GHIT Fund

ANNUAL REPORT 2019

GHIT Fund

ANNUAL REPORT 2019

CONTENTS

Igniting Innovation, #Together

FY 2019 represents a landmark year for GHIT, Japan, and global health alike, and we are proud to share the highlights with you. During the creation of this annual report, the 2020 COVID-19 pandemic placed intense pressure on the entire world, further challenging communities already struggling with neglected diseases, and underscoring the critical importance of public-private partnership (PPP) and Research and Development (R&D). Investing in product development for patients with malaria, tuberculosis (TB), and neglected tropical illnesses is more important than ever, and GHIT is committed to mobilizing our network, knowledge, and experience in ever more creative and flexible ways to ensure continuity. We can unite--and innovate--together, in spite of our physical distance, and without forgetting compassion for others.

As we reflect on FY2019 milestones, we also look forward. We are grateful for the opportunity to serve the global health R&D community and neglected patients worldwide, both of whose resilience and strength continues to astound us.

R&D: a critical component of "Health for all"

GHIT partners and stakeholders convened at the G20 Summit and Tokyo International Conference on African Development (TICAD7) in Japan in August 2019, as well as during numerous other major global health events. High-level side events complemented the Government of Japan's steadfast prioritization of global health and Universal Health Coverage (UHC) in key discussions among world leaders. Japan's long-standing leadership in UHC continued to make headlines into the autumn, laying the groundwork for the UN General Assembly High-Level Meeting on UHC in September 2019, when world leaders adopted the UN Political Declaration on UHC, the most comprehensive health agreement ever made at this level. The declaration highlights the value of R&D, focused in particular on innovative financing for new products and technologies and emphasizing cross-sector collaboration and new models for sustainable investment.

Tangible R&D progress

In FY 2019, GHIT invested USD 39.2 million in 19 projects. Newly awarded unique and innovative projects are critical to further strengthen our pipeline (P.13-16). To date, our current investments total USD 209 million. Currently, 25 discovery projects, 17 preclinical projects, and 6 clinical trials are under way. Our most advanced clinical candidates are progressing, with World Health Organization (WHO) endorsement and/or approval from a stringent regulatory authority expected within the next several years. These innovations include a urine-based rapid tuberculosis diagnostic kit and a pediatric formulation of the gold-standard drug for schistosomiasis (P.09-10). Getting these innovations into the hands of the patients who need them most represents a concrete realization of GHIT's mission and vision. Additionally, we held our second R&D Forum in December 2019, which enabled our development partners to connect in person to ideate around the global health R&D process broadly, share lessons learned, and further empower our network of innovators across the globe (P.17-18).

Bridging R&D and access and delivery

Because innovation without access is meaningless, we are dedicated to ensuring that our development partners consider access and delivery at every stage of the R&D process. We have also created, together with the Government of Japan and United Nations Development Programme's Access & Delivery Project (ADP), a thriving global platform for critical, ongoing global dialogue between funders, innovators, and access and delivery stakeholders to discuss common challenges and needs, and to jointly identify solutions. Furthermore, in March 2020 we were pleased to announce a new partnership with Unitaid, aligning GHIT's strength in product development and Unitaid's expertise in promoting access to and scale-up of health innovations (p.19-20).

Diversity, equity, and inclusion

We are proud to name diversity, equity, and inclusion (DEI) as a high-level institutional priority, explicitly recognizing it as an essential part of GHIT's DNA through several internal and external efforts. We do this because we believe that DEI is essential to the creation of new ideas, driving innovation, and enhancing operational excellence. That, in turn, helps us contribute to better health for all through our global R&D partnerships. In recognition of our efforts, Global Health 50/50, an evidence-based international platform to advance DEI action and accountability in global health, featured GHIT in its Stories of Progress (P.21-22).

Looking forward, and reflecting with appreciation

In FY 2020 our focus remains steadfast: continue to mobilize Japanese science and pharmaceutical capabilities in partnership with our global network of partners. We do this to push the boundaries of global health R&D so that innovative tools can reach those who need them most. Endorsement and approval of our first products are firmly in sight.

With every year we continue to see the limitless potential of global health R&D; our job is to deliver on it. We continue to be inspired and emboldened by the passion, energy, creativity, and unwavering commitment of our funders, partners, governors, and staff, as well as the broader global health community of which we are honored to be a part. #Together, we will ignite innovation -- in times of both crisis and calm.

Catherine Kaseri Ohura
CEO and Executive Director

Hiroki Nakatani
Board Chair & Representative Director

Global Dialogue

June 2019

Health20 Summit, Tokyo

In line with the G20 Summit in May 2019 hosted by the Government of Japan (GOJ), GHIT co-hosted with the independent G20 Health and Development Partnership the "Financing for Global Health Innovation & Sustainable Development" conference, which addressed innovative financing mechanisms in health, innovation for antimicrobial resistance and pandemics, and UHC.

Photo Credit: The G20 Health and Development Partnership

August

Auxiliary events at TICAD7, Yokohama

The 7th Tokyo International Conference on African Development (TICAD7) was held in Yokohama, Japan, with the theme "Advancing African Development through People, Technology, and Innovation." GHIT, together with the GOJ and Japanese pharmaceutical companies, WHO, UNDP, and NGO/NPOs co-hosted several high-level side events focused on unique collaborations with African partners, promising innovations utilizing Japan's technology and innovation, and uniting efforts globally to combat neglected diseases in Africa for achieving UHC and the SDGs.

October

World Health Summit, Berlin

Together with leaders from the European & Developing Countries Clinical Trials Partnership (EDCTP), the Global Fund, WHO, and German Federal Ministry of Education and Research, GHIT examined the clinical development of novel medical technologies for poverty related infectious diseases through creative collaboration and strategic alliances.

November

Women Leaders in Global Health Conference, Kigali

As a sponsor, speaker, and mentor, GHIT joined 1000+ global health leaders and young professionals in Rwanda to discuss women's leadership and career development, and how best to change the global health gender imbalance.

Photo Credit: University of Global Health Equity

Leaders across sectors urged the global community to maintain and increase momentum toward the elimination of neglected diseases and to continue development of life-saving tools, delivering those innovations to neglected patients, strengthening health systems, and supporting African ownership.

Photo Credit: TICAD7 JAGntd/GHIT

September

Uniting Efforts for Innovation, Access and Delivery at UNGA: Back-to-back technical meetings, New York City

GHIT hosted technical meetings on the sidelines of the 2019 UN General Assembly (UNGA) with the Government of Japan and UNDP-ADP. Discussions addressed planning for access and delivery in the R&D process, improving efficiency and use of target product profiles, costing and funding strategies, better engagement with country stakeholders, and resource mobilization.

Photo Credit: Uniting Efforts for Innovation, Access, and Delivery

December

GHIT R&D Forum, Tokyo

GHIT's biennial R&D Forum convened more than 100 R&D partners and funders from across the globe to share progress and lessons learned about GHIT-invested projects and accelerate partnership-driven innovations.

Sketched by: Alex Cagan

February 2020

Uniting Efforts for Innovation, Access, and Delivery, Bangkok

GHIT, the GOJ, and UNDP ADP convened over 100 funders, innovators, government officials, and experts for the Second Global Dialogue of the Uniting Efforts for Innovation, Access and Delivery platform, on the sidelines of the 2020 Prince Mahidol Award Conference. Stakeholders discussed the refinement of collective research, the funding landscape, and guidance on investment cases for neglected diseases.

