

A close-up photograph of a smiling woman with a vibrant, multi-colored headscarf (green, blue, and purple) and a matching patterned shawl. She is holding a young child wrapped in a purple cloth. The background is a textured, reddish-brown wall. The overall mood is warm and positive.

# Annual Report 2022

GHIT Fund

Global Health Innovative Technology Fund



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Global Health Innovative Technology Fund

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## Message from CEO & Chair

# Partnerships: GHIT Fund's Most Valuable Asset in the Fight Against Infectious Diseases Toward the Next 10 Years

In 2023, the Global Health Innovative Technology Fund (GHIT Fund) celebrates its 10th anniversary. We are grateful to our funding partners and sponsors for their support and collaboration over the past decade, to our product development partners for their passion and tireless efforts in the fight against neglected infectious diseases, and to the global health community for its solidarity and partnership.

The concept of the GHIT Fund was born from notes written on a paper napkin by the late Dr. Tachi Yamada and the GHIT Fund's founding CEO, Dr. BT Slingsby, in 2013. Since then, we have been fighting neglected diseases in low and middle-income countries by connecting ideas, people, and innovations from around the world. In our experience, passion and vision are more powerful tools than most people may realize. Each new drug in development or nearing approval has the potential to save tens of millions of lives.

Cumulative investments over the past 10 years have totaled approximately 30 billion yen, supporting more than 100 R&D projects. More than 50 projects are currently underway, of which 12 are in clinical development.

The second phase of our second Strategic Plan FY 2018-FY 2022 set goals for each stage of R&D, from lead compound discovery to clinical development, delivering significant progress at almost every stage. In particular, the number of diagnostics and discovery/preclinical projects significantly exceeded achievement targets, and despite the impact of the COVID-19 pandemic, we made steady progress in primary product development through close collaboration with our product development partners (pages 19-20).

### First Drug to Reach Regulatory Approval Since the GHIT Fund's Establishment

"Arpraziquantel," a new treatment option for schistosomiasis for preschool children (3 months to 6 years old) developed by the Pediatric Praziquantel Consortium, completed the application process for approval with the European Medicines Agency (EMA) in December 2022. The GHIT Fund is honored to have supported the Consortium since 2013, facilitating successful product development by Consortium partners Astellas Pharma of Japan, Merck of Germany, Lygature of the Netherlands, and Farmanguinhos of Brazil. Japanese innovation and technology are inextricably linked to arpraziquantel's development journey, and its R&D advancement through global partnerships truly embodies the mission of the GHIT Fund. When approved, this new pediatric formulation will bring health and hope to more than 50 million children. This achievement would not have been possible without the cooperation of the children, their families, and communities who joined in the clinical trial in addition to the ceaseless efforts of the Consortium. We would like to express our sincere gratitude to many people for their tremendous support over the years (pages 7-8).

### Together, in Partnership at Every Step

Our partnerships, cultivated and nurtured with care and mutual appreciation and admiration over the past decade, are our most valuable assets. With more than 110 global partners and 60 partners in Japan, the GHIT Fund has accelerated global health R&D innovation by



meaningfully connecting Japanese pharmaceutical companies and universities with global partners. We are also proud to have helped further advance the global health R&D field in Japan.

Our strategic partnerships have also notably evolved. For example, we strengthened our collaboration with the Coalition for Epidemic Preparedness Innovations (CEPI) in May 2022, through a mutual commitment to explore opportunities in strategic vaccine development and investment platforms. Additionally in February 2023, we signed a cooperation framework agreement with Unitaids, which focuses on addressing complex challenges such as the emergence of drug resistance in tuberculosis and malaria, vector-borne diseases that may recur and proliferate due to climate change, as well as accelerating global health product access (pages 21-22).

### The Promise of the Next Decade

Developing new medicines is no easy task, requiring an average of over ten years of painstaking effort and tens of billions of yen to develop a single medicine. But as all of us in the global health R&D community understand, the time and investment are worth it. It means a great deal to us that the GHIT Fund's projects, which have been created and nurtured over the past decade, are about to bear fruit. The

quick delivery of the therapeutics, vaccines, and diagnostics that result from our development partnerships will save countless lives and prevent untold suffering and stigma.

The GHIT Fund remains committed to promoting innovation and R&D from Japan and fighting neglected infectious diseases through global partnerships. We remain steadfast in our mission to reduce the suffering caused by neglected infectious diseases that afflict more than a billion people, in support of a healthy world for all. We are honored to embrace this work together with you, as partners.

We look forward to your continued support and cooperation.



*Osamu Kunii*

**Osamu Kunii**  
CEO & Executive Director



中谷 比呂樹

**Hiroki Nakatani**  
Chair & Representative Director

# Portfolio

## Discovery

## Preclinical

Drugs / Vaccines

Target Research

Screening

Hit-to-Lead

Lead Optimization

Diagnostics

Target Research

Product Design



NTDs

Buruli ulcer



Chagas disease



Leishmaniasis



Chagas disease, Leishmaniasis



Soil-transmitted helminths



Chagas disease



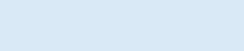
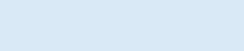
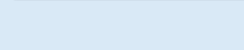
Leishmaniasis



Malaria



Tuberculosis



USD 392M

Co-investment  
GHIT investment



US dollar amounts represent conversions from Japanese yen, solely for the reader's convenience, at JPY 100 = USD 1.

Please visit the GHIT Fund's website to find out more about each project and partner's innovations.  
<https://www.ghitfund.org/investment/portfolio/en>

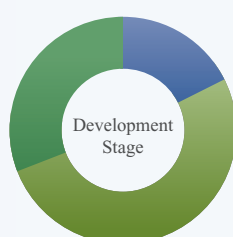
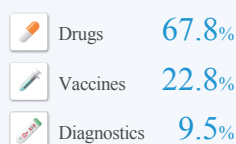
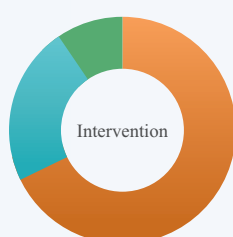
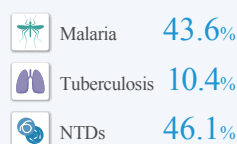
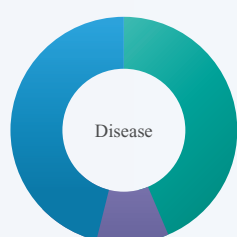


## Clinical

| Preclinical                          | Phase I                               | Phase II   | Phase III                    | Registration                  |
|--------------------------------------|---------------------------------------|--|------------------------------|-------------------------------|
| Product Development                  | Product Validation                    | Product Validation                                 | Product Validation           | Registration                  |
| <p><b>Dengue fever</b></p>           | <p><b>Buruli ulcer</b></p>            | <p><b>Lymphatic filariasis, Onchocerciasis</b></p> | <p><b>Chagas disease</b></p> | <p><b>Schistosomiasis</b></p> |
| <p><b>Visceral leishmaniasis</b></p> | <p><b>Cutaneous leishmaniasis</b></p> |  |                              | <p><b>Mycetoma</b></p>        |
| <p><b>Onchocerciasis</b></p>         | <p><b>Leishmaniasis</b></p>           |  |                              |                               |
|                                      | <p><b>Schistosomiasis</b></p>         |  |                              |                               |
|                                      |                                       |  |                              |                               |
|                                      |                                       |  |                              |                               |
|                                      |                                       |  |                              |                               |
|                                      |                                       |  |                              |                               |
|                                      |                                       |  |                              |                               |

As of March 31, 2023

## Investment Overview FY 2013-2022



**118**  
Total invested partnerships

**170**  
Total product development partners  
 59 Japanese partners  
 111 Non-Japanese partners

FY 2022

**USD 14M**  
Total investments

**7**  
Invested partnerships

**1**  
New Japanese partner

**3**  
New non-Japanese partners





# Featured Story



## “Arpraziquantel”, a potential Pediatric Treatment Option for Schistosomiasis: European Medicines Agency (EMA) Scientific Review Application validated and in progress

Since 2014, the Global Health Initiative Technology Fund (GHIT Fund) has supported the Pediatric Praziquantel Consortium’s development of arpraziquantel, which, once approved, has the potential to be a transformational new therapeutic option for the treatment of schistosomiasis in preschool children (3 months to 6 years old). In November 2022, Merck, on behalf of the Consortium, submitted the regulatory application to the European Medicines Agency (EMA), which has initiated its scientific review. A scientific opinion is expected by the end of 2023. Arpraziquantel represents the first investigational drug to reach the regulatory phase amongst the different projects supported by GHIT Fund.

### Objective: Control Neglected Tropical Diseases (NTDs)

Schistosomiasis is a chronic NTD transmitted by parasites. It has the second highest incidence rate in the world and over 90% of infections occur in Africa. Approximately

250 million people, including more than 100 million children, are infected worldwide. It is estimated that approximately 200,000 people die annually from complications of the disease.

