



GHIT Fund

ANNUAL REPORT

2020

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## Message from CEO and Chair

# Resilience and Partnership During an Unparalleled Year

Covid-19 has drawn unprecedented global attention to the value of innovation for life-threatening infectious diseases. The extraordinary speed of pandemic product development over the past year demonstrates the innovation and scale that is possible when stakeholders are incentivized to collaborate meaningfully, despite enormous challenges in their path. We at GHIT are committed to leveraging the power of this potential for R&D for neglected diseases. Over the past year, our development partners across the globe have demonstrated incredible tenacity, creativity, and grit in the face of global challenges. Our employees, too, have reimaged collaboration and efficiency in a new remote working environment, and we are proud of their unwavering enthusiasm and dedication.

We recognize that it is GHIT's duty to double down on our commitment to innovation in service to the communities that grapple daily with the threat and consequences of neglected diseases, and which are experiencing even more strain as a result of the pandemic. We know our partners and stakeholders share our steadfast commitment to continue to be a source of hope, inspiration, and collaboration in the fight against neglected diseases.

### R&D: Keeping our foot on the pedal

In the midst of the COVID-19 crisis, product development for malaria, tuberculosis (TB), and neglected tropical diseases (NTDs) has remained our – and our partners' – crucial priority. While we spent much of the year online, we sustained our performance and improved the way we work. We hosted two online Selection Committee (SC) meetings to identify investment recommendations to the Board for approval. Applicants joined SC members for remote interviews across multiple time zones. External reviewers continued to tirelessly evaluate proposals, helping ensure our ability to invest in critical innovation without pause. We are grateful for everyone's strong commitment and generous support and would like to emphasize that they made our continuous investment possible.

This year, GHIT invested USD 41.6 million in 22 innovative projects, which further strengthens our pipeline and provides new hope for patients and healthcare professionals in low-and middle-income countries. We successfully expanded our portfolio, especially innovative point-of-care diagnostics tools. Even in this difficult time, 15 new partners have joined us to accelerate R&D for neglected diseases. As of March 2021, our aggregate investments to date total USD 251 million in 101 projects. Our current portfolio features 23 discovery projects, 22 preclinical projects, and 7 clinical trials including 2 diagnostics field validation studies are in our portfolio (p.5-6). The World Health Organization (WHO)'s endorsement and/or approval from a stringent regulatory authority of our most advanced clinical candidates, including a urine-based rapid TB diagnostic kit and a pediatric formulation of the gold-standard drug for schistosomiasis, are in sight. At the same time, we are actively discussing access and delivery strategies for late-stage clinical candidates with our development partners to ensure patients and healthcare professionals have access to innovative tools (p.7-8).

Notably, SILVAMP™ TBLAM's proprietary silver amplification immunochromatography (a platform technology developed by Fujifilm), was repurposed for the development of an antigen test kit for SARS-CoV-2 diagnosis. While GHIT does not invest in product development for COVID-19, this is a remarkable example of how GHIT-invested innovation can also be utilized beyond its initial critical scope - for other infectious diseases and how peacetime investments in innovative technologies and scientific advancement prepares the globe against future threats.

### Access & Delivery: Knowledge products

In 2020, our Uniting Efforts for Innovation, Access & Delivery (Uniting Efforts) partnership with the Government of Japan and United Nations Development Programme (UNDP)-led Access and Delivery Partnership (ADP)





published two reports (p.19-20). The first, “Landscape of funding and financing opportunities for access and delivery of health technologies for neglected diseases” summarizes existing strategies to fund and finance access and delivery of health technologies for malaria, TB, and NTDs, opportunities to augment funding, and proposals to improve investment efficiency. The second report is the “GUIDANCE NOTE for the development of national investment cases for neglected diseases”, which inform national governments consider on the value of developing investment cases to improve access and delivery of health technologies for neglected diseases and support implementation of national programmes.

#### Strategic Plan 2.0 and beyond

In the midst (third year) of our second five-year operational plan (FY 2018-2022), we are steadily approaching our goals of GHIT’s Strategic Plan 2.0. Despite the impact of the COVID-19 pandemic, GHIT and our partners have progressed steadily through R&D milestones and are focused on meeting our original targets (p.17-18). Beyond our strategic targets, these efforts represent the foundation for GHIT 3.0 (FY 2023-2027), which will enable the candidates in our current portfolio to flourish further.

#### Professor. Kiyoshi Kita steps down from the SC

This year also marks the final year of Professor. Kiyoshi Kita’s expert service to and leadership of GHIT’s SC. As founding chair, Dr. Kita played a major role in establishing

the rigorous standards and due diligence that have guided the SC for the past eight years. Please take a moment to reflect on his important legacy and read about his passion for global health in our interview with him (p.21-22).

#### Looking forward, with gratitude

As we continue to mobilize our network, knowledge, and experience in ever more creative and flexible ways to advance progress and ensure continuity, we are deeply honored by the partnership, solidarity, and support of our stakeholders. We are more inspired than ever to push harder, further, and with compassion toward our common goals, #Together.



  
Catherine Kaseri Ohura  
CEO and Executive Director



中谷 比呂樹  
Hiroki Nakatani  
Board Chair & Representative Director

# GHIT Fund Portfolio

## Discovery

## Preclinical

Drugs / Vaccines

Target Research

Screening

Hit-to-Lead

Lead Optimization

Diagnostics

Target Research

Product Design



NTDs

Buruli ulcer



Chagas disease



Mycetoma



Chagas disease, Leishmaniasis



Chagas disease, Leishmaniasis



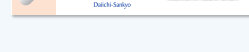
Chagas disease



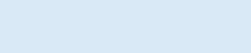
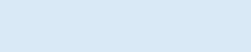
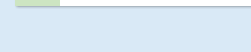
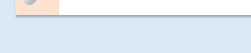
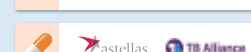
Leishmaniasis



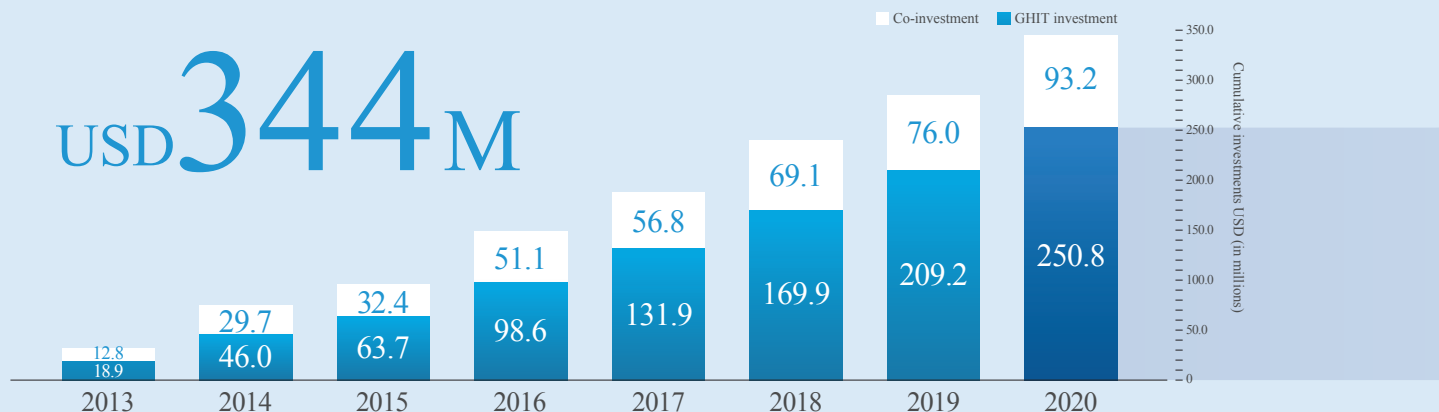
Malaria



Tuberculosis



USD 344M



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

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



Drug



Vaccine

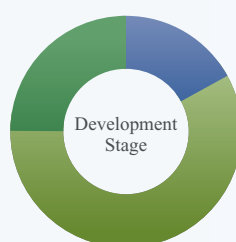
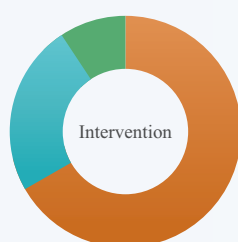
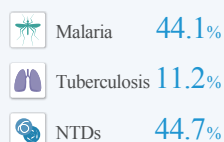
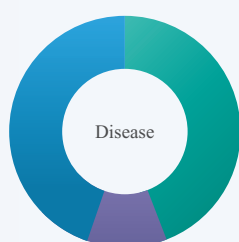


Diagnostics

## 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>Leishmaniasis</b></p> <p><b>Lymphatic filariasis, Onchocerciasis</b></p> <p><b>Soil-transmitted helminths</b></p>	<p><b>Cutaneous leishmaniasis</b></p> <p><b>Schistosomiasis</b></p>	<p><b>Mycetoma</b></p>	<p><b>Schistosomiasis</b></p>	

