5th ANNIVERSARY SPECIAL REPORT

English -

Sth Anniversary





We seek out R&D solutions to health where others don't

We catalyze creative partnerships across different sectors and cultures

2000-

1



We believe medicine is invaluable with access, valueless without it

AND

HEE-

-





GHIT Fund 5th Anniversary Special Report

Contents

Where We Began / Where We Stand	-11
STAKEHOLDER INTERVIEWS	-13
Funding	15
Discovery	-23
Development	-31
Access	- 39
Policy	-47
SPONSOR INTERVIEWS	- 55
ANA HOLDINGS INC.	- 57
Yahoo Japan Corporation	- 59
salesforce.com Co.,Ltd.	-61
Morrison & Foerster	-63
Mori Building Co., Ltd.	-65
Staff Story	-67
A Conversation with Our Chair and CEO —	-71
History	-73
Replenishment Press Conference	- 75
Messages from Partners on GHIT Fund Replenishment —————	- 79

Where We Began

The idea for GHIT was conceived at a Japanese soba restaurant in Tokyo in the Fall of 2011.

The problem on the table was: How do we leverage Japan's untapped technology, innovation, and insights to address infectious diseases affecting millions of people in the developing world?

A match funding model was the critical component of realizing the idea for GHIT.

The Government of Japan, the country's leading pharmaceutical companies, and international foundations established GHIT: an R&D fund to invest in Japanese innovation for global health product development.

The original idea was for a relatively small fund (several million USD) that would invest only in preclinical development of therapeutics.

However, the idea evolved based on key input from public and private stakeholders.

GHIT launched with USD 100 million for its first five years of operation to invest in product development from discovery through to licensure.

The concept driving the chart drawn on the paper napkin in a soba restaurant was officially realized when the GHIT Fund was formally established in April 2013.



Where We Stand



As of December 2017

FUNDING





Dr. Naoko Yamamoto Assistant Minister for Global Health, Minister's Ministry of Health, Labour and Welfare

Senior Program Officer, Life Scien Global Health Program, Office of 1 Bill & Melinda Gates Foundation

DISCOVERY





Dr. David Reddy CEO Medicines for Malaria Venture (MMV)

DEVELOPMENT





r. Christophe weber presentative Director, President and CEO reda Pharmaceutical Company Limited Mr. Yoshihiko Hatanaka Representative Director, President and Astellas Pharma Inc.

ACCESS



Mr. Tetsuo Kondo Director United Nations Development Representation Office in Toky

POLICY





Dr. Seth Berkley

STAKEHOLDER INTERVIEWS

Perspectives from 15 global health leaders on GHIT's catalytic role and Japan's transformational contributions to global health R&D





Partnerships President



Prof. Stephen Caddick Director, Innovations Division Wellcome Trust



nd CEO



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



d CEO



Dr. Nathalie Strub Wourgaft Medical Director Drugs for Neglected Diseases *initiative* (DND*i*



nme (UNDP)



Dr. Aya Yajima Technical Officer Malaria, Other Vectorborne and Parasitic Diseases Unit Division of Communicable Diseases World Health Organization Western Pacific Regional Office





Vember of the House of Councillors of Japan Chairman, Special Committee on Global Health Strate of the Liberal Democratic Party's Policy



STAKEHOLDER INTERVIEWS





STAKEHOLDER INTERVIEWS | FUNDING 01

Dr. Naoko Yamamoto

Assistant Minister for Global Health, Minister's Secretariat Ministry of Health, Labour and Welfare

"Indeed, Japan, which has experienced numerous health challenges, should proactively contribute to global health and play a leading role in this arena."



How did you first come to be involved in global health?

I first became in charge of HIV/AIDS in 1992 immediately after returning to the former Ministry of Health and Welfare from studying abroad in the United States. After that, I handled the preparations and management for the International AIDS Conference held in Yokohama in 1994. At that time, I remember that therapeutics for HIV/AIDS were limited and that there was also strong discrimination and prejudice against people living with HIV. In that kind of environment, and in cooperation with healthcare professionals and researchers, nongovernmental organizations, and patient groups around the world, I truly felt the power of solidarity as we tackled regional challenges with a global viewpoint.

Why is investing in global health R&D important for Japan?

Japan's pharmaceutical industry possesses technology and capabilities for developing new drugs on the same level as the United States and European Union. We see improving the environment for drug discovery and development as directly related to strengthening our international competitiveness.