Advancing Portfolio

	Discovery			Preclinical
Drugs / Vaccines	Target Research	Screening	Hit-to-Lead	Preclinical
Diagnostics	Target Research			Product Design

Malaria

Tuberculosis

Neglected Tropical Diseases

Chagas disease

Schistosomiasis

Mycetoma

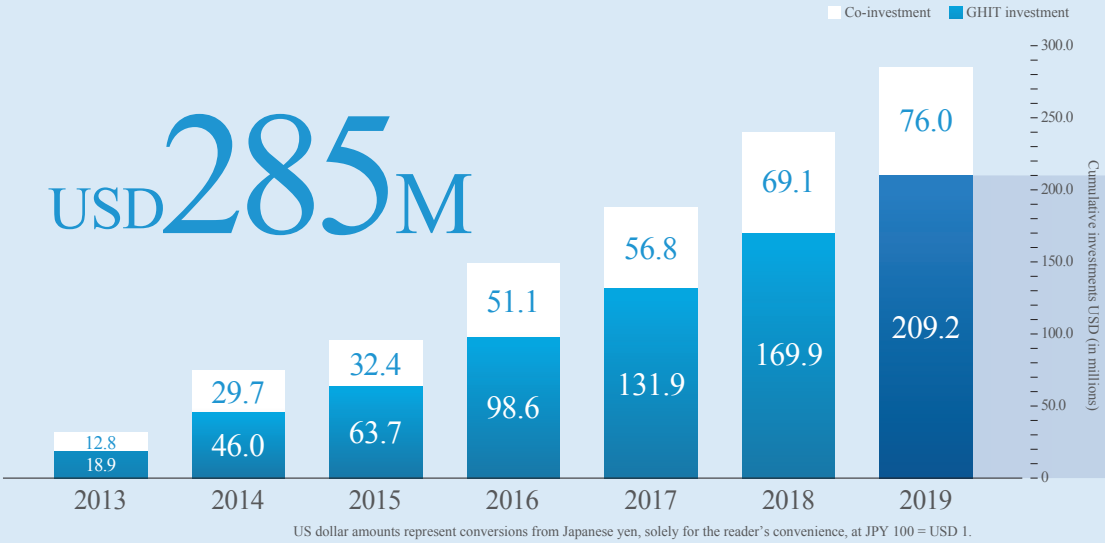
Chagas disease, Leishmaniasis

Leishmaniasis

Chagas disease

Dengue fever

Leishmaniasis



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

Clinical

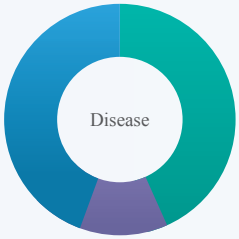
Phase I	Phase II	Phase III	Registration
Product Development	Product Validation	Product Validation	Registration

Lymphatic filariasis,Onchocerciasis

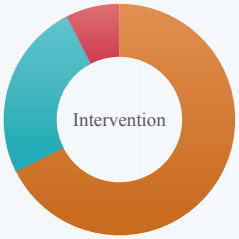
Mycetoma

Schistosomiasis

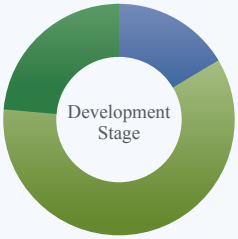
Investment Overview FY2013-FY2019



- Malaria 43.7%
- Tuberculosis 12.0%
- NTDs 44.3%



- Drugs 67.4%
- Vaccines 25.2%
- Diagnostics 7.4%



- Discovery 16.2%
- Preclinical 60.2%
- Clinical 23.6%

91
Total invested partnerships
48 Active investments
43 Completed investments

128
Total product development partners
47 Japanese partners
81 Non-Japanese partners

Clinical Candidates

As of March 2020, six clinical trials and/or field studies are underway in low-and middle-income countries. COVID-19 has affected the operation and progress of these projects, but GHIT is working closely with our partners to mobilize our knowledge and resources to support these activities.

BK-SE36/CpG

Disease: Malaria
Intervention: Vaccine
Development Stage: Phase Ib
Country: Burkina Faso

OSAKA UNIVERSITY, MTR, Nobelpharma, KM Biologics, GHIT Fund, GRIAS

SJ733

Disease: Malaria
Intervention: Drug
Development Stage: Phase IIa
Country: Peru

Eisai, MMV Medicines for Malaria Venture, University of Kentucky College of Pharmacy

SJ733 is a chemically novel and potent antimalarial candidate entering Phase II clinical trials for oral 3-day treatment of non-severe malaria, based on a dihydroisoquinolone platform and featuring good oral availability, excellent safety tolerability, and a low propensity for resistance. In humans, SJ733 is active against blood and sexual stages and possesses an excellent safety profile. SJ733 demonstrated rapid parasite killing in a Phase Ib human challenge. Phase IIa trial using SJ733 as a combination therapy will be tested at the clinical site in Peru to evaluate its effectiveness in the field setting.

Peru
SJ733 Malaria/Drug

PZQ

Disease: Schistosomiasis
Intervention: Pediatric Drug
Development Stage: Phase III
Countries: Côte d'Ivoire, Kenya, Zimbabwe

Astellas, Merck, Lygature, Swiss TPH, Farmanguinhos, SCI Schistosomiasis Control Initiative, Sabin

The Pediatric Praziquantel Consortium is developing the pediatric formulation of the gold-standard drug for schistosomiasis to address the unmet medical needs of infected preschool-age children. The new orally dispersible tablet under investigation is smaller and adapted to younger children. The study is now in Phase III clinical trials, with ongoing enrolment in Kenya and approval obtained for Côte d'Ivoire and Zimbabwe to test the safety and effectiveness of the new formulation. Implementation research plans have also advanced to assess acceptability and try different models of care for the formulation. Finally, GHIT is also supporting the Consortium on further refining the formulation's regulatory, access, and delivery strategies, including creating linkages with key stakeholders like WHO and planning for long-term financing for procurement and supply chain mechanisms to ensure timely and sustainable roll out.

TBLAM

Disease: Tuberculosis
Intervention: Diagnostic
Development Stage: Field Validation
Country: South Africa, Malawi, Zambia, Tanzania, Uganda, and Vietnam (currently planned and may expand)

FUJIFILM, FIND

This trial assesses the safety and reactogenicity of three doses of malaria vaccine candidate BK-SE36, formulated with TLR9 ligand adjuvants K3 CpG oligodeoxyribonucleotides (K3 CpG-ODN) in healthy adults and children exposed to the Plasmodium falciparum parasite in Burkina Faso. In parallel with this study, partners initiated the preparatory work for Phase II proof-of-concept (POC) study including pre-clinical studies on the new GMP lot of SE36 vaccine adsorbed on aluminium hydroxide (NPC-SE36) to show suitable formulation for clinical trial testing and importation; delivery of a new GMP lot of CpG-ODN (K3) as adjuvant for clinical trials; selection of Phase IIb clinical trial sites; preparation for the clinical trial documentation.

E1224

Disease: Mycetoma
Intervention: Drug
Development Stage: Phase IIb
Country: Sudan

This trial tests whether Fosravuconazole (E1224), an azole-class antifungal drug discovered by Eisai, may also be effective against fungal mycetoma. Current treatment for mycetoma is lengthy, expensive, and--with its 20-30% success rate--barely effective. The trial being conducted by Drugs for Neglected Diseases *initiative* (DND*i*), together with Eisai and the Mycetoma Research Center (MRC), a WHO Collaborating Center in Khartoum, Sudan, compares the effectiveness of Fosravuconazole with the current treatment, itraconazole. Fosravuconazole was initially developed by Eisai for treatment of other fungal infections and has a proven safety profile and shows strong antifungal activity against fungal mycetoma. If successful, Fosravuconazole would offer a more effective and affordable alternative treatment of shorter duration. The trial is currently in Phase II in Sudan, the country where the disease is most prevalent and where the government is uniquely committed at the highest levels to address this scourge. After a preliminary blinded evaluation in February 2019, which showed promising results, the DSMB (Drug Safety Monitoring Board) of Sudan recommended increasing the enrolment number to 165, which in itself is a positive sign. GHIT is also supporting the development partners in preparations for early access by catalyzing discussions on regulatory pathways, including WHO PQ (Pre-qualification).