## Investment Overview FY 2013-2020



**101**  
Total invested partnerships  
52 Active investments  
49 Completed investments

**143**  
Total product development partners  
52 Japanese partners  
91 Non-Japanese partners

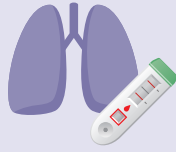
**FY 2020**  
**USD 41.6M**  
Total investments

**22**  
Invested partnerships

**5**  
New Japanese partners

**10**  
New non-Japanese partners

# SILVAMP™ TBLAM



**FUJIFILM**

**FIND**

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

Disease:

Tuberculosis

Intervention:

Diagnostics

Development Stage:

Field Validation

Country:

South Africa, Malawi, Zambia, Tanzania, Uganda, Vietnam, Thailand



TB infects 10 million people and causes almost 1.5 million deaths every year. Projections show that the COVID-19 pandemic's disruption of just three months of TB service in high-burden countries will result in an additional 1.3 million new cases and more deaths every year for the next five years. Of the 10 million estimated people with TB every year, almost three million (30%) are missed and one of the reasons for this is underdiagnosis. Current diagnostics rely on sputum, are time-consuming, and require trained laboratory personnel. Moreover, sputum samples are not always easy to get, for example in such some patient groups like children and people with severe HIV infection. In some cases of extra-pulmonary TB, using sputum might be inappropriate. There are currently no reliable, accurate, point-of-care and rapid diagnostic tests (RDT) that can be used in remote settings. The only RDT available has just 35% sensitivity and can only be used in a small proportion of people who might benefit from such a test: HIV-positive, severely sick, and/or with very low CD4 cells.

In response, Fujifilm and FIND have developed a diagnostic assay with high sensitivity and specificity in HIV-positive patients using Fujifilm's proprietary silver amplification technology to detect LAM (Lipoarabinomannan) in urine. LAM is a glycolipid found in mycobacterial cell wall and can be detected in urine in patients with disseminated TB, particularly in severe

immunocompromized states. Despite the disruptions to the field studies due to COVID-19, this project is currently in the field validation prospective study phase in South Africa, Malawi, Zambia, Tanzania, Uganda, Vietnam and Thailand.

Additional studies being conducted by other partners such as Médecins Sans Frontiers, McGill University, and KNCV, are under way. More data is also expected from multiple independent studies led by Fujifilm with expected completion by Q3-2021, with targeted WHO Guideline Development Group (GDG) review and

launch in early 2022. The prospective field studies are critical in providing evidence on assay sensitivity and specificity, as well as stability and ease-of-use in the real-life context which is critical for the evaluation by the WHO GDG. WHO GDG endorsement is an important step forward the technology's inclusion in WHO and National TB diagnostic guidelines and to facilitate procurement. Preliminary analysis based on retrospective testing has shown that the assay has almost double the sensitivity of the current LAM test available on the market. Although more research is still required, the test has also shown some promising results in HIV-positive people with higher CD4 counts, and even in some HIV-negative people, which could revolutionise point-of-care diagnosis for TB.

Fujifilm and FIND, with GHIT support, have now started working on a comprehensive launch plan covering regulatory process, manufacturing, procurement and supply. The COVID-19 pandemic has caused disruptions to services and modelling studies have shown that there will be at least 1.3 million TB cases resulting from pandemic-related service disruption increase the urgency to bring this technology to scale. To that end, Fujifilm has invested in technology transfer to a manufacturing plant in Vietnam that would facilitate volume manufacturing, which would significantly impact assay pricing and affordability.



# Pediatric PZQ



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

Schistosomiasis is a parasitic disease affecting more than 200 million people worldwide every year, 28 million of them children. It is mostly prevalent in sub-Saharan Africa and carries a significant public health burden and economic impact. Praziquantel is the current ‘standard of care’ treatment. The drug is safe, effective, and available for adults and school-aged children. However, the current tablets are too big for smaller children, especially those under the age of 6 (preschool age). Healthcare workers and caregivers must often crush the tablets, which is impractical in a mass drug administration (MDA) context. Crushing the tablets also brings out the bitter taste of the medication making it unpalatable for preschool-aged children, leaving this very vulnerable group of preschool-aged children untreated in public health programs, primarily due to the lack of an appropriate, child-friendly formulation of the drug.

The Pediatric Praziquantel Consortium is developing a child-friendly formulation of the drug, adapted for preschool-age children up through the age of 6 years old. The newly created tablet using Astellas’s formulation technology is smaller, taste-masked, orally dispersible meaning it can be taken with little or no water. The Consortium is conducting a clinical trial, now in Phase III, assessing the new formulation’s safety and effectiveness of the new formulation in Kenya and Côte d’Ivoire

The start of the COVID-19 pandemic brought significant disruptions of the clinical studies, setting back the pivotal Phase III clinical studies by several months and leading to the termination of a supportive trial that was being set-up in Zimbabwe. However, despite these challenges the trial resumed and is expected to conclude in Q3 2021, followed by EMA regulatory assessment (Article 58) and WHO endorsement anticipated by the end of 2023.

The Consortium has also launched an Implementation Research Project, ADOPT, at



Swiss TPH



MERCK



lygature  
pioneering medicine  
together.

SCI  
Schistosomiasis  
Control Initiative



Disease:

Schistosomiasis

Intervention:

Pediatric Drug

Development Stage:

Phase III,  
Registration, Access

Country:

Côte d’Ivoire, Kenya

the beginning of 2021, to assess and pilot different models of care for treatment implementation. The goal: to identify approaches for social mobilization and ensure wide acceptance and equitable access. The five-year program is co-funded by the GHIT and the European & Developing Countries Clinical Trials Partnership (EDCTP), each providing €2.1 million and €5.7 million respectively. A dosing and administration landscape analysis to assess community acceptability, operational aspects and practices of orally administered drugs in preschool-aged children, is also planned for 2021. Both the ADOPT program and the dosing and administration landscape analysis will inform the development of WHO and national guidelines, as well as preparation for the registration and access and delivery scale up of the new pediatric medication in endemic countries.

The Consortium has made significant progress on the launch preparations, particularly with GHIT support for further refinement of access and delivery strategies in preparation for launch. Merck KGaA, which will hold the marketing authorization for the pediatric praziquantel, is in advanced stages of discussions with a manufacturer in Africa for a technology transfer deal that would ensure a sustainable procurement and supply system.



# Clinical Candidates

## From Phase I to Phase II

### SJ733



Disease: **Malaria**

Intervention: **Drug**

Development Stage: **Phase II**

Country: **Peru**



SJ733 is a PfATP4 inhibitor that meets criteria for treatment of uncomplicated malaria. Phase I human data shows an excellent safety profile and tolerability, good oral availability, and moderate clearance. The project team has initiated an adaptive open label Phase IIa study in Peru to examine the antimalarial efficacy, safety, and tolerability of SJ733 in adult patients with uncomplicated *P. vivax* or *P. falciparum* blood-stage malaria mono-infection. SJ733 will be administered orally once every day for three consecutive days, with or without a fixed dose of the pharmacoenhancer cobicistat. The beginning of recruitment was delayed due to the COVID-19 pandemic, but officially opened in March 2021 and the first three patients enrolled have completed all doses. There are three cohorts with each cohort containing two treatment arms, *P. falciparum* (a) and *P. vivax* (b) and they will enroll max 60 patients. Cohort progression will be managed independently for each treatment arm. Interim analysis will determine whether the data for a given treatment arm meets the success criteria, is inconclusive, or meets the failure criteria. Antimalarial efficacy will be examined over the period of 42 days. Additional aims are to characterize the safety and pharmacokinetics of SJ733. The results of this trial will identify active, well-tolerated doses for investigation in a larger Phase IIb clinical trial.

### BK-SE36/CpG & NPC-SE36/CpG



Disease: **Malaria**

Intervention: **Vaccine**

Development Stage: **Phase Ib**

Country: **Burkina Faso**



SE36 is a blood-stage malaria vaccine candidate that primarily targets young children in endemic areas to reduce morbidity and mortality due to malaria. Though in principle all stages of parasite development are potential vaccine targets, the blood stage is the one that causes the symptoms of malaria and its complications, and thus has a significant public health impact. Early-stage clinical trials have demonstrated that the BK-SE36 vaccine (SE36 recombinant protein and aluminium hydroxide gel) has acceptable reactogenicity, no unexpected safety signals and was immunogenic. Vaccine responders experienced less malaria infection and have lower risk of developing clinical symptoms. A better immune response was achieved in Japanese adults when CpG-ODN (K3) adjuvant was added to the formulation. A Phase Ib trial to test safety and immunogenicity of BK-SE36/CpG in 1 year-old children to adults in Burkina Faso has recently completed its Last Subject Last Visit. Interim results indicate no unexpected safety concerns. Moving forward, new lots of SE36 and CpG (renamed NPC-SE36/CpG) are being manufactured for proof-of-concept studies. The aim is to show suitability of new SE36 vaccine GMP lot for clinical trials and importation. Preparations are under way for Phase IIb site selection and clinical trial design.