The Pediatric Praziquantel Consortium aims to reduce the global burden of schistosomiasis by developing, registering, and ensuring patient access to arpraziquantel for the very young population that, until now, did not have a suitable pediatric treatment. Arpraziquantel’s development and potential availability (once registered) forms a critical pillar of the fulfillment of World Health Organization’s pledge to eliminate schistosomiasis.

### A Cross-sector, Cross-border Journey: Development of an Easy-to-Administer Pediatric Treatment

Praziquantel, the current standard treatment for schistosomiasis, is safe and highly effective, and available





Photo credit: SCI Foundation/Uganda



Côte d'Ivoire

Uganda

Kenya

Disease: Schistosomiasis

Intervention: Pediatric Drug

Development Stage: Registration, Access

Country: Ivory Coast, Kenya, Uganda and other endemic countries.



for school-age children and adults. However, at present, around 50 million preschool-aged children have been left untreated in public health programs primarily due to the lack of an appropriate child-friendly medication.

In response, in the context of Pediatric Praziquantel Consortium, Japan's Astellas Pharma Inc. developed arpraziquantel, a pediatric formulation of praziquantel. The formulation was then optimized by Merck in Germany and transferred to Farmanguinhos in Brazil for manufacturing clinical supply. Arpraziquantel is small at 150mg, (oro)-dispersible, and has an acceptable taste. Critically, it can also withstand the heat and humidity that characterize the environments in which schistosomiasis is most prevalent.

### Phase III Study Completed, EMA Begins Scientific Review

The confirmatory Phase III Study on the efficacy and safety of arpraziquantel for children aged 3 months to 6 years infected with schistosomiasis was successfully concluded in Ivory Coast and Kenya.

Following this milestone, Merck, on behalf of the Pediatric Praziquantel Consortium, submitted a request for an EMA scientific review under the EU-M4all procedure for high priority medicines intended for use outside the European Union (EU). A positive EMA scientific opinion would expedite WHO prequalification, and inclusion on the Model List of Essential Medicines for Children.

### Delivering Innovation: Ensuring Access for Young Children

An access and delivery strategy that aligns with the unique contexts in endemic countries is essential to ensuring that the impact of this innovation reaches its full potential. In recognition, the Pediatric Praziquantel Consortium is exploring a new procurement mechanism for providing equitable and sustainable access to arpraziquantel (once approved); it also launched the ADOPT program - a 5-year (2021-2025) implementation research program to inform future large-scale delivery programs in endemic countries.

\* Reference: World Health Organization (WHO) : <https://www.who.int/en/news-room/fact-sheets/detail/schistosomiasis>

*"At the end of 2022, the European Medicines Agency validated our application and started the scientific review process for the potential new pediatric treatment option for schistosomiasis. Having reached this milestone after more than 10 years of intense and collaborative work makes me very proud. We are now close to our common goal of improving children's health with a potential innovative and suitable treatment option for the very young patients in need."*

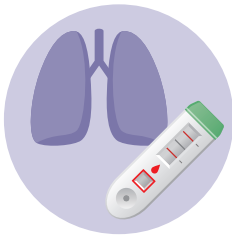


**Dr. Jutta Reinhard-Rupp**

Chair of the Pediatric Praziquantel Consortium Board  
Head of the Global Health Institute at Merck

# Clinical Candidates

## Phase I Trial – Phase III Trial



### Tuberculosis / Diagnostics

FUJIFILM

FIND  
Diagnosis for all

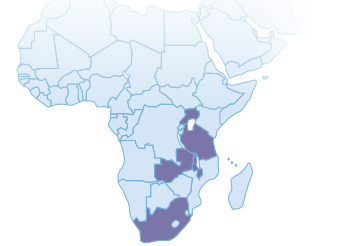
#### FUJIFILM SILVAMP TB LAM

Tuberculosis (TB) is the number one infectious disease killer in the world. Although the disease is curable with early diagnosis and treatment, conventional sputum-based diagnostic methods have led to delayed diagnosis and high morbidity and mortality rates due to the difficulty of sputum collection in some patients, such as children and patients with severe HIV infection. FUJIFILM SILVAMP TB LAM, jointly developed by Fujifilm and FIND, is a diagnostic test that detects LAM (lipoarabinomannan) antigen in urine with high sensitivity, enabling rapid, inexpensive and highly sensitive diagnosis. A prospective evaluation study of the prototype kit (FUJIFILM SILVAMP TB LAM) was conducted with samples collected from 1,624 HIV-positive patients with the aim of establishing clinical evidence, and the results were published (Rita Székely, 2022\*). Fujifilm has completed registration as a CE-IVD and compliance with Japanese export regulations, and is now planning to produce and conduct clinical evaluations of an updated design-locked product, FUJIFILM SILVAMP TB LAM II.

\* doi: <https://doi.org/10.1101/2022.09.07.22278961>

Development Stage: **Product verification**

Country: **South Africa, Malawi, Zambia, Tanzania, Uganda, Vietnam, Thailand**

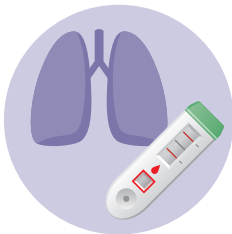


RIT/JATA

ACOUSTIC INNOVATIONS

INSTITUTE OF TROPICAL MEDICINE

CHPR  
Center for Health Promotion & Research



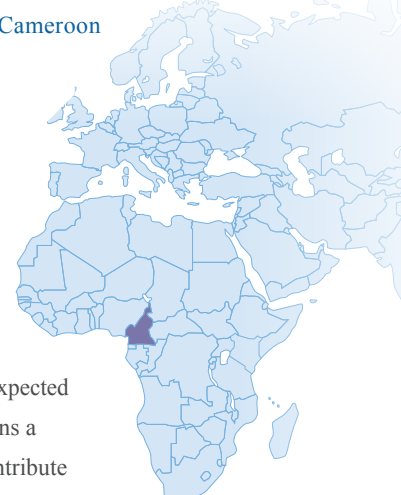
### Tuberculosis / Diagnostics

#### Lung Flute ECO

There are frequently occurring problems with the inability to obtain proper sputum for diagnosis, especially from vulnerable population like women, children and people living with HIV, even if there are abnormalities found in chest x-rays of active tuberculosis detection programs (tuberculosis screening). The Lung Flute is a small, light-weight device used to help remove sputum stuck on walls of airways through the resonance of sound waves. The use of the Lung Flute leads to improvements in the quality and quantity of sputum collected. It does not just improve one aspect of bacteriological examination of tuberculosis (TB), but also contributes to the improvement in accuracy of all examinations. The Lung Flute ECO, an inexpensive version of the Lung Flute, is made of paper, and it is expected to be a disposable tool to assist in sputum induction under limited resources. Furthermore, sputum contains a large amount of deep lung pathological information, and in addition to tuberculosis infections, it may contribute to the diagnosis of bacterial infections and malignant tumors. This study aims to evaluate the performance of the Lung Flute and Lung Flute ECO to improve sputum-based TB diagnosis, primarily in vulnerable groups, in a TB endemic setting. A large prospective comparative study is currently underway in Cameroon. The study will specifically test the effectiveness of Lung Flute ECO in increasing sputum quality and quantity. It will evaluate the proportion of presumptive TB clients who test positive in anti-acid smear and Xpert MTB/RIF Ultra between groups with and without Lung Flute ECO. The study will also assess the significance of Lung Flute ECO use and its potential contribution to safety, acceptability and cost-effectiveness.

Development Stage: **Product Validation**

Country: **Cameroon**







## Malaria / Drug

SJ733



Development Stage: Phase II Clinical Trial

Country: Peru



Malaria is an infectious disease that kills an estimated 620,000 people annually, despite the fact that it is preventable and treatable. The emergence of resistance to the insecticides and antimalarials used in endemic countries is a major concern, and we are aiming to develop SJ733, an ATP4 inhibitor, as a malaria treatment that is less likely to become resistant. In Phase Ia and Ib studies, SJ733 showed excellent safety and good oral absorption. In the Phase IIa study, the drug was evaluated in terms of *Plasmodium vivax* killing rate, minimum inhibitory concentration, the relationship between pharmacokinetics and pharmacodynamics (PK/PD), and the possibility of stopping transmission. Between March 2021 and April 2022, 22 patients participated. SJ733 was highly effective and fast-acting against *Plasmodium vivax* malaria.



