. (Japan) 3. Nagasaki University (Japan) 4. Kenya Medical Research Institute (Kenya) 5. Noguchi Memorial Institute for Medical Research (Ghana) 6. Big Eye Diagnostics, Inc. (USA)
Disease	Schistosomiasis
Intervention	Diagnostics
Stage	Product Development
Awarded Amount	JPY 472,729,041 (USD 3.2 million)
Status	Continued project
Summary	[Project objective] The overarching objective of this project is to deliver a fully TPP-compliant, easy-to-use, low-cost point-of-care test able to detect IgG1-type antibodies raised by the human host against selected S. mansoni antigens as an indicator for current or prior infection. The RDT delivered at the end of G2024-202 will have the required sensitivity and specificity to support Schistosomiasis monitoring, evaluation, and surveillance efforts in hypo-endemic areas post-MDA where stool-based or antigen-based diagnostics struggle to accurately determine disease prevalence. [Project design] The project team will pursue the following 6 specific objectives: -Objective 1: This first activity is aimed at defining the optimal use case(s) for our new serological test: Since serological testing is a new approach for schistosomiasis control and elimination programs, this work will be modelled in as much as appropriate on other NTDs that have already incorporated serological testing in their programmatic concepts (onchocerciasis, lymphatic filariasis, trachoma). -Objective 2: In the predecessor project, G2023-110, MBL produced the S. mansoni antigens and positive control antibodies in R&D grade quality. The production will now be moved to larger scale and ISO/QMS grade quality. -Objective 3: Given that the two prototype tests delivered at the end of G2023-110 (one for each S. mansoni antigen) already meet the TPP criteria, only limited further optimization work will be required, which may include generating and evaluating a biplex test as an alternative to the two singleplex tests. -Objective 4: Evaluate the laboratory diagnostic performance of the candidate RDT using extended patient sample panels and compare the results with egg count, PCR, CCA and/or CAA data as available, and determine the concordance with laboratory-based serological assays (ELISA/MBA). -Objective 5: Follow the clinical study plan established in Objective 1 to evaluate the

	diagnostic and operational performance of the candidate RDT in both endemic and non-endemic regions of Kenya and, potentially, Ghana. -Objective 6: A ISO13485-compliant automated large-scale manufacturing process will be developed by DDTD, modeled on those we have previously put in place for other tests. BEDx will then conduct an independent validation of the manufacturing process by producing 3 pilot lots of 10’000 units each, and quantifying the inter-lot consistency.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/235/en

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ID: G2024-203

Project Title	In Support of WHO Schistosomiasis Control and Elimination Programs: Development of a Sensitive and Specific Serological Rapid Diagnostic Test to Detect Infection by *Schistosoma haematobium*.
Collaboration Partners	1. Drugs & Diagnostics for Tropical Diseases (DDTD) (USA) 2. MBL, Medical & Biological Laboratories Co., Ltd. (Japan) 3. Nagasaki University (Japan) 4. Kenya Medical Research Institute (Kenya)
Disease	Schistosomiasis
Intervention	Diagnostics
Stage	Technical Feasibility
Awarded Amount	JPY 314,446,720 (USD 2.1 million)
Status	New
Summary	[Project objective] The overarching objective of this project is to deliver a fully TPP-compliant, easy-to-use, low-cost point-of-care test able to detect antibodies raised by the human host against selected S. haematobium antigens as an indicator for current or prior infection. The RDT delivered at the end of G2024-203 will have the required sensitivity and specificity to support Schistosomiasis monitoring, evaluation, and surveillance efforts in hypo-endemic areas post-MDA where other diagnostic methods struggle to accurately determine disease prevalence. [Project design] The project team will pursue the following 4 specific objectives: -Objective 1: Define the most appropriate use case(s) for a serological S. haematobium test and present the proposed rationale and justification to the Schisto DTAG for endorsement. -Objective 2: Express the 5-10 most promising S. haematobium biomarkers from the literature and from previous work at CDC and NEKKEN, and evaluate their performance in an S. haematobium ELISA. -Objective 3: Generate RDT prototypes for each of the biomarker candidates down-selected in the preceding Objective, and evaluate the performance of the resulting singleplex LFAs in comparison with ELISA based on LOD, sensitivity, and specificity (non-specific binding). -Objective 4: Evaluate the diagnostic performance of the prototype RDT(s) delivered in the preceding Objective using extended patient sample panels, and compare the results with those from laboratory-based serological tests (ELISA/MBA) as well as with other, non-serological diagnostic methods (microscopy, PCR, CAA-test) wherever available.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/236/en