# CpG-D35

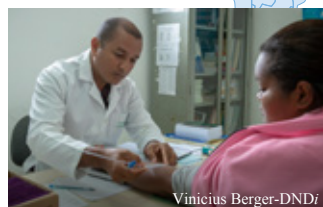
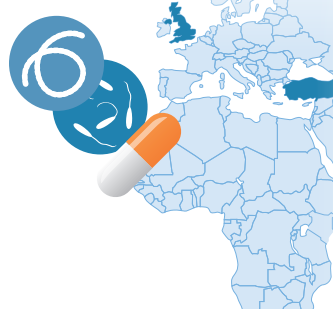


Disease: **Cutaneous leishmaniasis**

Intervention: **Drug**

Development Stage: **Phase I**

Country: **UK, Turkey**



Vinicius Berger-DNDi

Cutaneous leishmaniasis (CL), endemic in 87 countries worldwide, mainly affects poor populations in developing countries. Approximately 0.6 to 1.2 million new CL cases are estimated every year. While CL is not life-threatening, it is a disfiguring disease that results in stigma and economic loss. Currently, there are no satisfactory treatments for any form of CL. CpG-D35, as a combination therapy for the treatment of patients with CL, triggers the Toll-like receptor (TLR) 9 expressed on plasmacytoid dendritic cells and thereby activates the innate and adaptive immune system of the host. Data generated to date support the hypothesis that CpG-D35 alone or in combination with chemotherapy will reduce infection and accelerate the healing of CL lesions, as demonstrated in preclinical studies with CpG-D35. This project aims to; determine the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) after single subcutaneous dose of CpG-D35 in healthy volunteers, compared to matching placebo (SAD study) and after multiple doses administered in subjects infected with *L. major* parasites (MAD study); refine the current active pharmaceutical ingredient (API) manufacturing process to improve efficiency/overall quality of CpG-D35 substance; develop a more concentrated, affordable, and field-adapted subcutaneous dosage form for later-stage clinical trials; and further optimize the CAL-1 potency assay used for CpG-D35 quality control and stability testing.

# SCH-RDT

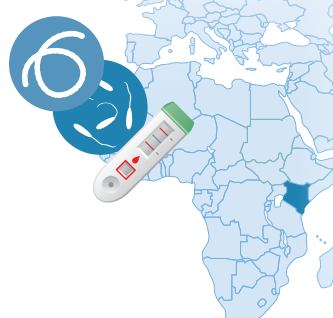


Disease: **Schistosomiasis**

Intervention: **Diagnostics**

Development Stage: **Product Development**

Country: **Kenya, Philippines**



The WHO's 2021-2030 roadmap calls for the elimination of Schistosomiasis (SCH) as a public health problem by 2030. In order to reach this target, the report explicitly highlights the importance of developing necessary diagnostic tests, including standardized point-of-care diagnostics for effective MDA campaigns and continued micro-mapping. Current WHO guidelines for the diagnosis of SCH recommend examination of stool and/or urine samples by microscopy, for the presence of schistosome eggs. Whilst these tests are useful in settings with moderate- to high-intensity infections, they become futile in settings where prevalence and intensity are low, due to their poor sensitivity. Sampling is repeated on multiple days and several slides are examined by trained microscopists, rendering the methods time-consuming and challenging to deploy. To address this challenge, partners are developing an easy-to-use, accurate and affordable SCH-RDT with a sensitivity comparable to repeated microscopy that detects the circulating anodic antigen (CAA), an antigen that is secreted continuously by living schistosomes. The results of the test will be obtained within 20 minutes. This project aims to; conduct field evaluations on semi-quantitative prototype SCH RDT; optimize the RDT, design-lock and transfer to manufacturing; validate the performance of the RDT in the detection of the major schistosome species, and determine its suitability as a replacement of current microscopy-based diagnostic tests; and develop an access strategy for the SCH RDT. The program's R&D work is co-funded by Bill & Melinda Gates Foundation to further characterize and validate CAA for *s.haematobium* and *s.japonicum*.



# E1224



Disease: **Mycetoma**

Intervention: **Drug**

Development Stage: **Phase II**

Country: **Sudan**



Mycetoma is a debilitating fungal or bacterial infection that leads to disfigurement, disability, and social stigma. The disease is mainly found in tropical and subtropical regions of the world, including in Chad, India, Mali, Mauritania, Mexico, Senegal, and Sudan. However, there is extremely limited data on the prevalence and incidence of the disease. Diagnosis requires a combination of clinical, imaging, histology, and molecular testing (if available) procedures. Low- and middle- income countries (LMIC) often lack access to these diagnostic tools and/or the skilled expertise needed to conduct the procedures. Additionally, no simple, rapid point-of-care diagnostic tools exist. Current treatment for eumycetoma (fungal) is itraconazole which has a limited cure rate (26%), long treatment duration, and is expensive for resource-limited settings. If not treated, in extreme cases it can lead to amputation or death. Eisai and the Drugs for Neglected Diseases *initiative* (DNDi) are conducting a Phase II trial to determine whether Fosravuconazole (or E1224), an azole-class antifungal drug discovered by Eisai (and already approved for onychomycoses in Japan) may also be an effective and affordable treatment for mycetoma. The trial is being conducted in Sudan with the WHO Collaborating Center on Mycetoma in Khartoum. The study is on-going after a temporary disruption due to the COVID-19 pandemic.



# BENDITA Study



Disease: **Chagas disease**

Intervention: **Drug**

Development Stage: **Phase II**

Country: **Bolivia**



The Lancet Infectious Diseases study shows that a two-week treatment for adults with chronic Chagas disease has similar efficacy and significantly fewer adverse effects than the current standard eight-week treatment. This study provides some hope for people affected by this neglected disease: a shorter treatment would remove some common caregiver and patient concerns, as well as improve treatment adoption. These results are extracted from a Phase II clinical trial that was carried out in three centers in Bolivia between 2016 and 2018. The GHIT-invested study was led by the DNDi in partnership with CEADES (Science and Applied Studies Foundation for Health and Environment Development), ISGlobal, Eisai and the Argentinian pharmaceutical company Elea, among others. The BENDITA study (Benznidazole New Doses Improved Treatment & Therapeutic Associations) is the first placebo-controlled study to compare different durations and doses of treatment with the standard treatment benznidazole, alone or in combination with Fosravuconazole (or E1224) produced by Eisai.

*“The BENDITA study provides hope for people affected by this neglected disease, as a shorter treatment will remove some concerns of caregivers and patients and will improve treatment adoption.”*

Dr. Sergio Sosa Estani, Head of the Chagas Clinical Programme at DNDi and researcher at CONICET (National Scientific and Technical Research Council) in Argentina

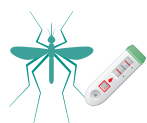
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# Invested Partnerships in FY 2020

## From Discovery to Preclinical



Malaria / Diagnostics

### Towards the rapid diagnosis of malaria hypnozoite infection: feasibility studies

Institute of Tropical Medicine, Nagasaki University (NU-ITM), National Institute of Technology, Kumamoto College (NIT-KC), Biomedical Primate Research Centre (BPRC)



Prof. Osamu Kaneko  
Nagasaki University



While clinical malaria cases in the Asia-Pacific and the Americas have gone down >90% in the last decade, a shift in malaria species composition has been observed, with *Plasmodium vivax* now being the predominant species outside Africa. This shift may relate to the unique biology of *P. vivax*, including the relapsing phenotype from dormant liver stages. Asymptomatic hypnozoite infections form a hidden parasite reservoir in the human population that can give rise to new symptomatic and transmissible malaria weeks, months or years after primary infection, without new infection through mosquito bites. Proper diagnostic tools to identify hypnozoite-infected individuals are currently lacking. Under

previous research, they pioneered an in vitro POC towards identifying targets for diagnostic tools for malaria hypnozoites, exploiting our unique experience in in vitro *P. cynomolgi* hypnozoite cultures, as well as in sensitive metabolomics. Specific metabolites have been identified and prioritized based on the unique signatures found in hypnozoite-enriched cultures. A second-phase in vivo feasibility study using the *P. cynomolgi*-rhesus monkey model is warranted to determine whether the specific signatures detected in the in vitro POC are confirmed in vivo and can thus be pursued in the subsequent development phase of a RDT for hypnozoite infection.