## Malaria / Vaccine

AnAPN1



Development Stage: Phase I Clinical Trial

Country: Gabon (Planned)



Malaria parasites *Plasmodium falciparum* (Pf) and *Plasmodium vivax* (Pv) infect humans through transmission by *Anopheles* mosquitoes. A “Transmission-Blocking Vaccine” (TBV) that can block the transmission of parasites from humans to mosquitoes is therefore a very promising tool for reducing malaria infections. This project aims to develop a universal TBV effective against both Pf and Pv by targeting the *Anopheles* midgut luminal surface protein AnAPN1. Targeting a mosquito protein receptor for *Plasmodium* rather than the parasite itself enables blocking of different *Plasmodium* species using a single antigen. With the support of the GHIT Fund, AnAPN1 was optimized to achieve high immune responses. By administering the optimized antigen (UF6b) to mice and monkeys, a strong transmission-blocking activity was induced. After completion of the toxicity study of UF6b, a Phase IA/B clinical trial will be conducted in the Republic of Gabon to evaluate safety, tolerability, and reactogenicity of the vaccine, as well as analyzing patient samples to measure the immune response. The study protocol was reviewed and approved by the Comité National d’Ethique pour la Recherche, Gabon in February 2023, and patient enrollment is expected to start in June 2023. All other requirements have been initiated and we are expecting to receive the first set of results of the clinical trial in August 2024 (interim report), and full analysis with the accompanying study report will be completed by June 2025, which are key milestones in the development of this important universal malaria TBV.



## Mycetoma / Drug

### Fosravuconazole

Mycetoma is a chronic infection which can be transmitted through the skin and thus common among those who walk barefoot, such as agricultural workers and herders in developing countries, and it is particularly prevalent in Sudan. While antibiotics are effective against bacterial mycetoma (actinomycetoma), there is currently no effective treatment for the fungal type of mycetoma (eumycetoma). The long duration of treatment, poor efficacy and high cost, are factors, among others, that result in poor outcome, including recurrence and amputation. Due to development of mass and amputation of limbs, the disease has severe socio-economic consequences including stigma. Fosravuconazole, an antifungal drug, approved in Japan for onychomycosis, was shown to have a potent *in vitro* activity against *Madurella mycetomatis*, the most common fungus that causes eumycetoma. Fosravuconazole can be administered once a week and has favorable safety profiles. Since 2017, a Phase II clinical trial was conducted in Sudan by DNDi, in partnership with Eisai Co., Ltd., and the Mycetoma Research Center (MRC), Sudan. The database lock for the clinical trial was conducted in March 2022. The top-line results were presented at the 21st Congress of the International Society for Human and Animal Mycology (ISHAM) held in September 2022 in New Delhi, India. The clinical study report was finalized in February 2023. An observational study is currently ongoing at the MRC to determine the possibility of long-term recurrence of eumycetoma after initial successful treatment.



Development Stage: Phase II Clinical Trial

Country: Sudan



© Purushottam Diwakar-DNDi



## Cutaneous leishmaniasis / Drug

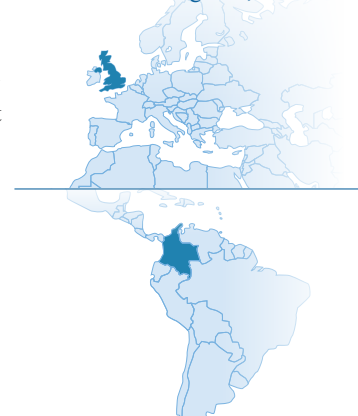
### CpG-D35

Leishmaniasis is one of the 20 neglected tropical diseases (NTDs) designated by the World Health Organization (WHO). Cutaneous leishmaniasis (CL) is the most common form of leishmaniasis. It is prevalent mainly among the poor in developing countries, and WHO estimates that there are between 700,000 and 1,000,000 new patients each year. Although this disease is not life threatening, stigma and economic loss caused by disfigurement have been a problem. Currently, limited drugs are available for the treatment of cutaneous leishmaniasis, and they all have serious drawbacks. CpG-D35 is expected to accelerate the re-epithelialization of lesions on patients, minimize scarring and reduce recurrence rates and the risk of drug resistance when used in combination with chemotherapy. A single ascending dose (SAD) study, a randomized, double-blind, placebo-controlled, single-center study with CpG-D35 administered subcutaneously to healthy subjects, has been completed in the UK and proved the safety and tolerability of CpG-D35 after single dose compared to a matching placebo. In addition, CpG-D35's PK and PD after single dose were also assessed, showing that although CpG-D35 has a very short life, it stimulates the production of several Th1 cytokines. The multiple ascending dose (MAD) study is under preparation. It will be a randomized, open label, multiple-dose escalation study to investigate safety, tolerability, and immunogenicity of CpG-D35 in patients with CL lesions in Colombia.



Development Stage: Phase I Clinical Trial

Country: United Kingdom, Colombia



© Sydelle Willow Smith-DNDi





## Lymphatic filariasis, Onchocerciasis / Drug

AWZ1066S

Lymphatic filariasis and Onchocerciasis are neglected tropical diseases, affecting more than 72 million people around the world. Existing drugs primarily act only on larvae, so there is a need for a safe, new drug that will kill adult worms, interrupting the transmission of long-living parasites. It has been demonstrated that the use of doxycycline can kill adult worms by eliminating the *Wolbachia* mutualistic bacteria within the parasite, but its use is restricted by long-term drug supply and contraindications for children and pregnant women. AWZ1066S is a new drug candidate that acts on *Wolbachia* mutualistic bacteria more rapidly and efficiently than doxycycline, and has been shown to be safe in preclinical studies. Subsequently, a series of Phase I clinical trials evaluating human safety were initiated in December 2021. Currently, an analysis of the results of randomized, double-blind, placebo-controlled single ascending dose study of AWZ1066S-HCL in healthy adult participants is being conducted. AWZ1066S-HCL has potential for use by all people including children and pregnant women, and it is expected to make a significant contribution to people and society suffering from lymphatic filariasis and onchocerciasis.



Development Stage: Phase I Clinical Trial

Country: United Kingdom,  
Cameroon (planned)

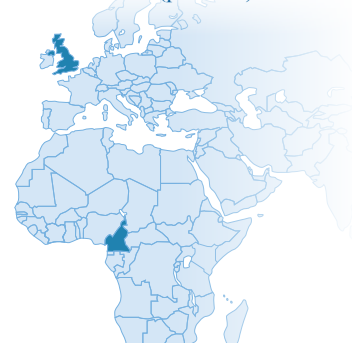
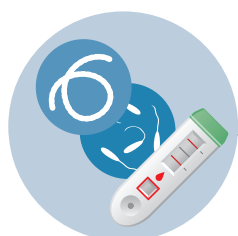


Photo credit: Kate Dodd



## Buruli Ulcer / Diagnostics

BU-MYCOLAC

Buruli ulcer is an infectious disease common in Africa, but there are reports of infections from over 33 countries around the world, including cases identified in Australia and Japan. Early diagnosis and treatment are effective at preventing after-effects such as deformity, and joint contracture, and there is a need for a simple diagnostic method that can be conducted close to the patient. The Buruli Ulcer pathogen produces a toxin called mycolactone, which penetrates the subcutaneous fatty tissue and causes necrosis, resulting in the formation of deep skin ulcers. This project aims to develop and evaluate a rapid diagnostic test for Buruli ulcer targeting mycolactone, to enable early diagnosis for Buruli ulcer patients especially living in regions where medical care is limited. A field-ready prototype BU-MYCOLAC RDT employing mycolactone-specific monoclonal antibodies and biotinylated mycolactone probes in a competitive assay format, was evaluated in BU-endemic areas (Cameroon and Cote d'Ivoire), to assess its operational characteristics, usability and initial diagnostic performance against the reference standard IS2404 PCR. Samples were evaluated using the IS2404 PCR, and mycolactone ELISA, and the concentrations of mycolactone determined to inform performance of the RDT.



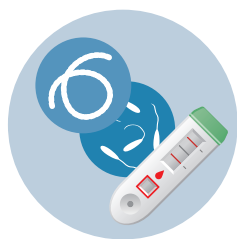
Swiss TPH



Development Stage: Product Development

Country: Cameroon, Ivory Coast





## Chagas disease / Diagnostics

### Chagas-LAMP



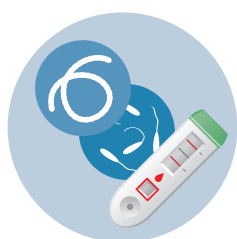
Development Stage: **Product Validation**

Country: **Argentina, Bolivia, Paraguay**

According to the Pan American Health Organization (PAHO), an estimated 1.12 million women of childbearing age are infected by *Trypanosoma cruzi* (*T. cruzi*), and around 9,000 infected babies are born each year, accounting for more than 20% of all new cases of Chagas disease in the region. Because drugs administered to *T. cruzi*-infected newborns in the early stages of infection are highly efficacious, the validation of highly sensitive and specific diagnostics that allow early diagnosis of newborns will greatly contribute to the control of this disease. However, detection of congenital *T. cruzi* infection requires either cumbersome and skilled microscopic examination or molecular biological diagnostic methods that are not well equipped in endemic areas. A field validation study of the prototype diagnostic kit Chagas-LAMP developed by Eiken Chemical Co., Ltd., is currently underway at nine maternity hospitals in Argentina, Bolivia, and Paraguay, with the aim of providing a point-of-care (POC) test suitable for diagnosing congenital Chagas disease. To date, more than 7,500 women have been screened and more than 630 newborns have been enrolled. Newborns born to mothers who test positive are being followed for several months with liquid whole blood samples collected to compare and evaluate the Chagas-LAMP prototype (and qPCR). In addition, we plan to evaluate Chagas-LAMP on dried blood spot samples from newborns. If the overall validation confirms the performance of the prototype, it could lead to the future adoption of this technology in healthcare systems and become a game changer in the fight against mother-to-child transmission. The follow-up of newborns is scheduled for completion in September 2023.