By leveraging Japan's excellent R&D technologies and capabilities and promoting public–private partnerships to develop drugs meant for developing countries, as well as supporting their supply, we aim to grow and expand Japan's pharmaceutical industry. The return we see is revitalization of the domestic economy through providing the underlying support for expanding Japan's pharmaceutical industry overseas. This is why we invested in GHIT.

What impact has GHIT's establishment had on Japan's global health R&D sector?

There are two distinctive features of GHIT to point out here. First, the



collaboration between Japan and overseas organizations is a prerequisite when conducting R&D. Second, GHIT targets neglected tropical diseases (NTDs), which are still a global health challenge, even though they are not prevalent in Japan. Such a partnership approach and substantive focus make GHIT's funding scheme completely different from other funding schemes for R&D in Japan. By leveraging this new platform, I think we have been able to demonstrate at home and abroad that Japanese pharmaceutical companies, research organizations, and universities possess technologies and capabilities which can contribute not only to the nation's health, but to global health as well.

Based on these successful experiences, I am hoping that many companies and research organizations in Japan become motivated to help address the challenges of global health, and this will lead to further advancing Japan's global health R&D.

Looking five to ten years from now, what kind of approach do you feel is needed from Japan in order to develop innovative new tools for global health?

The development of medical products requires a high level of expertise, a deep well of wisdom, and copious dialogue. Therefore, although corporate efforts are obviously needed for Japan to continually develop new innovative products in the future, leaders and experts from other sectors also need to get involved. And in the development of new medical products for infectious diseases, which is not driven by traditional market incentives, we need policies and so-called "push and pull" mechanisms. I also think it is important to help the general public understand this point so that we can invest taxes into developing new medical products.



Additionally, it is important for Japan to proactively engage in developing globally harmonized standards so that evidence-based evaluation for innovative products can be done consistently by pharmaceutical regulatory authorities in each country. Furthermore, it is critical to take advantage of Japan's experience and support the establishment of robust health systems in low- and middle-income countries so that innovative drugs can be utilized more effectively in those countries.

Naoko Yamamoto, MD, MPH, PhD, is Assistant Minister for Global Health in the Minister's Secretariat within the Government of Japan's Ministry of Health, Labour and Welfare. She has also been Director-General of Hokkaido's Regional Bureau of Health and Welfare and Director General at the National Center for Child Health and Development. Prior to that she served as Director of the Specific Disease Control Division at the Health Service Bureau in the Ministry of Health, Labour and Welfare. Before that she was Director of the Health and Medical Division in the Bureau of Personnel and Education within Japan's Ministry of Defense.

STAKEHOLDER INTERVIEWS | FUNDING 02

Dr. Hannah Kettler

Senior Program Officer, Life Science Partnerships Global Health Program, Office of the President Bill & Melinda Gates Foundation

"The philanthropic, for-profit, and government triad is an extremely valuable partnership that differentiates GHIT from lots of other organizations."

and luck, on the benevolence of

How has the global health R&D innovation funding landscape shifted in recent decades?

In the late 1990s and early 2000s, foundations like The Rockefeller Foundation as well as the Bill & Melinda Gates Foundation placed importance on the development of new products, technologies, vaccines, and diagnostics through public–private partnerships. There was a sense that global health R&D was exclusively reliant on charity individual scientists, or on companies doing something, such as a skunkworks project, or scientists working in suboptimal arrangements without access to the best technologies and partners. But that assumption changed in the mid-90s when the first product development partnerships (PDPs) were funded—the International AIDS Vaccine Initiative being the first, in 1995—and there was a shift toward organizing partners, research, and research dollars around the development of global health products as opposed to the development of science.

Along with the development of those PDPs—and philanthropic funding coming into the mix and making global health a priority—perhaps even more important was the engagement of aid agencies that did not traditionally fund R&D. Unlike traditional research funders (e.g., National Institutes of Health), aid agencies are focused on health and development outcomes. As product development portfolios become more outcome oriented, several of them-the US Agency for International Development, UK's Department for International Development, and most recently Japan's Ministry of Foreign Affairs via GHIT-started to invest in product development as well.

What role has Japan played in changing this funding landscape?

My impression is that Japan was a latecomer to funding product



development, even though it was a key player in global health more generally. Japan was instrumental in supporting The Global Fund to Fight AIDS, Tuberculosis and Malaria and had a very strong mandate to support health systems. While those things are all positive for health outcomes, Japan wasn't on the map as far as product development funding was concerned. I think the big change, clearly in the last five years, is their decision to support the GHIT Fund and take the risk of doing that as a public–private partnership.