Burkina Faso
BK-SE36/CpG Malaria/Vaccine

Sudan
E1224 Mycetoma/Drug

Vietnam
TBLAM TB/Diagnostic

Uganda
TBLAM TB/Diagnostic

Kenya
PZQ Schistosomiasis/Pediatric Drug

Côte d'Ivoire
PZQ Schistosomiasis/Pediatric Drug

Zambia
TBLAM TB/Diagnostic

Tanzania
DAR-901 TB/Vaccine
TBLAM TB/Diagnostic

Zimbabwe
PZQ Schistosomiasis/Pediatric Drug

Malawi
TBLAM TB/Diagnostic

South Africa
TBLAM TB/Diagnostic

DAR-901

Disease: Tuberculosis
Intervention: Vaccine
Development Stage: Phase IIb
Country: Tanzania

DAR-901 is the only novel TB booster vaccine candidate based on inactivated whole cell derived from Mycobacterium obuense that has shown efficacy in humans. The DAR-PIA trial is a Phase II study of the DAR-901 booster conducted among 13-15 year old adolescents in Tanzania. Unlike most TB vaccine trials that test whether a vaccine prevents full blown TB disease, the DAR-PIA trial tests whether DAR-901 works even earlier and prevents the initial TB infection. After two years of follow-up, all participants will be retested to determine if those in the vaccine group had a reduced risk of new TB infection.

This project aims to develop a highly sensitive, rapid point-of-care TB test to diagnose the disease from urine in high-risk, HIV-infected individuals. The project is a partnership between Fujifilm, which developed the technology, and FIND (Foundation for Innovative New Diagnostics) and is currently at the field validation stage. A review of the preliminary data by the WHO Guideline Development Grou (GDG) in May 2019 gave a positive outlook, with recommendations for additional studies to cover population groups not originally covered in the study. For example, HIV positive patients with higher CD4 cell counts and a broader geographical coverage. The prospective studies are being conducted (or planned) in South Africa, Malawi, Zambia, Tanzania, Uganda, and Vietnam, with possibility to expand. These are expected to end by Q4 2020, with targeted WHO GDG review by Q1/Q2 2021 due to changes in the WHO GDG set-up procedures. Fujifilm also submitted a dossier to the Global Fund/Unitaid-sponsored Expert Review Panel for Diagnostics, an early access mechanism that allows countries to use Global Fund or Unitaid money to procure technologies that do not have Stringent Regulatory Authority approval. Additional operational research is also planned by FIND's independent partners, such as Medicines Sans Frontiers, McGill University, and KNCV. More data is also expected from Fujifilm-led independent studies with multiple research partners. GHIT is also supporting the partnership to facilitate the SILVAMP™ TBLAM's transition to volume manufacturing, pricing strategy, and country entry and adoption through setting up strategic access and delivery partnerships.

Strategic Plan Progress

R&D: Investments in Product Development

Further leverage innovations from Japanese biopharma and academia

	Target Research	Hit Identification	Lead Identification	Preclinical
Progress by March 2020	4 Diagnostics		6 Leads	7 Candidates
Target by March 2023	5 Diagnostics Five innovative diagnostics identified and funded		5 Leads Five hit-to-lead programs	8 Candidates Eight preclinical candidates identified

Diagnostics

Malaria

- Development of LFA platform for improving sensitivity of point-of-care assays for infectious disease with main focus on TB and malaria. Asahi Kasei Corporation, and Biopromic AB. [2018]
- Commercial development of a saliva-based malaria asymptomatic and asexual rapid test (SMAART-1). CellFree Sciences Co. Ltd., ERADA Technology Alliance, Ltd., Frontier Institute Co., Ltd., Oasis Diagnostics Corp., and the University of Florida. [2019]

NTDs

- Production, validation, and use of the Leishmanin skin test for detection of Leishmania exposure and immunity. Institute of Tropical Medicine (NEKKEN) Nagasaki University, Gennova Biopharmaceuticals Ltd., McGill University, U.S. Food and Drug Administration, and the Ohio State University. [2019]
- MycEXomics, development of a field-friendly point-of-care diagnostic test for mycetoma. RIKEN, Hospital General de Mexico, Mycetoma Research Centre, University of Khartoum, and Erasmus University Medical Center. [2019]

Lead Identification

Malaria

- New hit-to-lead activity for new anti-malarials between MMV and Takeda. Takeda Pharmaceutical Company Limited, Medicines for Malaria Venture (MMV). [2018]
- Proteasome inhibitors as new potent antimalarials. Takeda Pharmaceutical Company Limited, MMV, The University of Melbourne's Bio21 Molecular Science and Biotechnology Institute. [2019]
- Development of nucleoside sulfamates as novel antimalarials. Takeda Pharmaceutical Company Limited, MMV, The University of Melbourne's Bio21 Molecular Science and Biotechnology Institute. [2019]

TB

- Hit-to-lead development of novel anti-TB natural products. Daiichi Sankyo RD Novare Co., Ltd., The Global Alliance for TB Drug Development [2018]
- Hit-to-lead development of phenotypic and mechanism-based screening hits. Takeda Pharmaceutical Company Limited, The Global Alliance for TB Drug Development. [2019]
- Hit-to-leade development of phenotypic screening hits. Chugai Pharmaceutical Co., Ltd., The Global Alliance for TB Drug Development [2019]

GHIT's Strategic Plan 2018-2022 was developed in 2017. The R&D pillar specifies targets at each development stage so that tangible results and impacts from GHIT investments can be evaluated objectively.

Advance R&D investment pipeline and prioritize late-stage candidates

Phase I	Phase IIa	Phase IIb	Phase III	Registration
1 FIH	0 POC			1 Product
5 FIH	3 POC			2 Products
Five First in Human (FIH) clinical trials conducted	Three clinical candidates with Proof of Concept (POC) achieved			Two products approved by a stringent regulatory authority

Design of clinical trials (e.g., PhIa/b, PhIIa/b) and point of testing for proof of concept depends on regulatory science; depiction above is only representative.

Preclinical

Malaria

- Preclinical and clinical development of SJ733, a novel PfATP4 inhibitor for the treatment of severe malaria. Eisai Co., Ltd., University of Kentucky. [2019]
- Preclinical studies of potent Gwt1p inhibitor toward IND for antimalarial agent with novel mechanism of action. Eisai Co., Ltd., MMV. [2019]

NTDs

- Development and production of cGMP lots of a novel tetravalent dengue virus-like particle (VLP) vaccine. Institute of Tropical Medicine (NEKKEN) Nagasaki University, The Johns Hopkins University, Latham BioPharm Group, National Institute of Infectious Diseases, and VLP Therapeutics. [2018]
- Preclinical development of an anti-dengue virus antibody that neutralizes all four serotypes. Chugai Pharmaceutical Co., Ltd., and A*STAR's Singapore Immunology Network (SIgN). [2018]
- Development of a novel immune therapy to reduce or prevent typical post-treatment sequelae of visceral leishmaniasis. University of Tokyo, International Center for Diarrheal Disease Research Bangladesh, and Infectious Disease Research Institute. [2018]
- Live attenuated prophylactic vaccine for leishmaniasis. Institute of Tropical Medicine (NEKKEN) Nagasaki University, Gennova Biopharmaceuticals Ltd., McGill University, The Ohio State University. [2019]
- Development of AWZ1066S, a small molecule anti-Wolbachia candidate macrofilaricide drug. Eisai Co., Ltd., University of Liverpool, Liverpool School of Tropical Medicine. [2019]

Phase I

- Fujifilm SILVAMP™ TBLAM – a sensitive point-of-care TB test. Fujifilm Corporation and FIND [2018]

Registration

- Fujifilm SILVAMP™ TBLAM – a sensitive point-of-care TB test. Fujifilm Corporation and FIND [CE Marked in 2018]

[Year] = The year when GHIT and/or partners met the milestone in the strategic plan.