Photo credit: CONICET-INGEBI



## Leishmaniasis / Diagnostics

### Leishmanin Skin Test (LST)

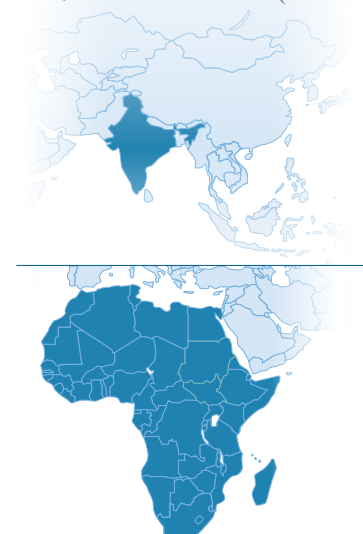


Development Stage: **Product Development**

Country: **India and in Africa (Planned)**

Leishmaniasis is one of the Neglected Tropical Diseases (NTDs) with 350 million people at risk of infection worldwide. The Leishmanin Skin Test (LST) had been used for decades to verify exposure and immune response to Leishmania infection, although Leishmanin antigens used for the LST are currently unavailable. This project aims to revive and reintroduce the LST widely used in the past. Toward the production of Leishmanin antigens from *Leishmania donovani* protozoa, a protocol was established. Some of the highlights of progress in 2022 were the completion of the production of GMP cell bank of *L. donovani*, optimization of the parameters for producing Leishmanin antigen, and validation of GLP grade Leishmanin in animal models.

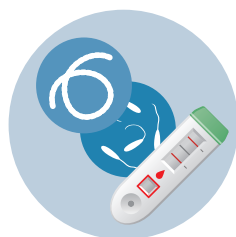
Discussions are ongoing with WHO' NTDs Department regarding providing Leishmanin globally. In addition, LST may also be an effective surrogate marker for determining the efficacy of the auspicious Leishmania vaccine currently under development.





Institute of Tropical Medicine  
NAGASAKI UNIVERSITY  
(INMKN)FIND  
Diagnosis for allLeiden University  
Medical Center

MERCK



## Schistosomiasis / Diagnostics

### SCH CAA RDT

Development Stage: **Product Development**Country: **Kenya, Philippines**

Schistosomiasis (SCH) is one of the major neglected tropical diseases (NTDs), and the WHO NTD roadmap calls to eliminate it as a public health problem from all SCH endemic countries by 2030. Approximately 90% of the 220 million people who are infected reside in sub-Saharan Africa; the disease affects the poorest and the most marginalized communities. Current WHO guidelines for the diagnosis of SCH recommends microscopy-based methods. Whilst they are useful in areas where moderate to high intensity infections occur, in settings where prevalence and intensity have been driven down by mass administration campaigns, these assays become futile due to their poor sensitivity. This project aims to develop a highly sensitive, accurate, easy-to-use and affordable SCH rapid diagnostic test (RDT), which will be able to provide results within 20 minutes using a drop of finger-prick blood. The partners in this project have conducted preliminary field evaluations of a prototype. Further development and optimisation is currently underway with field evaluations expected in Q4 2023, prior to design-lock and transfer to manufacturing. Once manufactured, validation of the RDT will be conducted, to determine its suitability as a replacement of current microscopy-based diagnostic assays. In parallel, the partners have developed an access strategy to bring the product to market. Ultimately, the SCH circulating anodic antigen RDT is critical in the fight against the disease to support the overall WHO SCH 2030 target of elimination, which can be achieved by making better use of available treatments by directing to those communities where SCH is present.



# Invested Partnerships in FY 2022

## From Discovery to Preclinical



### Malaria / Vaccine

#### Development of a potent Pvs230 mRNA vaccine to block transmission of *P. vivax*

Ehime University, Mahidol University



Dr. Wang Nguitragool  
Mahidol University

Target Research Platform

Screening Platform

Hit-to-Lead Platform

Product Development Platform

Malaria caused by *Plasmodium vivax* persists for a long time because the parasite lies dormant in the liver for several months after which time it can cause a relapse of malaria. Because these relapses repeatedly occur even after treatment, new interventions are required, including new vaccines that block parasite transmission and reduce the population of parasite carriers in affected areas. Although vaccines are the most cost-effective tools to fight many infectious diseases, a malaria vaccine targeting *P. vivax* is still not available. The project led by Mahidol and Ehime Universities seeks to develop new mRNA vaccines that block transmission of *P. vivax*. The vaccine target is the parasite protein called Pvs230, a well-known vaccine candidate expressed during the sexual-stage development of the parasite. The vaccine will promote powerful and long-term immunity in humans as well as induce antibodies that block transmission of the parasite from humans to mosquitoes.

Since Pvs230 is a large protein, the project will first screen several Pvs230 fragments to identify the subdomain that induces the strongest functional immunity. Then the project will employ both the classical linear nucleoside-modified mRNA and the team's newly developed circular mRNA to devise the best performing vaccine construct. Vaccine efficacy will be determined by the ability of the vaccine to induce antibodies that block transmission of the parasite from humans to mosquitoes using antibodies induced in mice by mRNA immunity.

Over the long-term, the project aims to eventually combine potent transmission-blocking vaccine with a pre-erythrocytic vaccine in a multi-valent vaccine formulation to block transmission both from humans to mosquitoes and from mosquitoes to humans.

Such a combination vaccine is expected to accelerate malaria eradication.



### Malaria / Drug

#### Irresistible series as anti-malarial agent

Takeda Pharmaceutical Company Limited, Medicines for Malaria Venture (MMV)



Dr. Stephen Brand  
MMV

Target Research Platform

Screening Platform

Hit-to-Lead Platform

Product Development Platform

There is an urgent need to provide access to affordable medicines that prevent or treat malaria in order to reduce the number of deaths and eradicate the disease to every extent possible. To overcome this issue, development is continuing around the world on new drugs for treatment of malaria that are single dose combinations with improved dosing regimen and lower cost compared to the Standard of Care. The key is to continuously create candidates for new treatments.

MMV1579683 is an 'Irresistible' Benzimidazole identified from a phenotypic screen of a Takeda compound library against *P. falciparum* blood stages.

The GHIT Fund has invested approximately 130 million yen in this project, which seeks to create new malaria treatments focusing on the properties of benzimidazole compounds. The project team comprising experts from Takeda Pharmaceutical Company Limited along with synthesis chemists and biologists from MMV will optimize compound structures based on the information obtained from the SAR study. The objective will be to identify a lead compound that meets GHIT Fund and MMV's Early Lead criteria\* in preparation for the next stage of development by assessing physiological activity, physicochemical properties, pharmacokinetics, and toxicity, and verifying that it has sufficient physicochemical properties suitable for oral administration and physiological activity that satisfies the criteria.

This project will contribute to new options for malaria treatments by identifying novel malaria treatment compounds with extremely attractive properties that do not induce drug resistance.

\* MMV Frontrunner template: early leads

<https://www.mmv.org/frontrunner-templates>





## Malaria / Drug

### A Hit-to-Lead study of screening hits for novel antimalarial compounds

Shionogi & Co., Ltd., Nagasaki University, Medicines for Malaria Venture (MMV)



Dr. Ken-ichi Matsumura  
Shionogi

Target Research Platform > Screening Platform > Hit-to-Lead Platform > Product Development Platform

In recent years, healthcare practitioners and patients alike have desired highly safe and effective novel treatments against drug-resistant malaria strains. Shionogi & Co., Ltd. and Nagasaki University are conducting joint research in the field of infectious diseases with a focus on malaria. Through this partnership, 80,000 compounds from Shionogi's chemical library were screened with a novel phenotypic method. With the support of Medicines for Malaria Venture (MMV), five structurally novel hit series were identified.

The objective of this Hit-to-Lead project is to identify a novel lead series that could overcome existing drug resistance issues and satisfy the MMV's early lead criteria\* by conducting structure activity relationship (SAR) studies for these five novel hit series. In the first six months of the project, all five hit series will be explored through the SAR studies to understand their potential for higher potency, safety and the activity on known drug resistance strains of malaria. In the remaining 18 months, priority will be given to series that show particular promise, as the project will continue to confirm further potency and characterization of the series through an efficacy study in mice.

The novel hit series in this project have novel chemical structures as antimalarials and are potentially working with novel mechanism of action, which is important to ensure the activity on drug resistant parasites. In this project, the GHIT Fund has invested approximately 130 million yen in order to identify a novel lead series from these hit series that could help to solve the issue of drug resistant malaria strains.