The way Japan co-funds with private investors, or private companies pooling and leveraging private investment with their public—is different. There haven't been a lot of organizations that have made the availability of private capital a prerequisite for their donor funding—a precedent that hadn't been well established anywhere else.

The other thing is that prior to GHIT's establishment one could argue that Japan's R&D capacity was not realizing its potential impact on global health:

Japanese companies, while on the Access to Medicine Index, were at the bottom of the Index. I think there was a perception that Japan was not exporting much of all that it knew how to do-the science, the capabilitiesinto the global network, the global institutions and ecosystem. What's exciting is that, beyond providing the pool of funding and putting Japan on the map for global health product development, GHIT's model has a requirement that there be global partnerships between Japanese and global organizations. This helps ensure both that what Japan is working on gets out and that companies can leverage and contribute to the existing global ecosystem. Companies are not







expected to build up whole internal departments and capacity to work in global health.

How would you summarize the most valuable contributions of GHIT?

Leverage, leverage, leverage. Leveraging across the different funders, and the globalization of Japanese expertise and global health R&D capabilities. The philanthropic, for-profit, and government triad is an extremely valuable partnership that differentiates GHIT from lots of other organizations in terms of both their role in governance and their optimization of each other's capabilities and funding.

Hannah Kettler, PhD, is Senior Program Officer for Life Sciences Partnerships at the Bill & Melinda Gates Foundation, where she has also been MNC Sector team lead, Deputy Director for Policy and Finance, and Senior Program Officer for R&D funding and advocacy. Previously, she directed a project at the Institute for Global Health at the University of California, San Francisco, which led to the launch of BIO Ventures for Global Health. Prior to that she was Senior Industrial Economist for the Office of Health Economics within the Association of the British Pharmaceutical Industry in London.



STAKEHOLDER INTERVIEWS | FUNDING 03

Prof. Stephen Caddick

Director, Innovations Division Wellcome Trust

"GHIT is definitely one of these strategic investments; it delivers an enormous return."

How do academia and pharmaceutical companies translate science into global health impact?

Translating scientific dreams into something beyond the pages of a journal requires purposeful project management, high levels of investment, and ruthless decision-making. All of those are things may be present in the academic community, but they're much more common in the private sector.

Being an academic is primarily about discovering something unexpected. The focus is on the beauty of the problem. Often, the greatest, most unexpected discoveries come from that blue-sky research. It's easy to become distracted by a compelling, albeit non-critical, path. Industry, by contrast, is particularly good at saying, "This is the line we need to take."

Different scientific cultures in the United Kingdom, United States, Europe, and Asia have different starting points for translation. I think the



pharmaceutical companies actually understand this extremely well and are able to then nuance their project management and investment styles in order to get the best out of the academic community. We shouldn't forget the role of organizations like the Gates Foundation and Wellcome Trust, or the central role of government.

How has Japan influenced the global health innovation funding landscape in

the 21st century?

Japan has always been very important in terms of innovative science and its commitment to translating that into impact. GHIT is one of the most important Japanese initiatives that I've seen, firstly, because it's based on the idea of partnership and everyone playing their own key role. Secondly, GHIT enables key institutions to pool their resources in a generous, innovative way. Thirdly, GHIT is focused on public health impact, not financial return on investment.

Importantly, GHIT offers a very unusual opportunity for collaboration. Together, we can act faster. We can pool our resources to move science more quickly from the research community through to implementation and adoption.

What do you see as the unique capacity of Japanese pharma?

The Japanese pharmaceutical industry is extraordinarily productive at delivering products that improve human health. The companies have a great understanding of how to translate the great science that comes from Japan. I think all the life science companies—Japanese and

international—that are involved in GHIT and more broadly in global health understand all the different elements of the global scientific culture. That matters because the early translation of promising findings requires a cultural understanding. Being able to properly mine the scientific community to find those gems is similar to mining for diamonds or gold. In other words you have to find them and then invest in cutting and polishing. Then you have to find ways to get them in front of the right people in order to ensure that they meet their market.

The Wellcome Trust joined GHIT as a funding partner in 2015. How does GHIT fit into Wellcome's investment strategy?

The aims and aspirations of the GHIT portfolio of grant investments line up perfectly with our interests at the Wellcome Trust. We want to focus on innovations that will make a big difference to people, particularly those in low-resource settings. The GHIT portfolio sits squarely in that.