Invested Partnerships in FY 2019

Malaria / Vaccine

Made-in-Japan, next-generation vaccine platform effective for multistage Plasmodium for infants

Kanazawa University, Hokkaido University, Jichi Medical University, Toyama University, University of Cambridge

Prof. Shigeto Yoshida
Kanazawa University

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

Many people living in tropical areas are demonstrably co-infected with helminths and malaria, which are known to adversely affect immune responses to a number of different existing vaccines. Based on the hypothesis that helminths and maternal antibodies are critical host factors, this project aims to develop a highly effective and durable next-generation multi-stage malaria vaccine that will be effective against both the pre-erythrocytic stage and sexual-stage parasites based on two viral vectors for African infants with pre-existing helminths and maternal antibodies.

Protective and transmission blocking efficacies of the heterologous prime-boost immunization regimen will be assessed by sporozoite challenge and a direct membrane feeding assay in a robust, proven mouse model, and then the regime will be further optimized. The desired protection rate is greater than 90%. Surrogate markers responsible for protection will be identified, and humoral and cellular immune responses induced by the heterologous prime-boost immunization regimen will be assessed.

Malaria / Vaccine

Development of a novel Pvs25 nucleoside-modified mRNA vaccine that induces potent and long-lasting transmission-blocking immunity

Ehime University, Mahidol University, University of Pennsylvania

Dr. Jetsumon Prachumsri
Mahidol University

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

The goal of this project is to develop a novel nucleoside-modified mRNA vaccine that induces potent, long-lasting transmission-blocking immunity and is able to interrupt transmission of P. vivax from human to mosquito. The vaccine target is the protein Pvs25, which is expressed on the surface of the transmission-stage parasite, a well-validated target. The nucleoside-modified mRNA encoding Pvs25 will be delivered by lipid nanoparticles (LNP), an approach which has been shown to be highly effective in other vaccines.

The project will test several mRNA-LNP formulations in animals to identify the best candidate. It will also explore several routes of administration and immunization schedules. Vaccine efficacy will be determined by the ability of the immune sera of immunized animals to block mosquito infection using a membrane feeding assay with P. vivax parasites isolated in Thailand. In addition to developing a new transmission-blocking vaccine, the project also investigates the immune mechanism that results in transmission-blocking activity.

Mycetoma / Diagnostic

MycEXomics aims to develop a field-friendly point-of-care diagnostic test for mycetoma

RIKEN, Mycetoma Research Centre (MRC), University of Khartoum, Erasmus University Medical Center, Hospital General de Mexico

Dr. Imad Abugessaisa
RIKEN

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

Mycetoma is caused by more than 70 different causative agents, but four of these are responsible for 79.5% of all mycetoma cases world-wide. The current mycetoma diagnostics tools are tedious, invasive of low sensitivity and specificity, and expensive. Presently there is no point-of-care diagnostic test for mycetoma. This project sets out to identify species-specific markers for the four most common causative agents of mycetoma in urine and plasma of mycetoma patients.

In order to identify these markers, the project will identify the causative agent by isolating exosomes from the urine and plasma, isolate RNA from the exosomes and sequence it, and then profile and transcriptomes identify markers. The markers identified can later be used to develop point-of-care diagnostic tools to detect early cases of mycetoma.

Tuberculosis / Drug

Hit-to-lead development of Phenotypic screening hits

Chugai Pharmaceutical Co., Ltd., TB Alliance

Dr. Tatsuya Tamura
Chugai Pharmaceutical Co., Ltd.

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

This project aims to identify lead compounds for TB utilizing hit compounds discovered from natural products in the previous GHIT-funded research. This involves not only improving the potency of the compounds against Mycobacterium tuberculosis (M. tb), but also improving their pharmacokinetic properties and safety liabilities to demonstrate their activity in animal models. Partners plan to identify a compound at the end of the two-year period to move to lead optimization.

The screening of natural products has been deemphasized in recent years in the face of parallel syntheses and target-based screening. By returning to this rich source of novel antibiotics while also applying the most advanced synthetic technology, project partners aim to combine the merits of these two approaches to create a new mechanism of action as M. tb-active agents.

Tuberculosis / Drug

Hit-to-lead development of phenotypic and Mechanism-based screen hit

Takeda Pharmaceutical Co., Ltd., TB alliance

Dr. Yuichiro Akao
Takeda Pharmaceutical Co., Ltd.

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

Joint screening efforts by Takeda and the TB alliance to identify potential new TB drugs identified two promising series of compounds. Of these series of compounds identified, one emerged from phenotypic screening of Takeda's compound library for their ability to kill M.tb, and the second from mechanism-based screening of Takeda's internal portfolio for their ability to inhibit a particular enzyme in M.tb. The goal of this project is to improve their potency and properties and ensure their safety to make them suitable for treatment. The project also aims to prove that the eventual drugs derived from these prototypes can be administered orally and in reasonable doses to be widely accepted among TB patients worldwide. Partners will synthesize several dozens of analogues in each series to evaluate them in the assay and, test selected analogues in mice to evaluate their activity in animal models.

Lymphatic filariasis / Drug

Development of AWZ1066S, a small molecule anti-Wolbachia candidate macrofilaricide drug

Eisai Co., Ltd., Liverpool School of Tropical Medicine, University of Liverpool

Prof. Stephen Ward
Liverpool School of Tropical Medicine

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

In the absence of a drug for Lymphatic filariasis (elephantiasis) and onchocerciasis (river blindness) that can kill adult worms, current eradication programmes require many years of annual or greater rounds of drug administration to large populations in the rural communities blighted by these diseases. Partners have demonstrated that adult worms can be killed by eliminating a bacterium that they contain called Wolbachia. The antibiotic doxycycline works in this way and proof of concept has already been proven in human field trials, however it requires weeks of daily treatment and carries contraindications in young children and pregnant women, who represent a large proportion of the target population. This project's candidate drug has shown quicker and efficient activity than doxycycline and has a safe profile in pre-clinical testing. Partners will complete a series of Phase I clinical trials to assess safety in humans.

Chagas disease / Drug

Lead optimization of a candidate series active against Chagas disease

Daiichi Sankyo Company Limited, Drugs for Neglected Diseases *initiative* (DND*i*)

Dr. Takuya Ikeda
Daiichi Sankyo Company Limited

Target Research Platform › Screening Platform › Hit-to-Lead Platform › **Product Development Platform**

This project aims to create a safe and efficacious new oral treatment for chronic Chagas disease, appropriate for acute patients and that is safe to use during pregnancy. Existing drugs for Chagas disease are associated with serious side effects and suboptimal efficacy for chronic Chagas patients. Drugs for Neglected Diseases *initiative* (DND*i*) and Daiichi Sankyo Co., Ltd. have been collaborating since early 2016 on the development of the new drug. This 2-year project aims to engineer this promising class of compounds into one optimized lead candidate for Chagas disease and elucidate its mechanism of action by the end of Q1 2022. This optimized lead candidate shall meet the criteria of the Chagas disease Target Candidate Profile defined by DND*i*.

Malaria / Vaccine

Preclinical development of malaria transmission-blocking vaccine candidate Pfs230D1+ formulated with SA-1 adjuvant

Ehime University, Sumitomo Dainippon Pharma Co., Ltd., PATH

Dr. C. Richter King
PATH

Target Research Platform › Screening Platform › Hit-to-Lead Platform › **Product Development Platform**

The goal of this project is to advance a novel candidate P. falciparum (malaria) vaccine to the clinical testing stage. This transmission-blocking vaccine incorporates an optimized immunogen, Pfs230D1+ formulated with a novel TLR7 adjuvant (SA-1). This project employs both an optimized immunogen Pfs230D1+, which contains the key regions necessary for antibody mediated inhibition of P. falciparum transmission, and a novel TLR7 adjuvant (SA-1) to promote a potent and durable effect. The project will ideally conclude with clinical phase manufacturing and the filing of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA).