\* MMV Frontrunner template: early leads  
<https://www.mmv.org/frontrunner-templates>



## Lymphatic filariasis / Onchocerciasis / Drug

### Phase II Clinical Development of AWZ1066S, a Small Molecule anti-Wolbachia Candidate Macrofilaricide Drug

Eisai Co. Ltd., Liverpool School of Tropical Medicine (LSTM), University of Liverpool (UoL), University Hospital of Bonn (UKB), University of Buea (UoB)



Prof. Stephen Ward  
LSTM

Target Research Platform > Screening Platform > Hit-to-Lead Platform > Product Development Platform

Lymphatic filariasis (elephantiasis) and onchocerciasis (river blindness) are two neglected tropical diseases that are caused by parasitic worms. These diseases affect more than 72 million people globally. Existing drugs principally target the young worms, not the adult worms. This means that sustained and prolonged delivery is required to break the transmission cycle of the long-living adult worms.

An investment project by the GHIT Fund, which started in 2013, has already demonstrated that adult worms can be killed by eliminating Wolbachia, a symbiotic bacterium the worms contain.

The objective of this project is to further develop this drug candidate by completing a Phase II clinical trial to assess its effectiveness in patients suffering from onchocerciasis. The project will involve completion of essential preclinical safety studies prior to the start of the clinical trial, completion and registration of the clinical trial protocol, and completion of the Phase II trial in line with international requirements for licensing new drugs to assess the new drugs effectiveness in patients suffering with onchocerciasis. This is an essential step in the development of a new drug and brings us closer to a new treatment for these diseases. For this reason, the GHIT Fund has invested approximately 790 million yen in the project.



## Mycetoma / Drug

Fosravuconazole treatment in eumycetoma:  
corroborating study outcomes, preparing for access

Eisai Co., Ltd. and Drugs for Neglected Diseases Initiative(DNDi)



Dr. Borna Nyaoke  
DNDi



Mycetoma is one of the most neglected tropical diseases (NTDs). It is an infectious disease that slowly destroys tissues and causes severe damage, resulting in severe deformity and disability; as a result it also brings psychosocial consequences and may lead to stigma. Fosravuconazole is an oral azole antifungal discovered by Eisai Co., Ltd. (Eisai), and developed by Eisai and a partner company as a treatment for onychomycosis. It has been shown to have potent *in vitro* activity against *Madurella mycetomatis*, the most common fungus that causes eumycetoma. The first randomized clinical trial (RCT) for patients with eumycetoma conducted in Sudan demonstrated good cure rates of fosravuconazole. Based on the results of the RCT, preparations for the application for approval of fosravuconazole in Sudan will be undertaken.

The project will also conduct a cohort study providing early access to treatment with fosravuconazole in a controlled manner, whilst monitoring treatment outcome and patient safety. Furthermore, a strategic plan will be developed. To understand the needs and opportunities in other endemic areas (e.g. India and Senegal), field visits and expert meetings will be organized, followed by outlining the next steps for use of fosravuconazole as a monotherapy or potentially in combination therapy in severe eumycetoma.

In response to the desperate need for new treatments against eumycetoma, fosravuconazole is expected to be an improvement over existing treatments considering its once weekly administration, its favorable safety profile, and that it can be taken without food or drink, in addition to the good cure rates shown by the recently completed RCT.



## Onchocerciasis / Drug

Preclinical development of DNDI-6166 (or CC1076166)  
a selective macrofilaricide for the treatment of river blindness

BoZo Research -ITR, Drugs for Neglected Diseases initiative (DNDi), The  
Mahidol Oxford Tropical Medicine Research Unit, The UKB University of Bonn

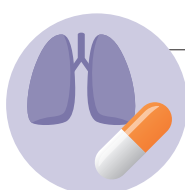


Mr. Ivan Scandale  
DNDi



Onchocerciasis, also known as river blindness, is the main cause of blindness in many African countries. The disease is also prevalent in Latin America. The World Health Organization (WHO)'s roadmap to 2030 for the control, suppression and eradication of neglected tropical diseases (NTDs) cites the need for antiparasitic drugs for onchocerciasis. This requires an integrated approach to antiparasitic development and treating dermal NTDs. Current control strategies are based on preventive chemotherapy programs administered to the population at risk as a whole via mass drug administration (MDA) of ivermectin. While successful, these programs need to be repeated for 10-12 years because the drug only kills juvenile worms – not the adult worms, which can live for more than ten years in the human body. Given the shortcomings of current therapies and the high rate at which R&D is terminated, adding novel compounds with new mechanisms of action to the pipeline is critical.

DNDI-6166 treatment has the potential to prevent specific side effects observed in patients with both onchocerciasis and loiasis because it does not target the filaria larva and therefore it could be administered in regions endemic with loiasis.



## Tuberculosis / Drug

Screening project

Daiichi Sankyo RD Novare Co., Ltd. and TB Alliance





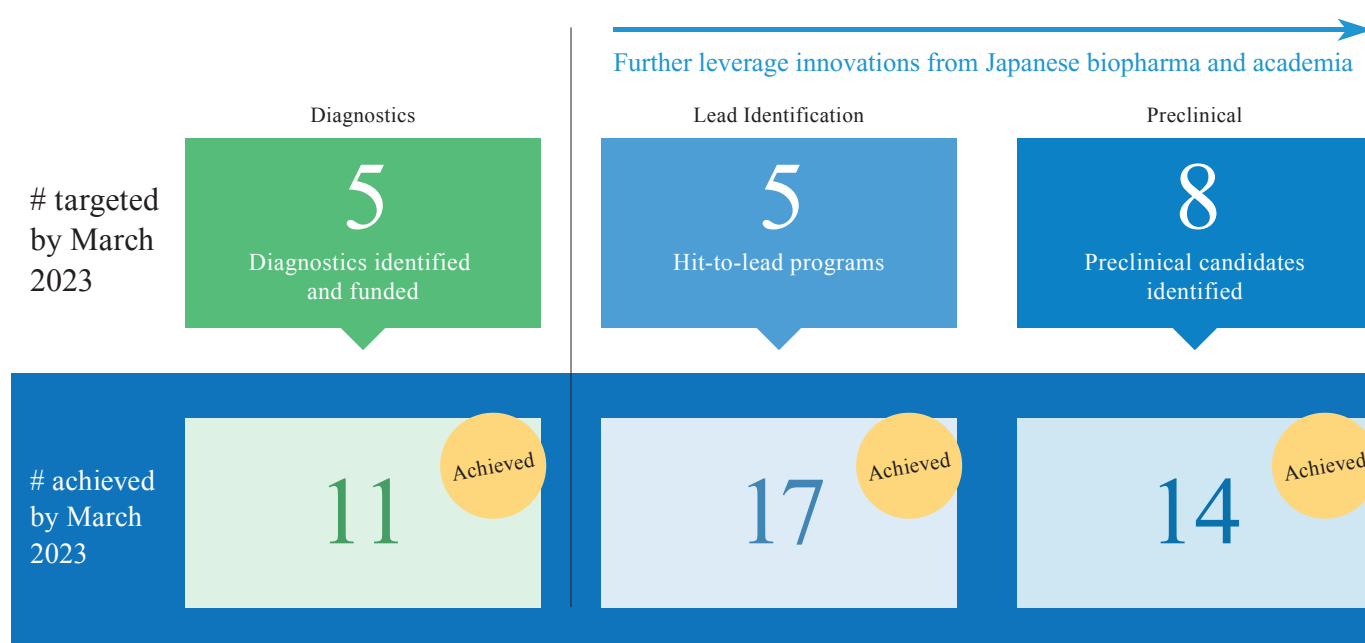


# Strategic Plan FY 2018-FY 2022 Results

We and our product development partners have progressed steadily toward key R&D milestones, despite the far-reaching impact of the pandemic.

In FY 2022, the final year of the GHIT 2.0, we continued to identify and fund projects aligned with strategic goals.