Malaria / Vaccine

### Evaluation of a malaria vaccine candidate comprised of full-length recombinant CSP formulated with SA-1 adjuvant, using RTS,S/AS01 as a benchmark

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



Dr. C. Richter King  
PATH



The world's first malaria vaccine, RTS,S/AS01, is a recombinant VLP containing truncated CSP as the target antigen and formulated with a TLR 4/QS21-containing adjuvant (AS01). In a large multi-center Phase III trial RTS,S/AS01 demonstrated a near 40% reduction in clinical malaria incidence in young African children, over four years of follow-up, and is currently undergoing pilot implementation in three African countries. A next generation malaria vaccine with improved efficacy and durability offers the potential for even greater public health impact. The project aims to rigorously test a novel vaccine candidate, fCSP/SA-1, comprised of a full-length recombinant CSP adjuvanted

with a novel TLR7 agonist, SA-1, for superiority to the RTS,S/AS01 benchmark vaccine, to inform whether to advance fCSP/SA-1 to preclinical development. The team will conduct two tests: first, how fCSP/SA-1, compares to fCSP/AS01, for induction of improved durability of antibody responses in non-human primate (NHP) model. NHPs are used as the test species because rodents do not adequately model the rapid decline of antibody titer observed with RTS,S/AS01 in humans. Second, testing will determine how the fCSP antigen compares to RTS,S, for induction of stronger protective efficacy in well qualified rodent challenge model.



Malaria / Drug

### Pioneering antisense oligonucleotides as long-acting malaria prophylactics

Eisai Co., Ltd., University of California, San Diego (UCSD)



Dr. Elizabeth Winzeler  
University of California, San Diego



Development of effective new liver-stage prophylactic agents is a priority for the antimalarial field. Antisense oligonucleotides (ASOs) are well-matched to this unmet need, offering the possibility of long-duration activity and benefiting from effective delivery to hepatocytes using well-established conjugation technology. Furthermore, ASOs are a platform technology that enable highly selective targeting of essential *Plasmodium* genes, with the potential to access previously undruggable targets and accelerate development of additional drugs following initial validation. Eisai has developed proprietary nucleic acid

technologies that enhance these advantageous properties. This project will undertake a rigorous investigation as a novel antimalarial strategy, with the goal of demonstrating in vivo proof-of-concept for ASOs as long-acting malaria prophylactics. Well-validated malaria target genes will be examined for tractability, and ASOs against the selected target will be optimized using high-throughput cell culture assays at UCSD and Eisai's nucleic acid technologies. High-potency optimized ASOs will be tested in a causal prophylaxis animal model to assess in vivo efficacy.





Malaria / Drug

## Prolyl tRNA Synthetase Inhibitors for New Antimalarials

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



Dr. Atsuko Ochida  
Takeda

Target Research Platform

Screening Platform

Hit-to-Lead Platform

Product Development Platform

Takeda and MMV are working on prolyl tRNA Synthetase (PRS) Inhibitors with the aim of identifying a potential new antimalarial drug. This PRS chemical series was directly repurposed from the Takeda portfolio. At the beginning of the collaboration between Takeda and MMV, screenings were performed at MMV testing centers against the liver, blood asexual and sexual stages of the malaria parasite. Data showed that the Takeda PRS chemical series has activity against both the asexual blood and liver stages of the Plasmodium lifecycle. The main objective of the project is

to transform PRS Inhibitors into lead series with proven in vivo efficacy in relevant animal disease models so as to identify at least one compound as an early lead molecule that meets the GHIT/MMV criteria for progression to lead optimization stage for prophylaxis. In this new phase the project team will perform medicinal chemistry activity to optimise the PRS chemical series in terms of drug metabolism and pharmacokinetics (DMPK) and physicochemical properties.



Malaria / Drug

## Hit-to-lead development of new antimalarial compounds from DDI library

The University of Tokyo, MMV



Prof. Tomoyoshi Nozaki  
University of Tokyo

Target Research Platform

Screening Platform

Hit-to-Lead Platform

Product Development Platform

The University of Tokyo and MMV collaborate to generate structurally optimized lead compounds effective against malaria parasites, based on the hit compounds they identified with GHIT support during 2018-2020. In the preceding project, the team identified a number of hits that kill the malaria parasites under micromolar concentrations, by phenotypic screening of 210,000 structurally defined compounds from the Drug Discovery Initiative, Japan. In the present project, partners will conduct structural optimization of the selected six series to develop new antimalarial leads. The project will

generate a few series of new compounds that kill malaria parasites by structural modifications of the initial hit series. The new compounds will be further tested for efficacy against both drug-sensitive and resistant malaria strains, as well as for in vitro safety. It will be also elucidated how the new compounds kill the parasites. Because malaria parasites are transmitted between humans and mosquitoes, the team will also evaluate what developmental stages of parasites the new compounds are efficacious to, e.g., parasites in the human liver, erythrocytes, mosquito gut, and the salivary gland.



Malaria / Vaccine

## First-In-Human Trial of the Pan-Malaria Transmission-Blocking Vaccine AnAPN1

Ajinomoto Bio-Pharma Services, GeneDesign (GeneDesign), CellFree Sciences Co. Ltd., Centre de Recherches Médicales de Lambaréné (CERMEL), University of Tübingen (UKT), The University of Florida



Dr. Rhoel Dinglasan  
University of Florida

Target Research Platform

Screening Platform

Hit-to-Lead Platform

Product Development Platform

The anopheline mosquito midgut-specific alanyl aminopeptidase N (AnAPN1) is a luminal midgut surface protein involved in blood meal digestion. At present, AnAPN1 is the only transmission-blocking vaccine (TBV) candidate, which blocks parasite transmission of *P. falciparum* and *P. vivax* in different *Anopheles* species. Working with a mosquito protein further reduces the risk that the parasite could develop resistance against the intervention, potentially allowing for a long-term use of the vaccine under elimination settings. AnAPN1 has been studied extensively in transmission-blocking experiments, where the protein induced very high titers in immunized animals. Because any TBV will require very high antibody titers within vaccinated individuals to be effective, development

of an optimized antigen to ensure transmission-blocking activity is essential. The optimized AnAPN1 immunogen, UF6b, has no purification tags, and when formulated with the GLA-LSQ adjuvant elicits potent transmission-blocking activity in mice and NHPs against natural *P. falciparum* strains. Partners envision that during the two-stage project they will complete preclinical manufacturing of UF6b and toxicology testing to obtain ethical approval for use of the vaccine and then enter directly into Phase IA/B clinical trials in Gabon. At the end points of the clinical trial, safety and dose will be confirmed. Antibodies obtained from immunized individuals will be fully evaluated using a set of functional, immunological, and biological assays.



Tuberculosis /  
Diagnostics

## Product Development of LFA platform for improving sensitivity of Point-of-Care assays for infectious disease with main focus on Tuberculosis

Asahi Kasei Corporation, Biopromic AB



Dr. Beston Hamasur  
Biopromic AB

Target Research Platform

Screening Platform

Hit-to-Lead Platform

Product Development Platform

The only available non-sputum TB test in the market has insufficient sensitivity to be used as a reliable diagnostics, especially in the non-HIV-infected TB population. The RDT co-developed by Asahi Kasei Corporation and Biopromic detects picogram amounts of the LAM TB biomarker in the TB patient urine, irrespective of HIV infection, in timely manner with high accuracy. The Asahi Kasei's and Biopromic's RDT test applies a novel proprietary technology regarding sample preparation and labeling particles that allows LAM TB biomarker detection at

lower picogram level, which is 100 times higher than the only test available in the market so far. The main objection is to validate the RDT which is currently developed by Asahi Kasei and Biopromic for diagnosis of tuberculosis in TB patients irrespective of HIV status and ensure that it meets WHO TPP criteria. Asahi Kasei's and Biopromic's RDT test will be evaluated by analysis of more than 1000 well-characterized clinical samples collected from South Africa and Uganda to determine test accuracy.



Buruli ulcer /  
Diagnostics

## Development of 'all-in-one' diagnostic kit for Buruli ulcer using lateral flow DNA-chromatography

Teikyo University, Keio University School of Medicine, Tohoku Bio-Array (TBA) Co., Ltd, Nagasaki University, FASMAC CO., LTD, Raoul Follereau Institute Côte d'Ivoire, Pasteur Institute Côte d'Ivoire, Hope Commission International



Prof. Koichi Suzuki  
Teikyo University

Target Research Platform

Screening Platform

Hit-to-Lead Platform

Product Development Platform

No point-of-care diagnostic method for the tropical NTD Buruli ulcer (BU), which results in delayed diagnosis and treatment. Many patients must live with serious sequelae. In addition to insufficient diagnostic resources, the low number of new BU cases reported to the WHO (about 2,000 per year) is due to the fact that the disease is not widely known and often goes unrecognized. In many cases patients are left without proper diagnosis, and in some cases inappropriate treatment. PCR, currently the only diagnostic method recommended by WHO,

requires a specialized laboratory with expensive equipment and technologists with a high level of knowledge and skills (unrealistic in many LMIC settings). This project aims to develop the first point-of-care diagnostic kit for BU by combining techniques for stably fixing and drying reagents, performing DNA amplification without a special device, and DNA chromatography that allows easy visual detection of its detection. The method is simple and requires no special equipment or technology, and the kit can be stored at room temperature for a long period of time.