Malaria / Drug

Preclinical studies of potent Gwt1p inhibitor toward IND for antimalarial agent with novel mechanism of action

Eisai Co. Ltd., Medicines for Malaria Venture (MMV)

Dr. Takaaki Horii
Eisai Co. Ltd.

Target Research Platform › Screening Platform › Hit-to-Lead Platform › **Product Development Platform**

Glycosylphosphatidylinositol (GPI) is a common moiety in all eukaryotes which has a role in anchoring many proteins to the cell surface. Gwt1p, one of the essential enzymes in the GPI biosynthesis pathway, was identified by Eisai as a novel target for an antifungal drug. After conducting discovery research, Eisai found that the GWT1 gene encoding Gwt1p enzyme is highly conserved among eukaryotes, including Plasmodium protozoa, the etiological pathogens for malaria. MMV and Eisai succeeded in creating the candidate compound with improved anti-Plasmodium activity and the long half-life required for single-dose malaria treatment. Partners aim to conduct IND-enabling Good Laboratory Practice (GLP) preclinical studies on an antimalarial candidate compound with a well-characterized and novel mechanism of action identified in a project funded through a previous GHIT investment.

Leishmania / Diagnostic

Production, validation, and use of Leishmanin skin test for detection of Leishmania exposure and immunity

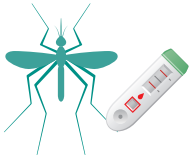
Institute of Tropical Medicine (NEKKEN) at Nagasaki University, Ohio State University, McGill University, Gennova Biopharmaceuticals, U.S. FDA

Prof. Abhay Satoskar
The Ohio State University

Target Research Platform › Screening Platform › Hit-to-Lead Platform › **Product Development Platform**

No tests are currently available to detect asymptomatic Leishmania infection and immunity against the disease. The objectives of this project are to produce and determine the stability of the L. donovani antigen (Leishmanin antigen), validate the Leishmanin skin test (LST) leishmanin antigen in immune animals, validate the LST in visceral leishmaniasis-cured and asymptomatic infected individuals.

Project partners will establish a protocol for making Leishmanin antigen from L. donovani parasites and produce GMP grade Leishmanin for the LST. Immune responses will also be analyzed in these preclinical animal models, followed by the validation of LST in visceral leishmaniasis patients and asymptomatic individuals from endemic regions.



Malaria / Diagnostic

Commercial development of a saliva-based malaria asymptomatic and asexual rapid test (SMAART-1)

CellFree Sciences Co. Ltd., ERADA Technology Alliance, Ltd., Frontier Institute Co., Ltd., Oasis Diagnostics Corp., University of Florida

Dr. Rhoel Dinglasan
University of Florida

Target Research Platform › Screening Platform › Hit-to-Lead Platform › **Product Development Platform**

Malaria rapid diagnostic tests (RDTs) have been a critical component of the eradication arsenal, but recent studies suggest that the P. falciparum parasite has developed mutations that effectively limit the diagnostic capacity of current RDTs to confirm parasitic infection in the field. The project addresses this limitation by producing and validating Saliva-based Malaria Asymptomatic and Asexual Rapid Test (SMAART-1) that have high enough sensitivity to diagnose asymptomatic cases with high reliability and greater acceptability, designed especially for easier diagnostic screening of children. Product development draws on the new P. falciparum protein marker PSSP17 identified by the University of Florida that could replace presently used parasite markers, which a growing prevalence of parasite mutations have rendered increasingly ineffective. The PSSP17 protein is present in infected red blood cells and is also present as a soluble molecule in the saliva of individuals with clinical and subclinical infections.

Photo credit: Jasses S. Jones, University of Florida Health Communications

GHIT R&D Forum 2019

GHIT's biennial R&D Forum creates a special opportunity for over 100 of the institution's R&D partners and funders across the globe to share progress and lessons learned about GHIT-invested projects, from discovery to clinical stages, and to connect people and accelerate partnership-driven innovations. By doing so, further expanded and strengthened R&D ecosystems for neglected patients have been built. Since the first R&D Forum in 2017, partnerships between Japanese and non-Japanese partners have proliferated and flourished. We continuously endeavor to catalyze and support these promising collaborations for neglected patients.

Dr. Atsuko Ochida

Associate Director
Drug Discovery Chemistry Laboratories
Neuroscience Drug Discovery Unit, Research
Takeda Pharmaceutical Company Limited

"Sharing our ideas with, and receiving constructive feedback from, experts in different fields are critical steps for shaping our research. The best science comes from embracing and inviting diversity, and the inclusion of different ideas. To address complex global health challenges, uniting with not only researchers like ourselves, but also funders, regulatory authorities, governments, international organizations, and NGO/NPOs will be essential. GHIT's R&D Forum is the place where we can do this for neglected patients."

Dr. Tomoko Ishino

Associate Professor
Division of Molecular Parasitology
Protea-Science Center (PROS),
Ehime University

"Joining forces to develop life-saving innovations with the global community is a source of great pride for me. Expanding our network proactively and exploring our potential beyond academia and Japan are critical to move our discovery science and technology to the development stage. Global collaboration and open innovation plays a pivotal role in GHIT, and the R&D Forum very literally demonstrates that. I believe that R&D partnerships will continue to have a central role in lifting up the quality of science, accelerating product development, and getting tools to the patients who need them most."

Ms. Lara Pandya

Strategic Partnerships Officer
European & Developing Countries
Clinical Trials Partnership
(EDCTP)

"We are proud to co-invest with GHIT in the paediatric PZQ Phase III trial, which is providing clinical data and support for registration of a new PZQ tablet formulation to treat schistosomiasis in preschool-aged children. GHIT's R&D Forum facilitates open dialogue between researchers and funders that creates synergies and generates innovative ideas for greater impact through partnership. Collaboration and coordination between funders is now more critical than ever to accelerate R&D for neglected diseases and populations with major unmet medical needs."

Dr. Charles Mowbray

Discovery Director
DND*i*

"While visiting Japan over the R&D Forum week, we had fruitful discussions with many scientists at both public and private organizations and identified several exciting opportunities for new projects and partnerships. Over the years partnerships with Japanese organizations from discovery to clinical stages have become critical elements of DNDi's portfolio. GHIT has been key to these many successes and has played a catalytic role in facilitating these collaborations and helping us to access important new technologies for neglected patients. I am proud of and inspired by the fact that our Japanese partners' motivation and commitment to exploring the best science for the most neglected has only grown stronger from year to year."