## R&D: Investments in Product Development



## Our actions in FY 2018-FY 2022 to advance innovation



### Strategic Partnerships

- Collaboration with the Coalition for Epidemic Preparedness Innovations (CEPI) to strengthen investment portfolios and accelerate technology collaboration including vaccine platform development
- Cooperation framework with Unitaid to strengthen ties to improve access to critical health tools



### Over 170 product development partners

- 59 domestic and 111 overseas institutions/partners participate in our product development
- The GHIT Fund plays an important role as a bridge that connects Japanese innovation with overseas institutions



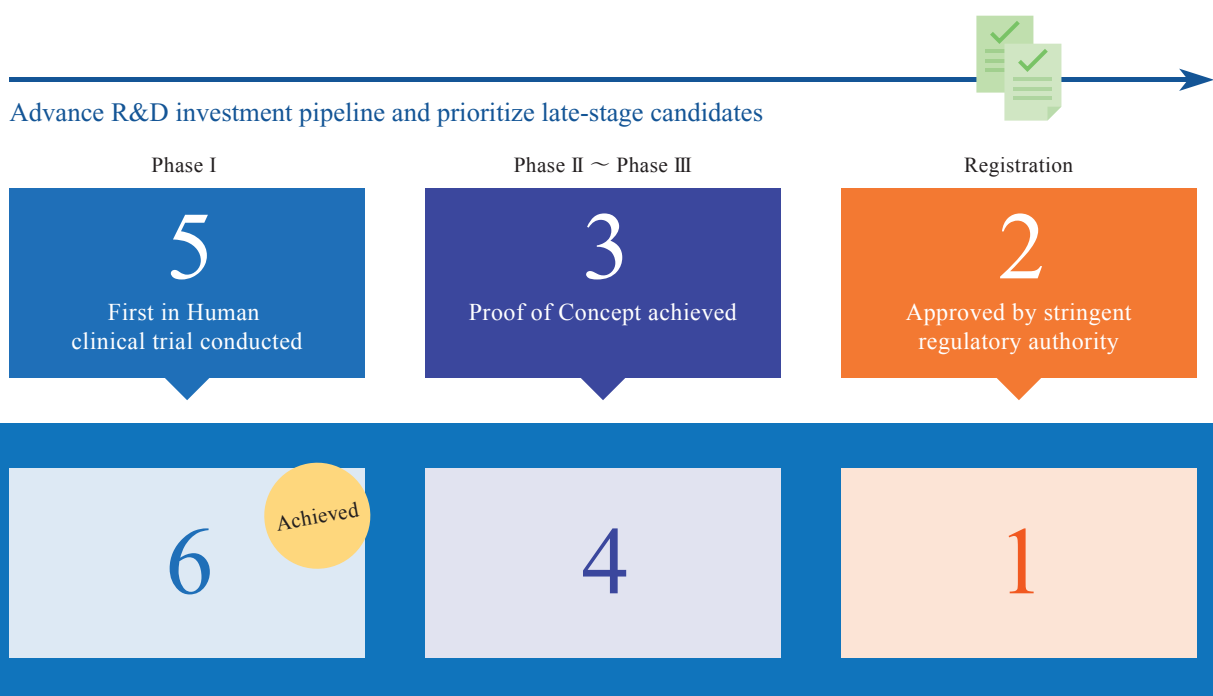
### Proactive portfolio management

- Timely risk identification and mitigation through semiannual progress report reviews and calls



### Access and Delivery Strategy

- Continued engagement with global stakeholders through Uniting Efforts for Innovation, Access and Delivery, a global platform launched by the Government of Japan, the UNDP-led Access and Delivery Partnership (ADP) and the GHIT Fund
- Enhanced coordinated engagement with Access Delivery Partnership (ADP) with the Government of Japan and the United Nations Development Programme (UNDP)



As of March 31, 2023



GHIT Fund has a two-pronged approach in its Access Strategy: A bottom-up approach where GHIT supports product developers in developing access strategies that ensure equitable access and affordability for GHIT-funded products, and a top-down approach where GHIT works with other global stakeholders exploring solutions to the systemic barriers to access. Both approaches leverage and catalyze the creation of strategic and sustainable partnerships between innovators, product developers, funders, private sector, communities, implementers (including governments) to ensure an end-to-end R&D ecosystem.

### Isaac T. Chikwanha

Senior Director, Investment Strategy, Portfolio Development & Innovations



GHIT is in daily communication with many of our partners. With investment strategies and portfolios in mind, we act and advance together with our partners to deliver positive results in developing the products that meet the unmet global health needs in a reliable and timely manner.

### Minako Funakubo

Associate Director, Investment Strategy, Portfolio Development & Innovations

# Highlights in FY 2022

## Forbes Japan Joins GHIT as a New Sponsor



In May 2022, Forbes Japan (operated by linkties Co., Ltd.) concluded a sponsorship program agreement to become a new sponsor of the GHIT Fund. Mr. Yutaro Tsunoda, President of linkties Co., Ltd., said, “Many leaders across sectors who want to make the world a better place come together on the Forbes JAPAN platform. Delivering information on the importance of global health issues and GHIT’s work to our network will combine diverse insights in creative ways to help meet the SDGs and facilitate cross-sector partnerships. We are delighted to collaborate with GHIT to be part of a great force to achieve SDGs.” Forbes JAPAN’s strong influence and broad network will help Japanese people across fields and industries learn about global health issues, great initiatives in Japan and abroad, and GHIT’s mission. Furthermore, the GHIT looks forward to the diversity and global health collaborations this partnership can potentially foster.

## Strengthening Collaboration with CEPI to Advance the Development of Tools



On May 18, 2022, the Coalition for Epidemic Preparedness Innovations (CEPI) and the GHIT Fund signed a Memorandum of Understanding (MoU) which will strengthen collaboration between the two organizations as they work to advance the development of tools to fight infectious diseases. This new collaboration will support both organizations to deliver their respective missions by enabling them to draw on each other’s comparative strengths and areas of expertise in the field of vaccine development. The partnership also aims to enhance vaccine and therapeutic development capabilities in Japan, furthering Japan’s participation in global efforts to counter the threats of infectious diseases through companies, universities and research institutions. The partners will now plan opportunities for practical cooperation in more detail including strengthening both organizations’ investment portfolios by jointly identifying promising vaccine development platforms and technologies and collaborating (to include potential co-funding or coordinated funding) on vaccine R&D for priority pathogens and virus families of mutual interest. In October 2022, members of CEPI’s R&D leadership team including CEO Dr. Richard Hatchett visited the GHIT Fund to discuss future strategic platforms for vaccine development and investment.

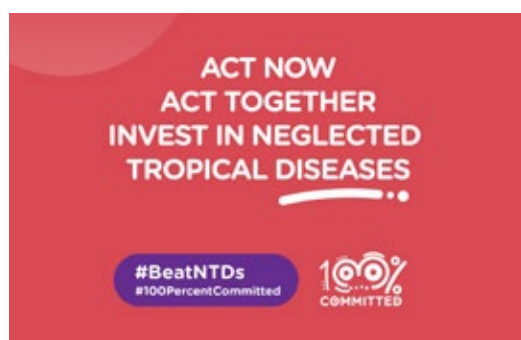
## Strengthening Collaboration with Unitaïd to Improve Access to Critical Health Tools



In February 2023, the GHIT Fund and global health agency Unitaid signed a cooperation framework that aims to strengthen collaboration between the two agencies to increase cooperation between the Japanese research and development industry and the broader global health response. This partnership will focus on tackling complex challenges such as emerging drug resistance in tuberculosis (TB) and malaria and shifting patterns of vector-borne diseases due to climate change. By reinforcing links between the GHIT Fund’s research and development pipeline and Unitaid’s expertise in product introduction and access, the framework will further efforts to connect partners and ideas dealing with topics of health innovation, access, and scale. The agreement unites the two agencies at a broad strategic level and creates a channel for continuous collaboration, scanning the innovation pipeline for late-stage products that address the most pressing global health needs. This work will further efforts to ensure that vulnerable and underserved populations have access to better health products and support progress toward universal health coverage.



## World NTD Day: United with Partners



The World Health Organization (WHO) has designated January 30 as World Neglected Tropical Diseases (NTD) Day. In 2023, the GHIT Fund and its partners in Japan held an online seminar called Roadmap to Achieve the 2030 SDGs and Control NTDs. On the day of the event, close to 200 people participated online. The GHIT Fund's CEO Osamu Kunii said, "The key to success is partnership. The GHIT Fund would like to unite in partnership with the NTDs community to accelerate research and development." Additionally, valuable presentations were made by global organizations, the Government of Japan, academia, and NTD patients on the current state of NTDs and expectations for future actions. Participants were united in launching preparations from Japan for worldwide action on NTDs ahead of the G7 Hiroshima Summit.

## Public Seminar: Game Changers-Japanese Innovation in Combatting Infectious Diseases



On the occasion of the executive director of the Global Fund, Peter Sands, visit to Japan, the GHIT Fund together with The Friends of the Global Fund, Japan (FGFJ) jointly held an event called *Game Changers-Japanese Innovation in Combatting Infectious Diseases* on March 1, 2023 using a hybrid online and in-person format. At the event, Mr. Sands talked about the technological innovation required to overcome barriers on the frontline of the fight against infectious diseases and shared his expectations that there are many areas where new Japanese technologies and products can contribute.

At the panel discussion called *Deploying Game-Changing Innovation on the Ground* moderated by the GHIT Fund's CEO Osamu Kunii, Yoshihiro Okada of FUJIFILM Corporation (General Manager, In Vitro Diagnostics Division) talked about the Rapid Diagnostic Test for Tuberculosis and other programs fighting tuberculosis, while Masanori Kawasaki of Otsuka Pharmaceutical Co., Ltd. (Global Project Leader, Anti-Tuberculosis Project, Pharmaceutical Division) explained the company's initiatives to develop an anti-tuberculosis drug. The panel held meaningful discussions on accelerating drug development and speeding up approvals for patients in need.

We leverage Japanese innovation and fight neglected diseases through partnerships.