Chagas disease / Drug

## Target validation and AI-guided identification of trypanosoma cruzi phosphodiesterase inhibitors for the treatment of Chagas disease.

Eisai Co., Ltd., Universidad Nacional de La Plata (UNLP)



Dr. Fabian Gusovsky  
Eisai

Target Research Platform

Screening Platform

Hit-to-Lead Platform

Product Development Platform

There is an urgent need for new treatments for Chagas disease. Existing medications lack effectiveness against chronic infection, require long regimens, and have several adverse effects. Given their integral roles in trypanosome signaling and low homology with human counterparts, phosphodiesterases (PDEs) have been posited as drug targets for Chagas disease. Given the paucity of identified targets and critical need for new mechanism-of-action drugs, these enzymes merit definitive evaluation followed by efficient identification and development of inhibitors. This project aims to validate PDEs as drug

targets for Chagas disease using CRISPR/Cas9 technology and identify selective inhibitors using a computationally-enhanced screening cascade. Candidate inhibitors identified in machine-learning-based virtual screens will be profiled experimentally, with promising compounds advanced to animal studies. An accelerated drug development path will be sought by focusing on repurposing opportunities that can be rapidly progressed to clinical trials, complemented by screening for new chemical matter from Eisai's compound library.



Soil-transmitted  
helminth / Drug

## Cry5B optimization for Trichuris - whipworm

Kao Corporation, PATH, University of Massachusetts Medical School



Dr. Manjari Lal  
PATH

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

The last new drug to treat soil-transmitted helminth (STH) infections was introduced more than 30 years ago. Increasing resistance threatens the efficacy of the drugs most widely used in MDA campaigns against STH infections and has already rendered some nicotinic agents, such as levamisole, largely ineffective in the treatment of livestock with parasitic nematodes. A significant gap in the profile of all of the currently approved anthelmintic drugs is that they are contraindicated for women in their first trimester of pregnancy, which leaves the mother and her fetus vulnerable to the effects of STH-induced anemia and malnutrition, and out of reach

of a therapeutic intervention. As a non-absorbed therapeutic agent that binds to a target known only in invertebrates, Cry5B is expected to have an excellent safety profile for all patients, including pregnant women and young children. Cry5B would be an inexpensive and potent addition to the therapeutic options for managing STH infections and can form part of a combination therapy with existing drugs. It acts synergistically with some nicotinic agents, and resistance to these can make STH hypersensitive to Cry5B.



Chagas disease, Visceral  
leishmaniasis / Drug

## Hit-to-Lead development for NTDs

Mitsubishi Tanabe Pharma Corporation, DNDi



Dr. Jean-Robert Ioset  
DNDi

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

Drug discovery and development at the early hit to lead stage for Chagas disease and visceral leishmaniasis (VL) is prone to a relatively high chance of failure. The objective of this project is to identify at least one series that meets DNDi lead stage criteria for Chagas disease and/or visceral leishmaniasis in line with DNDi published Target Product Profiles (TPPs) for new chemical entities. A critical mass of novel chemical series therefore needs to be identified and progressed beyond Hit-to-Lead to build up a solid portfolio of preclinical candidates aligned with the DNDi TPPs for Chagas disease and VL. Mitsubishi Tanabe and DNDi have been

closely collaborating since September 2019 on a GHIT-funded screening project, which has successfully identified nine series mainly active against *T. cruzi* although a couple of them display dual *T. cruzi* and *Leishmania donovani* activities. Three *T. cruzi* active series have been prioritized. All series are novel to DNDi discovery programs and satisfy all criteria set by the GHIT and DNDi, resulting in successful progression into the Hit-to-Lead stage. Medicinal chemistry efforts will be carried out in priority on the three most promising series.



Visceral leishmaniasis  
/ Drug

## Lead optimization and preclinical candidate selection from the NTD Drug Discovery Booster series S07 for VL

Takeda Pharmaceutical Company Ltd., DNDi



Dr. Eric Chatelain  
DNDi

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

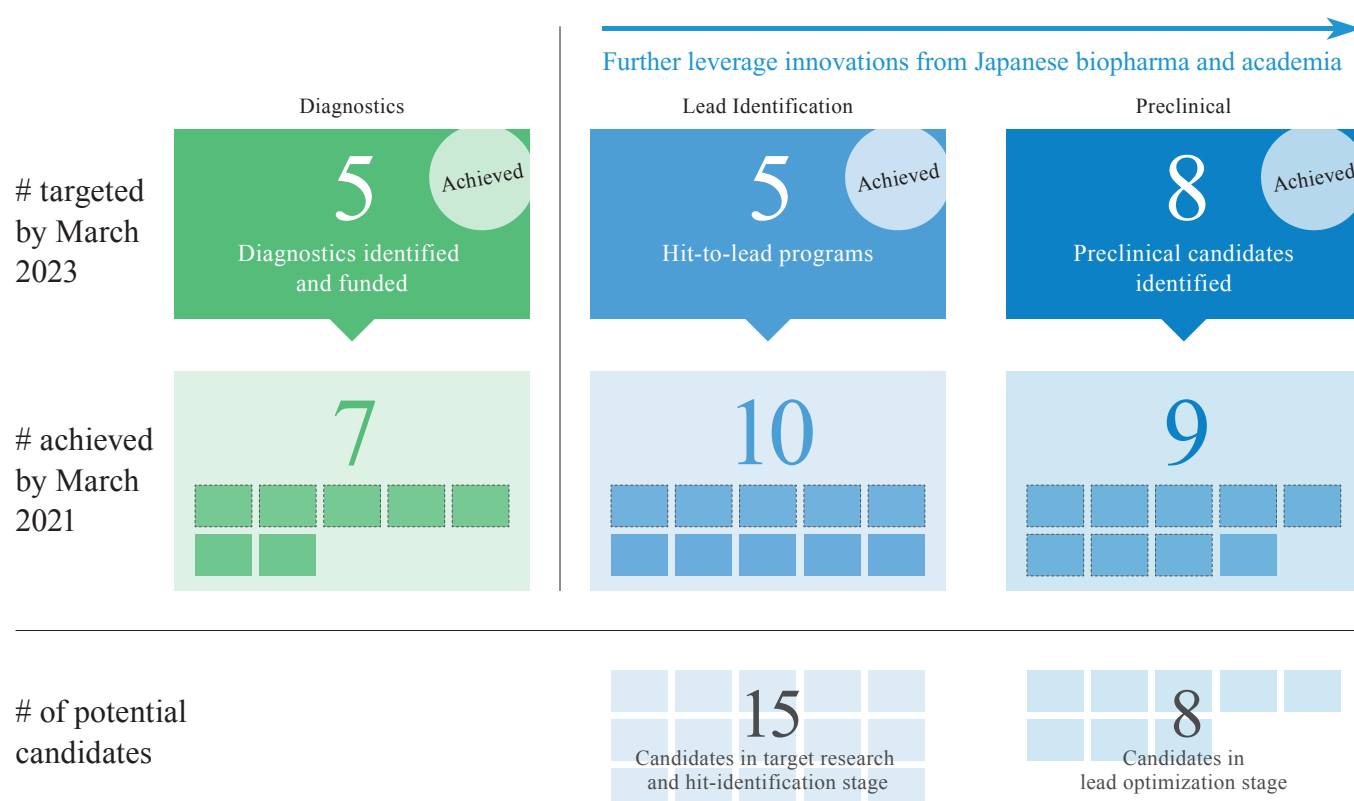
This project originates from a successful collaboration between Takeda and DNDi through the GHIT-funded NTD Drug Discovery Booster program, whose unique approach to identification and progression of novel compounds as inhibitors of protozoan parasites has ultimately led to the development of compounds with candidate-level efficacy in animal models of VL. Lead compounds in the series S07 with good efficacy and safety profiling have been identified and progressed in partnership with Takeda. Medicinal chemistry optimization around the identified leads and further development plans have been prepared to

support progression of at least one optimized lead to candidate status. The S07 series is synthetically tractable, the structure-activity- relationship is well-understood and extensive in vitro safety profiling has not highlighted any issues to date. The overall objective is to expand current selection of compounds meeting candidate level efficacy, investigate and determine PK/PD drivers for the S07 series, support compound development with preliminary CMC activities, and nominate one compound for preclinical development IND enabling studies.