Technology
Creativity
Connectivity
All drives innovation

Fostered from research
Realized with development

Your active and creative minds
Harmonized with other's
Ignites innovation for those most neglected

Thinking bigger, thinking differently
Outside the box
We can nurture a new dawn where
Health is a right, not an option

Japanese innovation
Connecting the dots
Of global partnership

Changing health
To save millions of lives

Enabling equality
So that they can thrive

Together
We are all GHIT

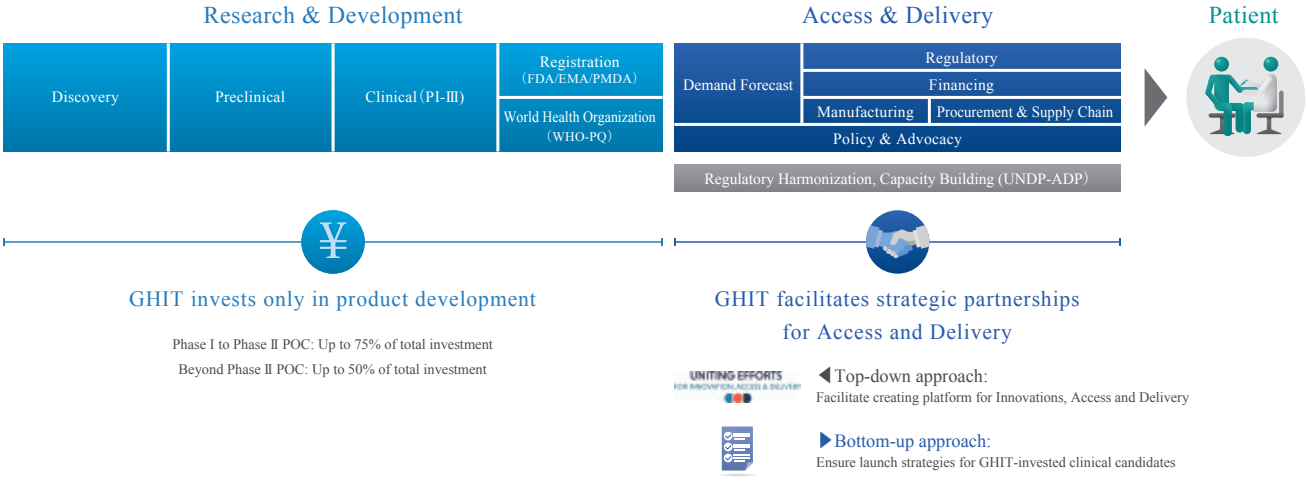
Preparing Innovations for Success

Linking R&D to access and delivery every step of the way

We fundamentally believe that without access, innovation is meaningless. Accordingly, GHIT is dedicated to ensuring that our development partners consider and prepare for access and delivery at every stage of the R&D process so that our invested innovations can move quickly from the lab into the hands of the people and communities who need them most. While GHIT's investments focus exclusively on R&D, facilitating critical access and delivery-focused dialogue and partnerships play an important role in setting up those innovations for success.

With registration and approval now in sight for several products, these considerations become increasingly important. As a result, our approach leverages GHIT's networks and unique positioning to influence and catalyze strategic access and delivery partnerships. This ensures that innovative health technologies have a direct impact on their target populations, and, ultimately, on health outcomes.

Our approach rests on two key pillars: a tactical, bottom-up pillar that ensures development partners are creating comprehensive product launch strategies to complement and inform R&D, and a policy-focused top-down pillar that launched a platform for critical, ongoing global dialogue among all relevant stakeholders about the inextricable link between R&D and access and delivery. GHIT partners with the Government of Japan and UNDP's Access & Delivery Partnership (ADP) on activities associated with the second pillar, entitled Uniting Efforts for Innovation, Access and Delivery. This platform fills a gap in opportunities for funders, innovators and access and delivery stakeholders to discuss common challenges and needs, and to jointly identify solutions.



UNITING EFFORTS
FOR INNOVATION, ACCESS & DELIVERY

Uniting Efforts for Innovation, Access and Delivery Global Dialogue

Back-to-back technical meetings in New York City (September 2019)

The first meeting on the sidelines of the 2019 UN General Assembly addressed how and when to start planning for access and delivery in the R&D process, improving efficiency and use of target product profiles (TPPs), and sharing lessons learned. The second examined costing and funding strategies, strategies for better engagement with country stakeholders, investment cases, and sustainable, coordinated resource mobilization.

Second Global Dialogue in Bangkok (February 2020)

In addition to revisiting the above topics, stakeholders discussed the refinement of collective research on access policies and practices in R&D, the neglected disease access and delivery funding landscape, and a guidance note on investment cases for neglected diseases. The dialogue's marketplace approach facilitated meaningful connections between experts and country stakeholders.

https://www.unitingeffortsforhealth.org/

Unitaid
Innovation in Global Health

Partnership with Unitaid

In March 2020, GHIT and Unitaid signed a collaboration framework to increase awareness of and access to innovation and expertise in key areas such malaria, TB, and NTDs. In the context of achieving health-related SDGs and UHC, the framework facilitates continuous dialogue and operates at a broad strategic level to align GHIT's strength in product development and Unitaid's expertise in promoting access to and scale-up of health tools. It also coordinates actions to accelerate access to innovative solutions, focusing on products and technologies that can deliver the most impact for vulnerable and underserved populations and address the global health-related needs.

"Innovation is at the heart of Unitaid's work and we are pleased to be able to create this platform for dialogue with GHIT. The Fund has recognized strengths in product development, which complement those of Unitaid to identify innovation, promote access and ensure scale-up by partners. I look forward to exploring opportunities with GHIT to deliver our strategic objectives of serving vulnerable and underserved populations, and bringing innovative solutions to achieve universal health coverage."

Dr. Philippe Duneton, *Executive Director*

Delivering Impact through

Diversity, Equity, and Inclusion

DEI as GHIT's DNA

GHIT's Management Team explicitly recognizes diversity, equity, and inclusion (DEI) as critical to GHIT's DNA. Why? A more diverse workforce and flexible work-style enables our team to maximize their full potential and empowers them to leverage their creativity and productivity, fueling new ways of thinking. Fostering an inclusive culture that encourages openness, respect, and fairness, and finds value in differences and similarities so that all employees feel that they belong, is a day-to-day priority. These collective impacts bring innovative ideas and approaches, and then lead to better organizational performance and success. That, in turn, helps us contribute to better health for all through our global R&D partnerships.

GHIT's internal DEI task force, set up in September 2019, is composed of C-suite leaders and individuals across departments and holds regular meetings to identify challenges and opportunities and discuss improvements to internal DEI policies and programs. Externally, we have initiated dialogue across a diverse range of sectors to share best practices and lessons learned, as well as collaborations for creating and accelerating more innovations and sustained social change.

"We have long known that DEI, including gender diversity, is key to effective, innovative organizations. In the for-profit world, DEI relates directly to sales and profits. In global health, where non-profit organizations are striving to create a healthier world, it is even more critical to embrace DEI as a mechanism to maximize our ability to deliver on our missions… DEI is not just a question of fairness, it's a driver of success."

Catherine Ohura
CEO & Executive Director, GHIT Fund

WOMEN LEADERS IN GLOBAL HEALTH
RWANDA

The Women Leaders in Global Health conference, launched in 2017, takes place in a different country each year and brings together established and emerging leaders from across sectors and cultures to work towards gender equity in health leadership and to improve health for all. At the 2019 conference in November in Kigali, GHIT CEO Catherine Ohura spoke alongside Peru's former Minister of Health, the Rockefeller Foundation's Managing Director of Health Programs, Nigeria's Chief Humanitarian Coordinator, and Israel's first woman to lead a governmental hospital on the "Leadership Labyrinth" panel, which featured honest discussion about the career growth of women across global health sectors. Additionally, as a Founding Partner of the event, GHIT sponsored a 100-person breakfast mentoring session for young professionals and students.

Photo Credit: University of Global Health Equity

Global Health 50/50

Global Health 50/50 is an independent, evidence-driven initiative to advance action and accountability for gender equality in global health. Its yearly report and accompanying index provide comprehensive, in-depth analysis of the gender-related policies and practices across 200 of the world's most influential health and health policy organizations, including GHIT. The 2020 report provides an unprecedented birds-eye view of the global health system and warns that inequalities are impeding progress towards health goals. In 2020 GHIT featured prominently among Global Health 50/50's Stories of Progress, making notable strides across all 11 evaluation areas.

"The GHIT Fund stands out among Japanese organizations for its prioritization of gender equality and its commitment to diversity, equity, and inclusion more broadly. While a small organization compared to its counterparts across the globe, the presence of strong and committed leadership within GHIT is already demonstrating positive results. Over the past year, GHIT has made significant progress in the Global Health 50/50 Index, and I congratulate the team and the leadership for their success in pushing for gender equality that benefits everyone."