Members of the GHIT Fund



## Dialogue: Reflections on GHIT's catalytic role

In January 2023, the GHIT Fund's Selection Committee (SC) met in person for the first time in three years. This welcome reunion, overlapping with the institution's 10th anniversary, sparked meaningful reflection on the GHIT Fund's evolution and achievements, as well as expectations for the future. The GHIT Fund's Hayato Urabe sat down with SC Co-Chairs Naoto Uemura and Ann Mills-Duggan to capture these reflections and thoughts, specifically exploring the Fund's key differentiators, its role in helping develop global health R&D talent, and its evolution over the past 10 years.

**Urabe:** What do you see as GHIT's key differentiators as an institution?

**Mills-Duggan:** The format of the partnership that underpins GHIT is key, and it has been a catalyst for global health R&D partnership in other countries. Japan, with its leading role in global health, led the development of this new kind of partnership between government, pharmaceutical companies, and charitable foundations working together in a way that hadn't been seen before. And this has not only

led to a significant portfolio of projects, but it has also created a model for how other organizations and countries can tackle the fight against NTDs.

The variety of therapeutic-style projects we've seen come to GHIT amazes me. GHIT's investments in R&D ranges from identifying novel targets, screening novel compounds, optimizing lead compounds to developing products tested in local clinical trials nearing licensure. This broad spectrum is absolutely fascinating and really

encouraging to see.

**Uemura:** GHIT is a vital organization, that, while led by Japan, represents a truly international team of scientists and investors. The innovative tools we have helped catalyze and develop over the past 10 years owe a great deal to the international nature of GHIT's public-private partnership structure. And conversely, that structure will make the products we help develop in the future all the more powerful and impactful. Japan's ability to nurture and lead such a team and its cross-border collaboration is a big part of GHIT's contribution to the neglected disease field.

**Urabe:** What is unique about the collaboration that GHIT supports between Japan and overseas partners?

**Uemura:** In my experience, academic research institutions and departments within pharmaceutical companies can often be rather insular. While one



Naoto Uemura, MD, PhD (Professor, Department of Clinical Pharmacology and Therapeutics Oita University Faculty of Medicine)





Ann Mills-Duggan, PhD (Independent Consultant)

particular area of research may be unique and cutting edge, its practical potential will often remain unrealized without collaboration. GHIT creates many opportunities by supporting collaboration between academic institutions in Japan and around the world.

**Mills-Duggan:** The fact that Japan's pharmaceutical companies, academia, and research institutes are all willing to put forward their research and findings towards GHIT-funded projects—and that we are able to source the science from this amazing pool of research occurring across multiple different kinds of institutions in Japan—is also an incredible strength.

**Urabe:** How has GHIT helped develop global health research talent?

**Mills-Duggan:** The cross-border partnerships that GHIT facilitates takes researchers out of their comfort zones and challenges teams to do and think about things in new ways. This not only brings the basic building blocks of scientific projects together more innovatively, but it also benefits the product development team members and the broader scientific environment.

When I first came on board, proposals would generally be presented by a

senior member of a research team, and that senior person would answer all the questions. Now, more and more proposals are being presented by younger members of the team who participate actively during the interview.

**Uemura:** GHIT certainly plays a role in helping Japanese researchers frame projects differently than they may be used to - with a clear, simple question to answer or problem to solve, and solid hypotheses to structure the research. So many proposals we review are unnecessarily complex; many researchers (especially in Japan) are not taught to frame their approach more succinctly, and that kind of education may be needed in the future.

**Urabe:** What are your hopes and expectations for GHIT 3.0?

**Uemura:** I think GHIT can go much further in raising awareness among Japanese and foreign global health researchers about the incredible opportunity it provides. We have a solid group of wonderful development partners, but we need to get the word out to potential new partners and grow that community.

Additionally, GHIT has built a fantastic Selection Committee and group of

External Reviewers, and these groups need to continue to grow, both to keep perspective fresh and energized, but also to meet growing demand. It would be interesting to facilitate more ongoing dialogue (and deeply leverage collective expertise) among the researchers, Selection Committee members, and the management team (outside regular meetings) to come together around R&D process challenges. The collective expertise of these groups is astounding.

**Mills-Duggan:** During these first 10 years there have been a lot of achievements. GHIT now has a large portfolio of projects—a lot of them in clinical trials. We're very close to getting our first drug onto the market. I look forward to seeing that portfolio fulfill its promise, especially in areas where no other tools or innovation are available. It will be game-changing to bring one of those projects to patients.



Hayato Urabe, PhD, MPIA (Senior Director, Investment Strategy, Portfolio Development & Innovations)

GHIT has evolved significantly. It is different and bigger than when it first started out. We are now taking account of things like access, where we're paving the way by helping research teams to actually think about what needs to come next, what needs to happen. Let's keep evolving as the portfolio progresses, while maintaining our core strengths.



# Finances

## FY 2022 Financial Summary

### Balance Sheet

| Assets (in millions)                    | JPY            | USD         |
|---|----------------|-------------|
| Current Assets                          | 73.5           | 0.6         |
| Fixed Assets                            | 5,530.2        | 41.4        |
| <b>Total Assets</b>                     | <b>5,603.7</b> | <b>42.0</b> |
| Liabilities (in millions)               | JPY            | USD         |
| Current Liabilities                     | 66.5           | 0.5         |
| Non-current Liabilities                 | 1.0            | 0.0         |
| <b>Total Liabilities</b>                | <b>67.5</b>    | <b>0.5</b>  |
| Net Assets (in millions)                | JPY            | USD         |
| Designated Net Assets                   | 5,536.2        | 41.5        |
| General Net Assets                      | -              | -           |
| <b>Total Net Assets</b>                 | <b>5,536.2</b> | <b>41.5</b> |
| <b>Total Liabilities and Net Assets</b> | <b>5,603.7</b> | <b>42.0</b> |

The US dollar amounts in this section represent translations of Japanese yen, solely for the reader's convenience, at JPY133.54 = USD1, the exchange rate as of March 31, 2023.

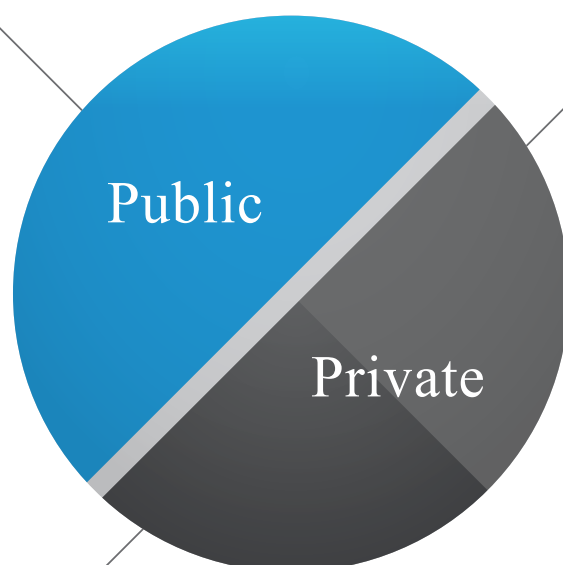
This financial summary is an excerpt from the GHIT Fund's audited financial statements, which are audited by Ernst & Young ShinNihon LLC.. The GHIT Fund is a Public Interest Incorporated Association and is registered in Japan. The GHIT Fund also received in-kind support from its sponsors.

## Our Funding Partners & Sponsors

### Full Partners



### Full Partners



## Net Assets Variation Statement

| Change in General Net Assets (in millions)           | JPY            | USD         |
|--|----------------|-------------|
| <b>Ordinary Income</b>                               |                |             |
| Grants Received                                      | 3,002.0        | 22.5        |
| Contribution Received                                | 519.5          | 3.9         |
| Exchange Gain  | 44.3           | 0.3         |
| Misc. Income   | 1.6            | 0.0         |
| <b>Total Ordinary Income</b>                         | <b>3,567.4</b> | <b>26.7</b> |
| <b>Ordinary Expenses</b>                             |                |             |
| Operating Expenses                                   | 3,424.0        | 25.6        |
| Management Expenses                                  | 143.4          | 1.1         |
| <b>Total Ordinary Expenses</b>                       | <b>3,567.4</b> | <b>26.7</b> |
| <b>Extraordinary Loss</b>                            |                |             |
| Extraordinary Loss                                   | 0.1            | 0.0         |
| <b>Total Extraordinary Loss</b>                      | <b>0.1</b>     | <b>0.0</b>  |
| <b>Change in Designated Net Assets (in millions)</b> |                |             |
| Grants Received and Others                           |                |             |
| Governments, NGOs, Multilateral Organizations        | 776.0          | 5.8         |
| Foundations  | 1,157.4        | 8.7         |
| Contributions Received                               | 829.4          | 6.2         |
| <b>Total Grants and Contributions Received</b>       | <b>2,762.8</b> | <b>20.7</b> |

### Full Partners



### Associate Partners



### Affiliate Partners



### Sponsors



As of March 31, 2023

# Leadership

## Council

Composed of representatives of the Japanese government, global foundations and private companies which contribute funding, GHIT's Council votes on important affairs, such as the election and dismissal of governors, amendments to the articles of incorporation, and the approval of financial statements.