Our strategy is to do three things. First, we want to make a more explicit link between discovery science and the world being a better place through innovation. Second, we want to create an effective network of partners who, together, can drive innovation faster to improve human health. Finally, we want to invest in a small number of things that can make a meaningful, tangible impact on human health within 5 to 20 years. GHIT is definitely one of these





strategic investments; it delivers an enormous return.

Stephen Caddick, PhD, is Director of the Innovations Division at the Wellcome Trust. He is also Professor of Chemical Biology at University College London (UCL). Previously, he was Vice Provost (Enterprise & London) for UCL, among other leadership roles. He is a member of the Scientific Advisory Board for MRC Technology and Chair of the League of European Research Universities Enterprise and Innovation Community. He helped develop the chemical biology strategy and facilities within the Francis Crick Institute and is co-founder of Synthetic Pages—an open access website—and Thiologics—an antibody-drug conjugate biotech spinout company.



DISCOVERY

STAKEHOLDER INTERVIEWS



STAKEHOLDER INTERVIEWS DISCOVERY 01

Dr. David Reddy CEO

Medicines for Malaria Venture (MMV)

"Japan really was a logical choice, but was difficult to approach as an outsider. That all changed with GHIT's establishment."



Why is malaria important today?

Aggressive, coordinated efforts to control the disease have had a significant effect over the last 15 years. Yet this disease remains one of the major health problems in the developing world, killing an estimated 429,000 people in 2015. A child dies every two minutes from the disease, and the world's poorest countries are effectively being robbed of the next generation.

The progress that has been made is the result of using insecticide-treated bed nets, vector control, and drugs designed to prevent or cure the disease. Yet overuse—and often misuse—of these interventions has contributed to growing drug resistance. As a result, we urgently need to develop new drugs active against resistant parasites, as well as new insecticides to address the same problem of resistance.

How and when did MMV's collaboration with Japan begin?

MMV had been interested in partnering with Japanese companies since 2009 because of the country's excellence in pharmaceutical drug development. Japan has a wealth of diversity in its compound collections and extensive global reach. But without the contacts and a real understanding of the Japanese pharmaceutical industry, it was very hard for us to make inroads and form the connections that we needed.

That all changed with the establishment of GHIT, which helped us to form strategic alliances with the Japanese pharmaceutical companies that we are now forging relationships with.

What makes Japanese entities valuable partners for your work?

The pharmaceutical industry in Japan has not only developed innovative drugs to very high-quality standards



with very good ethics, they also do that in their interactions and in the distribution of those drugs. We really wanted to be able to leverage this expertise and the core set of values that go with it. Another really interesting factor is the diversity Japan has developed within its chemical libraries, which are really the base of drug discovery and the seeds for tomorrow's medicines.

Why is antimalarial drug candidate DSM265 (with research led by MMV and Takeda and funded by GHIT) unique?

DSM265 attacks the parasite in a totally different way to current drugs. First, it will be active against drug-resistant parasites. Second, because it's very potent, we can see that this drug, even on its own, can kill the majority of parasites in the blood. And when administered orally it persists in the bloodstream long enough to kill all the parasites. This means that it has the potential to be used as a single-dose treatment. This overcomes a key challenge in some of the environments where we work, where patients often don't complete the full course of treatment.

Looking ahead, what role do you hope Japan will play in malaria research and product development over the next five to ten years?

I firmly believe that in good working partnerships, where the partners get to know one another, they work together successfully. Success would be is progressing with drugs like DSM265, DSM421, and the non-artemisinin compound SJ733 that is being developed in collaboration with Eisai, and moving these compounds forward through the clinical development pathway and ultimately to patients towards the end of that ten-year horizon. This will be the true proof that we have succeeded



But behind this effort there are even more promising molecules to come, and we will need them because we know that drug development is characterized by the failure of compounds. Our job is to make them fail as early as possible if they are going to fail, so we don't waste resources, and to bring through the next generation. Working with Japanese companies, we hope to be able to have that next generation of drugs to maintain the vibrancy of our pipeline and to create the drugs for the future that ultimately will be needed to eradicate malaria.

STAKEHOLDER INTERVIEWS DISCOVERY 02

Mr. George Nakayama

Representative Director, Chairman and CEO Daiichi Sankyo Company, Limited

"By more directly linking Japanese techniques and craftsmanship to the type of global ideas and concepts embodied by GHIT, I think that we are certain to create great results."

What motivated your company to join GHIT?

Partnering with GHIT enables us to effectively incorporate our chemical compounds into the global health R&D process and utilize Daiichi Sankyo's various resources to make wider-reaching contributions to society. This is the fundamental reason we decided to become a founding partner.