Prof. Sarah Hawkes
Co-founder of Global Health 50/50
Professor of Global Public Health, University College London

Communications

In FY2019, GHIT released a series of short films that highlighted global partnerships and innovative technologies to overcome global health challenges. Each film is available on our YouTube channel. Additionally, GHIT is now active on social media. Please follow us for the latest news about us and our partners.

https://youtu.be/zRCYMLTSr5A

First-ever clinical trial for potential new effective, lower cost mycetoma drug

Challenge Mycetoma (Eumycetoma), caused by a fungal infection, slowly and progressively destroys soft tissue, particularly on the feet. Mycetoma has no effective treatment and is currently managed with sub-optimal, expensive drugs carrying strong side effects and often requiring surgery, including amputation of affected limbs. In rare cases, it affects the lungs or brain and can be fatal. In all cases, patients are unable to work and face severe social stigma.

Innovation Fosravuconazole, originally developed by Eisai to treat other fungal infections, has a proven safety profile and shows strong in vitro antifungal activity against mycetoma. This candidate drug can be administered once weekly and would drastically improve patient compliance and reduce costs for individuals and health systems alike. This drug, if successful, could transform their quality of life.

A new pediatric formulation of the gold-standard drug - smaller in size, less bitter, and orally dispersible

Challenge Schistosomiasis is the second-most socioeconomically devastating parasitic disease after malaria. Exposure leaves infected children vulnerable to increased risk for anaemia, stunting, and a reduced ability to learn, although the effects are usually reversible with treatment. Praziquantel (PZQ), an affordable, gold-standard drug, exists, but treatment for preschool-aged children has not been implemented due to several key obstacles: difficulty in swallowing and risk of choking give the large-sized commercially available tablets and high rejection rates due to bitter taste when pills are crushed and dispersed in liquids.

Innovation By utilizing Astellas' formulation technology, the new pediatric tablets are about a quarter of the size of the existing commercial PZQ tablets and are orally dispersible (can be taken with or without water). This, together with agents that minimize PZQ's bitterness and improve the taste of the tablets, helps children swallow more easily, which facilitates compliance and efficacy. In addition, the tablets are heat-stable in hot and humid African environments.

https://youtu.be/JirTRmJ8VKM

Novel, urine-based, point-of-care test for TB diagnosis for people living with HIV in low-resource settings

https://youtu.be/xPV_XvYtDuI

Challenge TB is leading cause of death in HIV Patients. In order to provide appropriate care and treatment to HIV patients, early diagnosis is essential. However, advanced HIV-positive patients presenting for TB diagnosis are unable to produce a sputum sample and many patients cannot be diagnosed in time, which results in high morbidity and high mortality. The world needs a non-sputum based, rapid diagnostic tool that can be used in LMICs with resource limited settings.

Innovation SILVAMP™ TBLAM uses patients' urine to diagnose TB, detecting low concentrations of LAM (lipoarabinomannan), which is found in the cell walls of mycobacterium tuberculosis. The partnership successfully leverages FUJIFILM's proprietary silver halide amplification technology, originally developed for processing photographs, to create highly sensitive immunochromatography, which is capable of detecting viruses and bacteria.

GOOD DESIGN AWARD 2019

FUJIFLM's SILVAMP™ TBLAM received the "GOOD DESIGN GRAND AWARD" - Japan's most prestigious design award. This GHIT-invested urine-based rapid diagnostic test for tuberculosis is highly evaluated by the Good Design Award jury and the most popular design of the year in Japan. "We highly praised the ambition, technology and design that has made it possible to easily diagnose TB in developing countries with a 70% sensitivity, which is equivalent to expensive diagnostic equipment…The utilization of silver amplification technology, which is now considered nonessential, has reminded us the importance of discovering new things by taking lessons from the past."
https://www.g-mark.org/award/describe/49146

Follow us on Twitter & LinkedIn

@GHITFund

Global Health Innovative Technology (GHIT) Fund

Selected media coverage in 2019 GHIT Fund

Asian Scientists, Financial Times, Japan Times, World Economic Forum, The Chemical Daily, Forbes Japan, JIHO, Mixonline, Nikkei, Yakuji Nippo, Yomiuri Shimbun etc

Finances

FY 2019 Financial summary

Balance Sheet

Assets (in millions)	JPY	USD
Current Assets	1,009.4	9.3
Fixed Assets	5,355.9	49.2
Total Assets	6,365.3	58.5

Liabilities (in millions)	JPY	USD
Current Liabilities	604.2	5.6
Non-current Liabilities	466.5	4.3
Total Liabilities	1,070.7	9.9

Net Assets (in millions)	JPY	USD
Designated Net Assets	5,294.6	48.6
General Net Assets	-	-
Total Net Assets	5,294.6	48.6
Total Liabilities and Net Assets	6,365.3	58.5

The US dollar amounts in this section represent translations of Japanese yen, solely for the reader's convenience, at JPY108.81 = USD1, the exchange rate as of March 31, 2020. This financial summary is an excerpt from the GHIT Fund's financial statements, which were audited by Ernst & Young ShinNihon LLC. The GHIT Fund is a Public Interest Incorporated Association and is registered in Japan.

Our Funding Partners and Sponsors

Full Partners

外務省
MOFA Japan

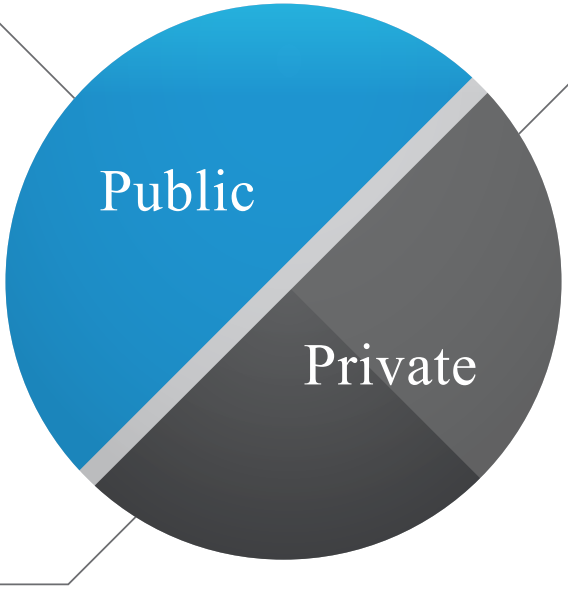
厚生労働省
Ministry of Health, Labour and Welfare

UNDP

Full Partners

BILL & MELINDA GATES foundation

wellcome



Net Assets Variation Statement

Change in General Net Assets (in millions)	JPY	USD
Ordinary Income		
Grants Received	3,102.5	28.5
Contribution Received	668.9	6.1
Misc. Income	6.1	0.1
Total Ordinary Income	3,777.5	34.7
Ordinary Expenses		
Operating Expenses	3,629.3	33.3
Management Expenses	148.2	1.4
Total Ordinary Expenses	3,777.5	34.7

Change in Designated Net Assets (in millions)	JPY	USD
Grants Received and Others		
Governments, NGOs, Multilateral Organizations	3,415.5	31.4
Foundations	875.3	8.0
Contributions Received	739.2	6.8
Total Grants and Contributions Received	5,030.0	46.2

Full Partners

Associate Partners

Affiliate Partners

Sponsors

Leadership

Council

The Council consists of the Japanese government, various foundations, and private companies that provide funding to GHIT. The Council resolves important matters as provided by applicable laws and regulations or the Articles of Incorporation, including appointment and dismissal of members of the Council and the Board of Directors, amendment of the Articles of Incorporation, and approval of financial statements.