**Takeshi Akahori**

Ambassador, Director-General for  
Global Issues Ministry of Foreign Affairs



**Eiji Hinoshita, MD, Ph.D, MSc.**

Assistant Minister for Global Health and Welfare  
Ministry of Health, Labour and Welfare



**Trevor Mundel, MD, PhD**

President, Global Health  
Bill & Melinda Gates Foundation



**Cheryl Moore**

Chief Research Programmes Officer  
Wellcome



**Astellas Pharma Inc.**

Kenji Yasukawa  
Representative Director,  
Chairman of the Board



**Chugai Pharmaceutical Co., Ltd.**

Osamu Okuda, PhD  
Representative Director, President & CEO



**Daiichi Sankyo  
Company, Limited**

Sunao Manabe, Ph.D  
Representative Director,  
Executive Chairperson & CEO



**Eisai Co., Ltd.**

Haruo Naito  
Representative Corporate Officer  
and CEO



**Shionogi & Co., Ltd.**

Isao Teshirogi, PhD  
Representative Director,  
President and CEO



**Takeda Pharmaceutical  
Company Limited**

Christophe Weber  
Representative Director  
President and CEO

## Board of Directors

Composed of global health and management experts, GHIT's Board of Directors oversees the work of the leadership team and votes on important affairs related to business management, such as the approval of important regulations, mid-term strategies, annual plans, budgets, and investment opportunities.



**Chair & Representative Director  
Hiroki Nakatani, MD, PhD, MHPed**

Visiting Professor  
Keio University School of Medicine



**Vice Chair  
Peter Piot, MD, PhD**

Professor of Global Health, London School of  
Hygiene & Tropical Medicine  
Special Advisor on COVID-19 to the President  
of the European Commission



**Executive Director  
Osamu Kunii, MD, PhD, MPH**

CEO, GHIT Fund



**Mahima Datla**

Managing Director  
Biological E. Limited



**Satoshi Ezoe, MD, MPH, MPA, PhD**

Director, Global Health Policy Division  
International Cooperation Bureau  
Ministry of Foreign Affairs



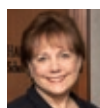
**Tetsuya Itani**

Director  
Office of Global Health Cooperation  
Ministry of Health, Labour and Welfare



**Daikichi Momma**

Vice Chairman  
Institute for International Economic Studies



**Ann M. Veneman, JD**

Former Executive Director, UNICEF  
Former Secretary  
United States Department of Agriculture



**Supervisory Board Member  
Hikaru Ishiguro, LLM**

Statutory Auditor  
INSPIRE Corporation



**Supervisory Board Member  
Saori Nakamura**

Attorney at Law  
Hirayama Nagareya Shirai Law Office



**Supervisory Board Member  
Ko-Yung Tung, JD**

Lecturer on Law, Harvard Law School,  
Former Senior Vice President  
and General Counsel, World Bank



**Ex-Officio  
Katey Einterz Owen, PhD**

Director, Neglected Tropical Diseases  
Pharmaceutical Industry Leadership  
Engagement  
Bill & Melinda Gates Foundation



**Ex-Officio  
Richard Seabrook, PhD, MBA**

Independent Senior Advisor, Innovations,  
Wellcome CEO 360Biomedical Ltd  
Royal Society Entrepreneur in Residence University of Bristol



## Selection Committee

Composed of domestic and foreign experts with a wealth of knowledge and experience in R&D of therapeutic agents, vaccines, and diagnostic agents, the Selection Committee (SC) examines and evaluates applications and progress reports from program applicants and recommends investment opportunities to the Board of Directors. To avoid any conflict of interest between our backers and development partners, the SC does not include private sector representatives.



Co-Chair  
**Ann Mills-Duggan, PhD**  
Independent Consultant



Co-Chair  
**Naoto Uemura, MD, PhD**  
Professor, Department of Clinical Pharmacology and Therapeutics  
Oita University Faculty of Medicine



**Sophie Allauzen, PhD**  
Independent Diagnostic Expert



**Ralf Clemens, MD, PhD**  
Independent Vaccine Expert



**Ken Duncan, PhD**  
Deputy Director  
Discovery & Translational Sciences  
Bill & Melinda Gates Foundation



**Ken Ishii, MD, PhD**  
Professor, Institute of Medical Science  
University of Tokyo



**Timothy Jinks, PhD**  
Head, Infectious Diseases Interventions  
Wellcome



**Hiroo Koyama, PhD**  
Platform Unit Leader  
Drug Discovery Chemistry Platform Unit  
RIKEN Center for Sustainable Resource Science



**Karen L. Menge, PhD**  
Independent Consultant



**Gerd Michel, PhD**  
Independent Consultant



**Dennis Schmatz, PhD**  
Former Vice President of R&D,  
Merck Research Labs, USA  
Former Site Head - Merck Research  
Labs, Japan



**Anna-Karin Tidén, PhD, MRSC**  
Independent Medicinal Chemistry Expert



**Rieko Yajima, PhD**  
Director, Drug Discovery Innovation  
SPARK Program in Translational Research  
Stanford University School of Medicine

## Leadership Team

The leadership team facilitates the development of business, investment, and organizational growth strategies, executes strategies based on the approval of the Board of Directors, and implements administrative tasks.



**Osamu Kunii, MD, PhD, MPH**  
CEO



**Kio Yamabe, MBA**  
COO



**Kei Katsuno, MD, MPH**  
Senior Director, Investment Strategy  
Business Development



**Eriko Mugitani**  
Associate Director,  
Brand Communications



**Kazue Seki**  
Director, External Affairs &  
Corporate Development



**Miho Takazawa, MBA**  
Senior Director, Finance & Operations



**Hayato Urabe, PhD, MPIA**  
Senior Director, Investment Strategy  
Portfolio Development & Innovations

# Funding Partners & Sponsors

Support from our generous funding partners and sponsors helps GHIT's investments and operations advance and create meaningful impact.

## Full Partners



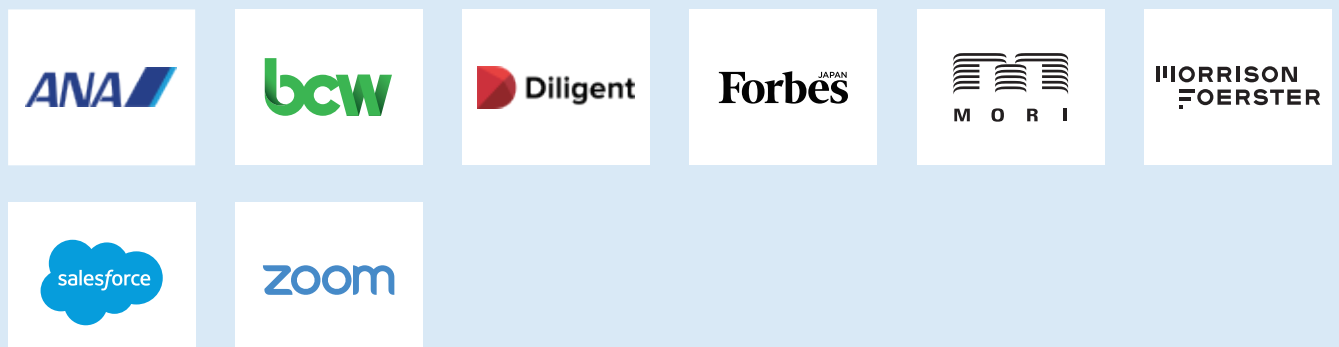
## Associate Partners



## Affiliate Partners



## Sponsors



As of March 31, 2023

# Fight Neglected Diseases through Partnerships



## Overview

|                                 |  |
|---------------------------------|--|
| Name                            | Global Health Innovative Technology Fund (GHIT Fund)   |
| Address                         | Ark Hills Sengokuyama Mori Tower 25F, 1-9-10 Roppongi, Minato-ku, Tokyo 106-0032<br>TEL: +81-36441-2032 FAX: +81-36441-2031  |
| Launched                        | November 6, 2012 (Operations started in April 2013)  |
| Chair & Representative Director | Hiroki Nakatani  |
| CEO & Executive Director        | Osamu Kunii  |
| Activities                      | <ol style="list-style-type: none"><li>1. Facilitation of global R&amp;D partnerships for the discovery and development of new health technologies for the developing world</li><li>2. Investment in these global R&amp;D partnerships through a grant-making mechanism</li><li>3. Advancement of Japan's contribution to global health</li></ol> |
| Website                         | <a href="https://www.ghitfund.org/en">https://www.ghitfund.org/en</a>  |



Fight Neglected Diseases through Partnerships



Global Health Innovative Technology Fund

Global Health Innovative Technology Fund

Ark Hills Sengokuyama Mori Tower 25F, 1-9-10 Roppongi, Minato-ku, Tokyo 106-0032, Japan TEL: +81-36441-2032 FAX: +81-36441-2031