# Strategic Plan FY 2018-2022 Progress

## R&D: Investments in Product Development



## Our actions in FY 2020 to advance innovations



### NTD scope expansion

- Expanded in-scope NTDs from 10 to 20 (all WHO-identified NTDs) in GHIT Product Development Platform
- Recruited and onboarded 30 new external reviewers (currently 150 in total)



### Partnership formation for new innovations

- Catalyzed partnerships between Japanese and non-Japanese entities through multiple consultations
- Conducted a proposal writing seminar and engaged in various scientific conferences



### Proactive portfolio management

- Monitored progress and identified risks for each project through semiannual progress report call

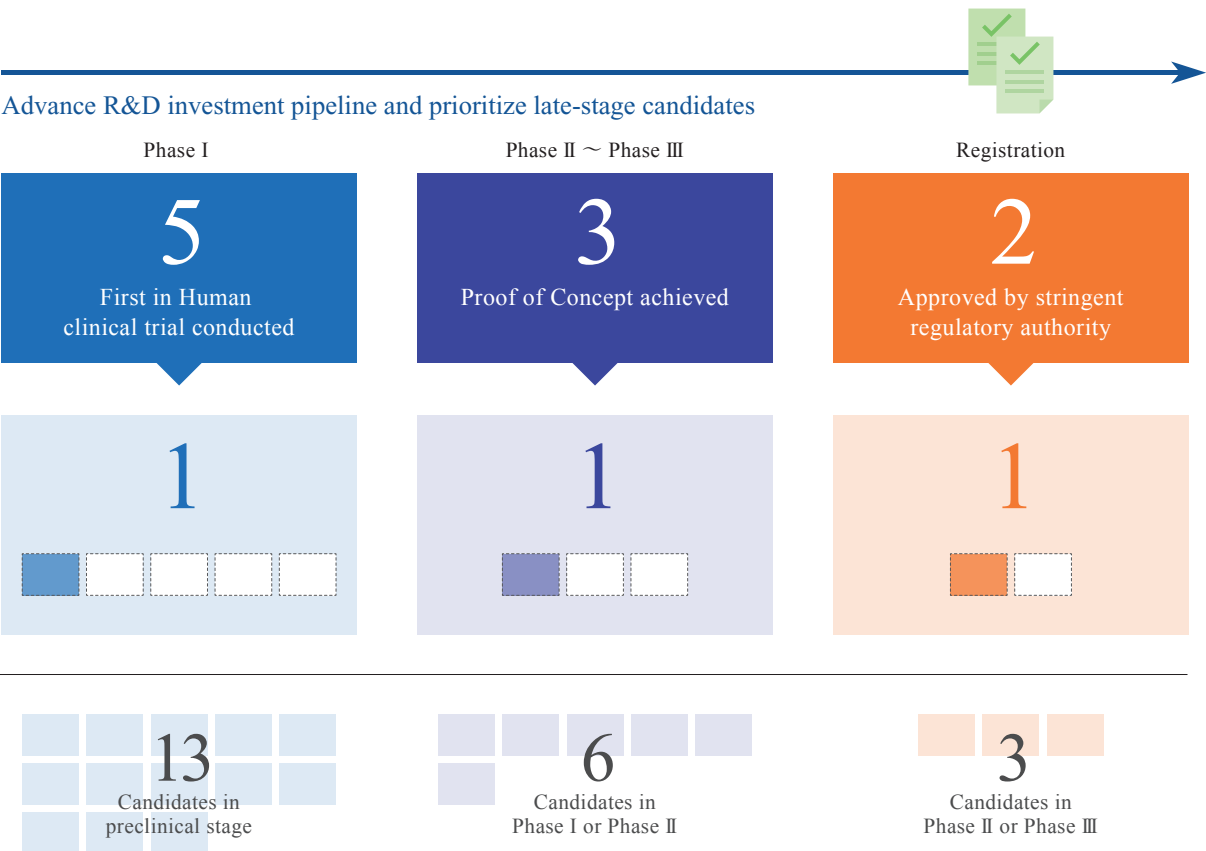


### Supplemental budget injection

- Provided supplemental emergency COVID-19 budget support for several projects



In GHIT 2.0’s third year, GHIT, we and our product development partners have progressed steadily toward key R&D milestones, despite the far-reaching impact of the pandemic. Additionally, we continued to identify and fund projects aligned with strategic goals without disruption, as summarized below.



As of March 31, 2021



*“Regular and ad-hoc calls with our development partners are the most important of our portfolio-management activities. They help us review our strategy and take the best measures to ensure we achieve R&D milestones together.”*

**Maki Kanesaka**

Associate Director, Investment Strategy, Portfolio Development and Innovations



*“Exploring untapped technologies, connecting R&D partners, and catalyzing new innovations for neglected patients are our fundamental roles in service to our strategic plan. This goes hand-in-hand with strengthening the global health R&D ecosystem’s R&D pipeline.”*

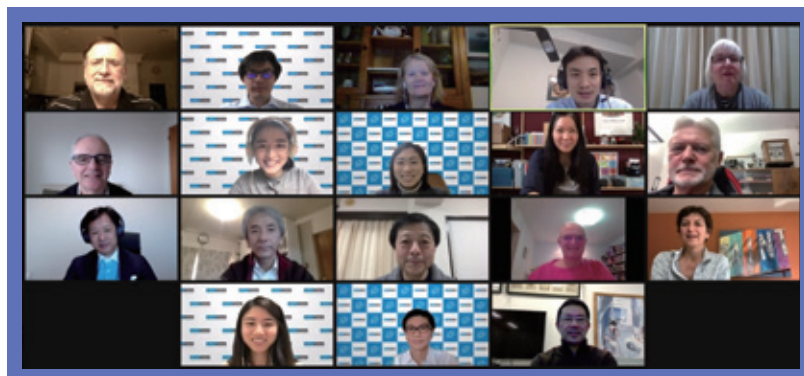
**Eriko Koyama**

Manager, Investment Strategy & Business Development

# Highlights in FY 2020

## Ensuring continuity and excellence

GHIT's first-ever virtual Selection Committee (SC) meeting took place in June 2020 due to travel restrictions during the COVID-19 pandemic. Incorporating the experiences and lessons learned in June, the second SC meeting took place in January 2021. SC members and invited applicants joined from over 20 countries across multiple time zones for interactive, in-depth interviews to inform SC investment recommendations to the Board. Improved operational efficiency made our meetings successful, embracing a new form of human connection while ensuring adherence to appropriate investment processes.



## Virtual proposal writing seminar

Our July 2020 online proposal writing seminar helped future development partners deepen their understanding of our proposal process and investment platforms. Participants from private companies, academia, and research institutions discussed the critical points to be considered and/or addressed when creating a proposal, with a special focus on GHIT's Target Research Platform and Product Development Platform. Past proposal writing seminar overviews are available on our website.

<https://www.ghitfund.org/newsroom/films/en>

## NTD webinar series

2020 marked the launch of the WHO NTD Roadmap 2030, which will serve as a key guiding document for the global response to NTDs over the next decade. In response to the global movement, GHIT partnered with the Japan Alliance on Global Neglected Tropical Diseases (JAGntd) to host a webinar series on NTDs focused on global trends and Japan's experience. During these webinars, Japanese experts on NTDs presented their programs and activities and discussed challenges and opportunities associated with the aim to eliminate NTDs by 2030. All archived webinars are available on JAGntd's website.

<https://jagntd.org/ntdwebinar2020>





## Publications

### Uniting Efforts knowledge products

The Uniting Efforts partnership between GHIT, the Government of Japan, and the UNDP-led ADP published two reports this year. “Landscape of funding and financing opportunities for access and delivery of health technologies for neglected diseases”, and “GUIDANCE NOTE for the development of national investment cases for neglected diseases” were designed to support national governments in their efforts to improve access and delivery of health technologies for neglected diseases and the implementation of national programs.

<https://www.uniteffortsforshealth.org/resources>



### Scientific article archive

More than 40 scientific articles have been published over the past eight years as a result of GHIT-funded research and clinical studies. Now available on our website, this growing archive of articles demonstrates our partners' important scientific accomplishments while illustrating the progress of GHIT's investments. Articles are authored by GHIT's product development partners and refer to projects that have been fully or partially funded by GHIT.

<https://www.ghitfund.org/newsroom/scientificarticles/jp>



### Publications with GHIT contributions

Hooft van Huijsduijnen R, Kojima S, Carter D, Okabe H, Sato A, Akahata W, Wells TNC, Katsuno K. Reassessing therapeutic antibodies for neglected and tropical diseases. *PLoS Negl Trop Dis*. 2020 Jan 30;14(1):e0007860. doi: 10.1371/journal.pntd.0007860. PMID: 31999695; PMCID: PMC6991954. <https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007860>

Katsuno K. Japan's innovation for global health - GHIT's catalytic role. *Parasitol Int*. 2021 Feb;80:102232. doi: 10.1016/j.parint.2020.102232. Epub 2020 Nov 2. PMID: 33144196.