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

Yasuyuki Sahara, MD, MPH
Senior Assistant Minister for Global Health
Minister's Secretariat
Ministry of Health, Labour and Welfare

Trevor Mundel, MD, PhD
President, Global Health
Bill & Melinda Gates Foundation

Jeremy Farrar, MD, PhD, FRCP
Director
Wellcome

Astellas Pharma Inc.
Yoshihiko Hatanaka
Representative Director
Chairman of the Board

Chugai Pharmaceutical Co., Ltd.
Tatsuro Kosaka
Representative Director
Chairman and CEO

Daiichi Sankyo Company, Limited
George Nakayama
Representative Director and Chairman

Eisai Co., Ltd.
Haruo Naito
Representative Corporate Officer and CEO

Shionogi & Co., Ltd.
Isao Teshirogi, PhD
President and CEO

Takeda Pharmaceutical Company Limited
Christophe Weber
Representative Director
President and CEO

Board of Directors

The Board of Directors consists of global health experts and management professionals. In addition to overseeing operations by the Leadership Team, it also resolves important business matters, including approval of major rules, strategic plans, annual operational plans/budget, and funding decisions based on recommendations from the Selection Committee.

Chair & Representative Director
Hiroki Nakatani, MD, PhD, MHPEd
Project Professor
Global Research Institute
Keio University

Vice Chair
Peter Piot, MD, PhD
Director and Professor of Global Health
London School of Hygiene and Tropical Medicine
Former Executive Director, UNAIDS

Executive Director
Catherine K. Ohura, MS, PMP
CEO, GHIT Fund

Mahima Datla
Managing Director
Biological E. Limited

Daikichi Momma
Former Director-General, International Bureau
Ministry of Finance
Former Executive Director
International Monetary Fund representing Japan

Manabu Sumi, MD, PhD, MPH
Director, Global Health Policy Division
International Cooperation Bureau
Ministry of Foreign Affairs

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

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
Ko-Yung Tung, JD
Lecturer on Law, Harvard Law School,
Former Senior Vice President
and General Counsel, World Bank

Ex-Officio
Stephen Caddick, PhD
Professor, University College London
Former Director of Innovations Division
Wellcome

Ex-Officio
Andrin Oswald, MD
Director, Life Sciences Partnerships
Bill & Melinda Gates Foundation

Selection Committee

The Selection Committee consists of domestic and international experts who have extensive knowledge and experience in research and development of drugs, vaccines, and diagnostics. This committee evaluates investment proposals and reports from development partners and recommends investments to the Board of Directors. This committee includes no private company representatives to avoid any conflict of interest between our backers and development partners.

Co-Chair
Dennis Schmatz, PhD
Former Head, Infectious Diseases Research
Merck Research Labs, USA
Former Head, Research, MSD-Japan

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

Ann Mills-Duggan, PhD
Head, Seeding Drug Discovery Fund
Business Development, Innovations
Wellcome

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

Ken Ishii, MD, PhD
Professor, Institute of Medical Science
University of Tokyo
Professor, the Laboratory of Vaccine Science
at the Immunology Frontier Research Center
(IFReC), Osaka University

Kiyoshi Kita, PhD
Professor Emeritus, The University of Tokyo
Professor and Dean, Nagasaki University School
of Tropical Medicine and Global Health

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

Gerd Michel, PhD
Chief Scientific Officer
Vela Diagnostics

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 is responsible for the design and development of business and investment strategies and, upon Board approval, the execution of strategies, administrative operations, and organizational growth of GHIT.

Catherine K. Ohura, MS, PMP
CEO

Kio Yamabe, MBA
Chief Operating Officer

Daisuke Imoto, MBA
Vice President
External Affairs & Corporate Development

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

Nozomi Nakade
Senior Manager, CEO Office

Miho Takazawa, MBA
Senior Director, Finance & Operations

Bumpei Tamamura, MPH
Senior Director, Brand Communications

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

As of March 31, 2020

Acknowledgement

External Reviewers

The GHIT community's work could not progress without the vital support of these experts and their institutions.

Yukihiro Akeda
Pedro Alonso
Peter Andersen
Rip Ballou
Lewellys Barker
Michael Barrett
Clif Barry
David Bell
Marleen Boelaert
Maria Elena Bottazzi
Tom Brewer
Martin Brusdeilins
Simon Campbell
Eric Chatelain
Philip Cole
Stewart Cole
Simon Croft
Roy Curtiss
Peter Dailey
Julian Davies
Christine Debouck
Thierry Diagana
Thomas Dick
Carter Diggs
Boro Dropulic
Filip Dubovsky
David Edwards
Sabine Ehrt
Hiroyoshi Endo
Alan Fairlamb
Hermann Feldmeier
David Fidock
JoAnne Flynn
Michael Free
Takashi Fujitsu
Tamio Fujiwara
Jennifer Gardiner
Nisha Garg
Ricardo Gazzinelli
Ann Ginsberg
Daniel Goldberg
Federico Gomez de las Heras
Glenda Gray
Brian Greenwood
Sanjay Gurunathan
R. Kiplin Guy
Lee Hall
Yoshihisa Hashiguchi
Thomas Hawn
Chris Hentschel
D. Gray Heppner
Philip Hill
Toshihiro Horii
Sanjay Jain
Takushi Kaneko
Niranjan Kanesa-thasan
Shigeyuki Kano
Subhash Kapre
Paul Kaye
Naoto Keicho
David Kelso
Kent Kester
Akinori Kimura
Sue Kinn
Harajeshwar Kohli
Somei Kojima
Peter Kremsner
Sanjeev Krishna
Michael Kurilla
Dennis Kyle
Nancy Le Cam Bouveret
James LeDuc
Carole Long
Timothy Lu
Christian Mandl
John Mansfield
Greg Matlashewski
James McCarthy
Joseph McCune
James McKerrow
Charles Mgone
Gerd Michel
Toshiyuki Miura
Valerie Mizrahi
Katsuhiko Mochizuki
Kouichi Morita
Charles Mowbray
Peter Myler
Daniel Neafsey
Christian Ockenhouse
Tsuyoshi Ogiku
Giuseppe Pantaleo
David Persing
Meg Phillips
Punnee Pitisuttithum
David Pompliano
Dominick Pucci
Regina Rabinovich
Rino Rappuoli
Zarifah Reed
Rebecca Richards Kortum
Paul Roepe
Eric Rubin
Peter Ruminski
Philip Russell
David Sacks
Judy Sakanari
Dirk Schnappinger
Ami Shah Brown
George Siber
KJ Singh
Peter Smith
David Soane
Lynn Soong
Gerald Spaeth
Nathalie Strub-Wourgaft
atlas support
Yasuhiko Suzuki
Marcel Tanner
John Telford
Kaoru Terashima
Katsushi Tokunaga
Nadia Tourniporth
Bruno Travi
Takafumi Tsuboi
Moriya Tsuji
Mickey Urdea
Stephen Ward
Tim Wells
Bruce Weniger
George Whitesides
Samuel Wickline
Judith Wilber
Elizabeth Winzeler
Dyann Wirth
Michael Witty
Paul Wyatt
Kazuhisa Yoshimura
Takeshi Yura
Fidel Zavala
Donato Zipeto

Funding Partners & Sponsors

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

Full Partners

外務省 MOFA Japan
厚生労働省 Ministry of Health, Labour and Welfare
UNDP
Bill & Melinda Gates foundation
wellcome
astellas
CHUGAI Roche Roche Group
Daiichi-Sankyo
Eisai
SHIONOGI
Takeda

Associate Partners

FUJIFILM
Otsuka
sysmex

Affiliate Partners

gsk
Johnson&Johnson
KYOWA KIRIN
MERCK
Mitsubishi Tanabe Pharma
ono
Sumitomo Dainippon Pharma

Sponsors

ANA
burson cohn & wolfe bcw
MORI
MORRISON FOERSTER
salesforce
YAHOO! JAPAN

GHIT 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
www.ghitfund.org