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ID: G2023-201

Project Title	Phase I clinical trial of novel dengue virus-like particle (VLP) vaccines
Collaboration Partners	1. VLP Therapeutics, Inc. (USA) 2. Nagasaki University (Japan)
Disease	Dengue
Intervention	Vaccine
Stage	Clinical Phase I
Awarded Amount	JPY 885,198,600 (USD 5.9 million)
Status	Continued project
Summary	[Project objective] This Phase I clinical trial aims to evaluate the safety, immunogenicity, and efficacy of the tetravalent DENVLP vaccine. We will assess antibody titers, neutralizing antibody levels, and antibody-dependent enhancement (ADE) following vaccination. Additionally, we will evaluate the efficacy of infection protection using a challenge strain of the dengue virus. Objective 1: Manufacturing the DENVLP Vaccine | We will produce a high-quality, GMP-grade of the tetravalent DENVLP vaccine using our stable cell lines for dengue virus types 1-4. We will assess quality and stability. Objective 2: Phase I Clinical Study | We will conduct a placebo-controlled Phase I trial with four groups of healthy adults (ages 18-60) to test different vaccine doses. Participants will receive three doses. [Project design] Manufacturing and IND Submission: VLP Therapeutics (VLPT) will oversee the manufacturing and regulatory submission for the tetravalent DENVLP vaccine and design the clinical trial plan. Its group company, VLP Therapeutics Japan, will conduct GMP-compliant manufacturing of the tetravalent vaccine. After manufacturing, the vaccine will undergo quality testing before submitting an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA). Phase I Clinical Trial: A Phase I clinical trial will be conducted to evaluate the safety, immunogenicity, and efficacy of the DENVLP vaccine. The vaccine's safety and immunogenicity will be assessed, and a six-month follow-up will be conducted after vaccination. At six months, all participants will be exposed to a dengue virus challenge strain to evaluate vaccine efficacy.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/237/en

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ID: S2024-112

Project Title	AI-based screening for the identification of novel compounds against Chikungunya virus
Collaboration Partners	1. Medicines for Malaria Venture (MMV) (Switzerland) 2. Eisai Co. Ltd. (Eisai) (Japan)
Disease	Chikungunya
Intervention	Drug
Stage	Screening
Awarded Amount	JPY 23,894,400 (USD 159,689.90)
Status	New
Summary	[Project objective] The project aims to use advanced computer-assisted screening to find new compounds that can prove effective in combatting Chikungunya virus. Initially, using state-of-the-art machine learning models, a large library of Eisai compounds will be screened in silico. Thereafter, hits from the in silico screen will be tested in vitro using established assays. This collaboration brings together the power of artificial intelligence, antiviral screening, and drug development expertise from a pharmaceutical company, Product Development Partner (PDP), and academic investigators in a country where Chikungunya virus is endemic. [Project design] The primary screening process will use an innovative two-step approach to maximize the available space for testing potential activity against Chikungunya virus. Around 50 primary hits will be chosen for further activity confirmation studies. Eisai will provide additional compounds for conducting these assays. For selected compounds, dose response curves (EC50) will be generated in the CHIKV assay, and their cytotoxicity profile (CC50) will be evaluated using the MTS assay. 5-10 confirmed active compounds will be prioritized for further profiling. To further assess their potential for broad spectrum activity within a virus family, these confirmed active compounds will be profiled against other alphaviruses. To assess specificity for the alphavirus genus, these confirmed actives will also be tested against SARS-CoV2 and mosquito-borne flaviviruses.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/238/en

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ID: S2024-121

Project Title	Screening project between DNDi and Shionogi & Co., Ltd.
Collaboration Partners	1. Drugs for Neglected Diseases initiative (DNDi) (Switzerland) 2. Shionogi & Co., Ltd. (Japan)
Disease	Chagas disease
Intervention	Drug
Stage	Screening
Awarded Amount	JPY 23,200,938 (USD 155,055.38)
Status	New
Summary	[Project objective] The primary objective of this project is to identify novel T. cruzi active series from a unique proprietary compound collection made available by Shionogi & Co., Ltd. (Shionogi). [Project design] A chemically diverse library of approx. 42,000 compounds specifically designed for this project from Shionogi's chemical library will be screened against the intracellular amastigote stage of T. cruzi at Institute Pasteur Korea in a cell-based, high-throughput screening system. A sequential single concentration followed by full dose-response scheme will be applied. Hit series meeting GHIT/DNDi criteria for potential Chagas disease treatments will be prioritized for further development.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/239/en

*All amounts are listed at an exchange rate of USD1 = JPY149.63, the approximate exchange rate on February 28, 2025.

Appendix 2. Investment Overview (as of March 18, 2025)

Investments to date
Total investments: 37.5 billion yen (USD 251 million[1])
Total invested projects: 136 (35 active projects and 101 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