<https://www.sciencedirect.com/science/article/pii/S1383576920301823>

Nakatani H, Katsuno K, Urabe H. Global health landscape challenges triggered by COVID-19. *Inflamm Regen*. 2020 Sep 15;40:34. doi: 10.1186/s41232-020-00144-5. PMID: 32939226; PMCID: PMC7491013. <https://inflammregen.biomedcentral.com/articles/10.1186/s41232-020-00144-5>

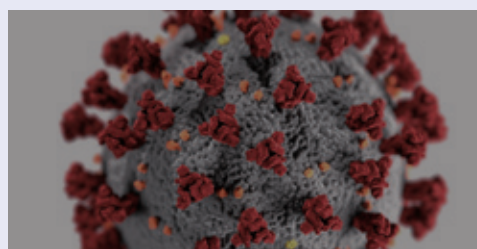
### Promoting DEI

During a year of change and challenge, our commitment to diversity, equity, and inclusion (DEI) remained steadfast. We endorse Global Health 50/50's evidence-based approach to advance action and accountability for gender equality and DEI in global health and are honored by GHIT's inclusion in its annual Index. This initiative helps us improve our policies, programs, and workplace. <https://globalhealth5050.org/2021-report/>



### Respond to COVID-19

While we do not invest directly in product development for COVID-19, GHIT served as a mediator, connecting our development partners whose technologies and innovations have potential in the fight against the pandemic with other funding agencies, resulting in some awarded projects. In addition, TBLAM's proprietary silver amplification immunochromatography (a platform technology developed by Fujifilm and funded by GHIT), was repurposed for the development of an antigen test kit for SARS-CoV-2 diagnosis. This exemplifies how GHIT-invested innovation can also be utilized beyond its initial critical scope for other infectious diseases. Lastly, GHIT joined the Access to COVID-19 Tools (ACT) Accelerator workstream to share our knowledge and perspective.



# Farewell Message from Prof. Kiyoshi Kita, stepping down from GHIT SC

Professor Kiyoshi Kita, inaugural chair and member of the GHIT Selection Committee (SC) since its inception in 2013, retired from the Committee following its January 2021 meeting. The GHIT staff members spoke with him about his unique support to and reflections on GHIT's evolution. Together, we recognize his countless contributions to the institution and to strengthening the relationship between the GHIT and Japanese academia.



**Katsuno:** You led the SC for eight years, starting from GHIT's establishment. What stands out to you about the beginning of the process?

When I heard GHIT was being established, I had been researching several infectious diseases, and I thought it would be a good opportunity to get research grants. However, when officials from the Ministry of Health, Labor and Welfare and the Ministry of Foreign Affairs came to see me and asked me to be the chair of the SC, it was the first time I recognized GHIT's fund size. I appreciated that a fair and equitable selection process was essential to expedite good product development. When I received an offer to lead that process I realized that my contribution to global health R&D would not just be to do my own research, but also to advance product development through helping GHIT invest in good projects.

**Katsuno:** How would you summarize the SC's evolution over the past eight years?

GHIT's SC members have a wealth of experience in R&D and are very strict



and sincere about science. SC members in the early days were a small group; we recognized our strong need for more diverse and objective opinions to evaluate proposals fairly. Later, we introduced the "external reviewer" system in which experts in product development and infectious diseases from Japan and abroad peer-review proposals before the SC evaluates them. The objective comments of the external reviewers inform SC members and help them make fairer decisions. We are sincerely grateful for the expertise and commitment of more than 100 GHIT external reviewers.

**Katsuno:** What do you see as the key characteristics and expertise of SC members?

In terms of experience and expertise, I believe that we have a diverse and almost ideal composition, which can be

attributed to our constant recruitment of highly qualified experts. Personally, I think that GHIT is essentially a Japanese entity, but it requires international R&D collaboration, therefore it would be desirable to have someone with a wealth of experience in both Japan and overseas take the lead. In this regard, I am very excited that Professor Naoto Uemura (Oita University) has taken over as SC chair. I believe this will lead to a further leap forward for GHIT. It is also vital for us to keep an eye open to find future potential SC members.

**Urabe:** How did the Japanese academic community initially respond when GHIT was first established?

At that time, Japan's infectious diseases community was brimming with highly motivated young researchers with a hungry spirit. That hunger for



knowledge and discovery, for example in the field of parasitology, only increased when GHIT was established. GHIT's creation provided a tailwind for academia; in fact many researchers have submitted applications to GHIT, and the number of proposals actually increased. In order to further strengthen its partnership with academia, however, GHIT needs to build more awareness of what it does and what it has to offer. For example, at a symposium co-hosted by the University of Tokyo, MMV, and GHIT in 2015, Nobel Laureate Satoshi Omura, Distinguished Emeritus Professor of Kitasato University, gave a keynote speech. This was well received by experts in Japan and abroad. Although it is difficult to hold such a large-scale event now due to COVID-19, I hope that GHIT will continue to provide opportunities for researchers to convene.

**Ohata: Have you seen any changes among the mindsets or priorities of Japanese researchers over the years?**

I think they have made tremendous progress. In the early days, proposals from organizations with Japanese principal investigators were often inadequate in terms of explanation and content in English. However, over the past years I feel that the proposals have become more and more robust, and the gap between the level GHIT is looking for and the proposals submitted by applicants is closing. The result has been increasingly strong proposals and a more competitive selection process.

In addition, the number of young researchers with a global mindset has increased, and their success has been truly remarkable. I believe this can be attributed to GHIT's investment prerequisite that projects must be

partnerships between Japan and global entities. In the past, there have been a number of projects that might have been selected if the interview with SC members in English had been well managed. I know it is hard for Japanese researchers who are not used to it, but I hope that they will be able to overcome their language challenges. I wish for their global success. I strongly hope that GHIT continues to encourage passionate researchers and help Japanese technologies can be utilized for global health.



**Ohata: What are your hopes for the GHIT's future?**

After working with all of you on a daily basis, I strongly feel that GHIT as an institution and a team of talented individuals is highly motivated and sincere about the goals it has set. I believe that you will be able to continue working at this speed and further strengthen collaborations with various partners to achieve your goals. Innovative partnerships have been made through GHIT. Please continue match-making good R&D partners and projects.

Furthermore, I believe there are many more things that GHIT can support beyond its existing investment projects. For example, why not support young researchers who may not have enough data but have great ideas? Additionally, supporting start-up projects could lead to applications to the GHIT Fund in the future. This will be good training for researchers to prepare for the real application.

**Urabe: What message do you have for researchers overseas and in Japan?**

What I would like to tell overseas researchers is that Japanese researchers are resilient; they do not give up easily and could be good partners. I would also like to see more international and domestic acceptance of and intentional collaboration with young Japanese researchers.

For Japanese researchers, especially those who will lead the next generation: always give 100% in your research field. Research ranges from usefulness to the world and people to the research for the truth. Strive to find your original research that only you can do, no matter where you are. Good research will surely contribute to society and people someday. I hope that you will keep in mind that only 1% of your new discoveries will be for your own enjoyment, and the remaining 99% will be for the benefit of those in need.



From left to right: Dr. Hayato Urabe (Senior Director, Investment Strategy, Portfolio Development & Innovations), Prof. Kiyoshi Kita (Dean, the Graduate School of Tropical Medicine and Global Health, Nagasaki University), Mina Ohata (Manager, Investment Strategy, Portfolio Development & Innovations), Dr. Kei Katsuno (Senior Director, Investment Strategy, Business Development)



***“Together” is all about***

# GHIT's Culture and Future



From left to right: Daisuke Imoto (Vice President, External Affairs & Corporate Development), Nana Arai (Manager, Brand Communications), Ayaharu Moriwaki (Associate Director, HR & Office Management)

In FY2020, the COVID-19 pandemic transformed the world and disrupted organizations in every industry. GHIT, now in its eighth year of operation, also experienced many changes. The pandemic significantly impacted our investment projects and shifted our working style. Three GHIT staff members reflected on GHIT's evolution during the pandemic and discussed our organizational strategy, human resource (HR) strategy, culture, and hoped-for future.

## Advancing innovation, Together

**Imoto:** Eight years have passed since GHIT was established, and we are currently working on about 50 R&D projects, including several late-stage candidates which are approaching launch. We are excited to show results. We live and breathe “open innovation” at GHIT and are strongly driven to further strengthen collaboration with diverse stakeholders around the world to advance and bring innovations to neglected patients as soon as we can.

**Moriwaki:** In 2020, the world was engulfed in turmoil due to the COVID-19 pandemic. One of the ways the pandemic disrupted GHIT's (and our partners') activities was by putting a temporary halt to clinical trials all over the world. “Together” became our slogan against this backdrop to help us share our aspirations internally and externally. I think the “Together” slogan demonstrates the solidarity and mutual support between GHIT staff

and our stakeholders in overcoming this crisis and continuing to move forward to achieve our mission of creating accessible products for people in need.

**Arai:** In order to create new innovations and advance product development, it is important to step outside of existing boundaries and communities, collaborate with people who have never been involved before, and take dynamic action. This is also true when you are faced with challenges you have never experienced before. I think “Together” motivates us to move forward and involve many people.



**Imoto:** In order to increase the number of promising R&D projects, GHIT not only issues public calls for proposals, but it also proactively reaches out to potential partners with good compounds and technologies, and helps facilitate and build partnerships. We actively participate in international and domestic gathering moments to try to identify

which organizations can create synergies with GHIT and find new opportunities for collaboration.

For example, GHIT, together with the Government of Japan and the UNDP-led ADP, launched “Uniting Efforts for Innovation, Access and Delivery” which aims to build a global platform bridging from drugs, vaccines, diagnostics, other novel medical technologies, and innovations that address unmet health needs in low- and middle-income countries to access and delivery.

## The team player spirit of “Together”

**Imoto:** The spirit of “Together” is deeply embedded in GHIT staff culture. I know that all staff feel a sense of responsibility and pride in contributing to the organization as a member of the team. I think this is a culture that took root in GHIT's early days. I joined GHIT last year, and have really felt how open the environment is--even mid-career



employees can easily speak up and be heard. The decision-making process is also much faster than in other organizations I have experienced.

**Arai:** I think the reason all this is possible is because all GHIT staff members have flexible mindsets and diverse experiences, and they naturally accept each other's differences. I believe that diversity, equity, and inclusion (DEI) are among GHIT's greatest strengths.

**Imoto:** GHIT is a Japanese organization, but also like an international organization. We cannot achieve our mission without cooperating with many stakeholders from diverse backgrounds. In order for GHIT to be successful, it is important for our entire staff to have excellent international sensibilities, language skills, and expertise. It is also essential for us to have a deep understanding of what DEI means in practice, and to be able to carry out our duties with the "Together" spirit.

## GHIT's vision for itself

**Moriwaki:** GHIT's has a team of only 20 people, but it needs to create a big impact, so a high level of self-discipline and professionalism are required. On top of that, from an HR perspective, we believe that by bringing people into the organization who are passionate about contributing to global health, as well as people who have unique experiences and a high level of expertise, regardless of race, nationality, gender, sexual preference, age, culture, or any other attribute, we can continuously revitalize the organization and create new challenges and value. In addition, because of the diversity of the

environment, I believe that people who embody the "Together" (e.g., "team player") spirit will have a great opportunity to play an active role.

**Arai:** There are a lot of things that are required of our staff, but we never feel negatively pressured. I think this is because we all have the desire to work "Together", rather than solving difficult issues alone. More than anything, it is because we want to do our best to realize GHIT's mission of delivering products to neglected patients.

## A year in which change was encouraged

**Moriwaki:** Our whole team started working-from-home in February 2020, even before the COVID-19 pandemic was declared. We had previously introduced working-from-home once a week on a test basis from the winter of 2018 as part of our workstyle reforms, so although this was our first experience with working remotely every day, it was a smooth transition. It allowed us to take appropriate countermeasures against infectious diseases, and we have been able to improve the efficiency and digitization of our work by going online. I think we have created an environment that allows us to achieve a good work-life balance while maintaining high performance. In order to increase productivity and create maximum value as an organization, we need to constantly review and improve our work environment with the deepest consideration for the health of our



staff, and promote a working style that uses time effectively and efficiently. The COVID-19 had many downsides, but it also presented an opportunity to expand these ways of working all at once.

**Arai:** Since the start of working-from-home, I have not experienced any major problems in communication. Each staff member is at a different stage in life (some live overseas in different time zones, some have families) but we all understand the importance of work-life balance and support each other as we move things forward. This is possible because we trust each other, and because GHIT is an organization that respects the mental and physical health of its staff.

## Toward the future

**Imoto:** It is true that the COVID-19 had an enormous impact, but we would like to promote dialogue and collaboration with our stakeholders on what we will do now through the difficulties and what we need to do for the future.

We have all experienced the pandemic and have seen how well governments, businesses, academia, international organizations, and all sectors can work together and in solidarity to overcome various difficulties and quickly develop and deliver products to people. GHIT wants to realize this potential for neglected diseases. To achieve this, we share the spirit of "Together" with our stakeholders in Japan and overseas, and work more diligently than ever.

# Finances

## FY 2020 Financial summary

### Balance Sheet

Assets (in millions)	JPY	USD
Current Assets	467.1	4.2
Fixed Assets	4,970.8	44.9
<b>Total Assets</b>	<b>5,437.9</b>	<b>49.1</b>
Liabilities (in millions)	JPY	USD
Current Liabilities	520.0	4.7
Non-current Liabilities	0.5	0.0
<b>Total Liabilities</b>	<b>520.5</b>	<b>4.7</b>
Net Assets (in millions)	JPY	USD
Designated Net Assets	4,917.4	44.4
General Net Assets	-	-
<b>Total Net Assets</b>	<b>4,917.4</b>	<b>44.4</b>
<b>Total Liabilities and Net Assets</b>	<b>5,437.9</b>	<b>49.1</b>

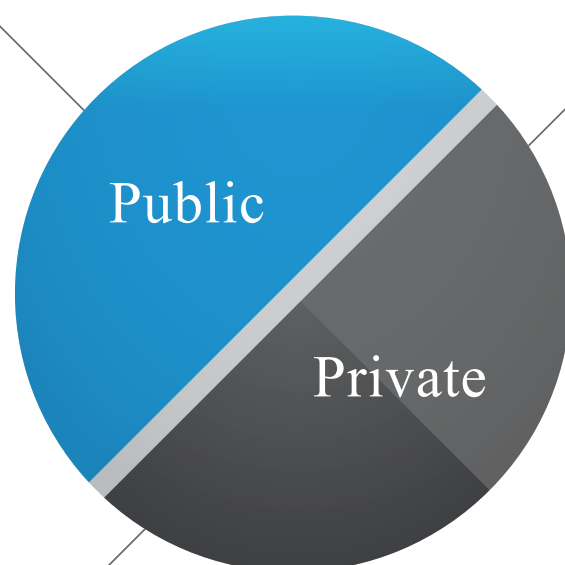
The US dollar amounts in this section represent translations of Japanese yen, solely for the reader's convenience, at JPY110.71 = USD1, the exchange rate as of March 31, 2021. This financial summary is an excerpt from the GHIT Fund's financial statements, which were audited by Ernst & Young ShinNihon LLC. The GHIT Fund is a Public Interest Incorporated Association and is registered in Japan.

## Our Funding Partners and Sponsors

### Full Partners



### Full Partners





## Net Assets Variation Statement

Change in General Net Assets (in millions)	JPY	USD
<b>Ordinary Income</b>		
Grants Received	3,350.9	30.3
Contribution Received	463.1	4.2
Misc. Income	0.5	0.0
<b>Total Ordinary Income</b>	<b>3,814.5</b>	<b>34.5</b>
<b>Ordinary Expenses</b>		
Operating Expenses	3,694.3	33.4
Management Expenses	120.2	1.1
<b>Total Ordinary Expenses</b>	<b>3,814.5</b>	<b>34.5</b>
<b>Change in Designated Net Assets (in millions)</b>		
Grants Received and Others		
Governments, NGOs, Multilateral Organizations	1,003.3	9.0
Foundations	1,645.2	14.9
Contributions Received	788.2	7.1
<b>Total Grants and Contributions Received</b>	<b>3,436.7</b>	<b>31.0</b>

### 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.



**Keiichi Ono**

Assistant Minister/Director-General and  
Ambassador for Global Issues  
Ministry of Foreign Affairs



**Yasuyuki Sahara, MD, MPH**

Senior Assistant Minister for  
Health Security and Technology  
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



**Daiichi Sankyo  
Company, Limited**

George Nakayama  
Senior Advisor and Corporate Advisor



**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**

Visiting Professor  
Keio University School of Medicine



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



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

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

**Katey Einterz Owen, PhD**

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

## Selection Committee

The Selection Committee (SC) 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 SC 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**  
Partner, Innovations  
Wellcome



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Professor, the Laboratory of Vaccine Science  
at the Immunology Frontier Research Center  
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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



**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



# Acknowledgement

## Funding Partners & Sponsors

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

### Full Partners



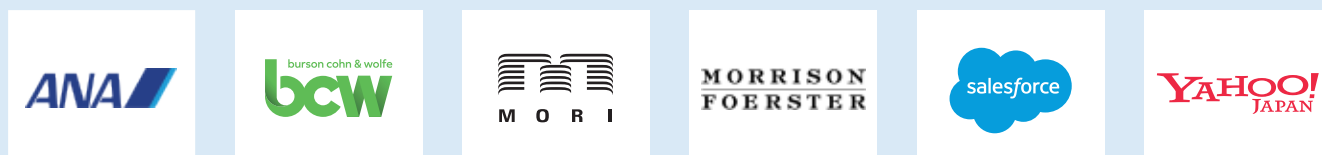
### Associate Partners



### Affiliate Partners



### Sponsors



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

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Michael Frimpong	Ole Lagatie	Judy Sakanari	



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