Because of this partnership, we have

identified promising compounds from among Daiichi Sankyo's compound library to be used in developing antimalarial agents. These compounds have advanced to the next preclinical stage.

Has engaging in global health R&D influenced your employees?

Our compound library is unique in that we synthesize almost all compounds in-house and stock the raw materials we use in this process. We hope that

GHIT's R&D activities will be aided by our compound library. In fact, we have already produced numerous successes through our various efforts. Our researchers are very inspired and invigorated when GHIT effectively uses Daiichi Sankyo's drug discovery technologies and R&D capabilities to move forward with the development of pharmaceuticals.

I am always trying to pinpoint exactly what motivates our employees. Thank-you letters from patients are one of the clearest contributors to employee motivation. These expressions and stories are major sources of pride, and the majority of the people that work in the pharmaceutical industry gain inspiration from these sources.

Successfully contributing to global health is a joyous experience. We are proud to go beyond simply helping fund GHIT to actually contributing to global health through our drug discovery technologies and R&D activities. The inspiration and



motivation we receive in return is invaluable.

Has GHIT's establishment impacted the engagement of Japanese pharma in global health R&D?

Through our involvement in a malaria project with MMV, we are sharing approaches and know-how with people outside of Daiichi Sankyo. In this way, GHIT serves as a kind of innovation hub, helping various companies and research institutions learn from each other while leveraging their unique technologies for global health and making all parties stronger as a result. The existence of GHIT holds exceptional meaning for this reason.

Many of the pharmaceutical products developed by Japanese pharmaceutical companies are competitive in the global market. However, Japanese pharmaceutical companies still have a long way to go before becoming major global players. This is likely because these companies have not yet formed the networks necessary to have their expertise and technologies utilized around the world. By more directly linking Japanese techniques and craftsmanship to the type of global ideas and concepts embodied by GHIT, I think that we are certain to create great results.

GHIT is not only supported by private-sector companies and foundations but also by the Government of Japan. This is the first time such a union of private-sector companies, foundations, and government has been formed. The way in which Japan will contribute to global society is constantly being questioned. I think it is possible that this type of union will help create tangible contributions in the future. The potential is so clear to me, and I therefore want to push products out onto the market through GHIT as quickly as possible.

Looking ahead, what would you prioritize for Japanese global health innovation over the next five years?

The Japanese government has expressed its commitment to ongoing investment in GHIT from a long-term perspective. Once commenced, it is





important to continue such support. We, as a private-sector company, will also provide consistent support to GHIT

Moreover, as GHIT's name suggests, it is important to continue to advance the development of truly innovative technology. If Japanese pharmaceutical companies and research institutions can contribute to global health by utilizing their innovative technology, I think GHIT can become even more capable and grow further.

It is also important to raise awareness among the global community with regard to the extent to which Japanese pharmaceutical technologies and R&D capabilities are aiding society and saving lives.

eorge Nakavama, MBA, is Representative



STAKEHOLDER INTERVIEWS DISCOVERY 03

Prof. Kiyoshi Kita

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

"My hope is that some GHIT projects will lead to products that can be provided to patients in endemic regions of infectious diseases."

What drove you to make parasitology and infectious diseases your life's work?

In the mid-1980s I conducted epidemiological surveys of patients with Chagas disease and leishmaniasis in Paraguay as the team leader of a Japan International Cooperation Agency medical cooperation project. Before I would head out to conduct a field survey, I would usually meet with Paraguayan village leaders. Once one of those leaders asked, "What do you do if the blood test result is positive?" It stumped me. Although some medications for these diseases do exist, the side effects are severe. It has been nearly 30 years since I was first asked that question, and unfortunately there have been very few medical advances.

Through my work in the field in Paraguay, I became hyperaware of the way all these diseases take away patients' quality of life, as well as the elements that are necessary for economic development, growth of children, and a nation's prosperity. When I returned to Japan, I decided to



dedicate myself to drug discovery for parasitic diseases through basic and applied research. Over the years that have since passed, the concept of global health has gradually gained more attention and traction, along with globalization, and the field of parasitology has become extremely dynamic. When I finished graduate school, I never dreamed I would be doing the work I am pursuing today.

What do you see as the core strengths of Japanese academia?

Japan's strength is its perseverance. We are fortunate to be able to conduct studies on diseases that are no longer present in Japan using the cutting-edge scientific techniques of Japan. Careful basic research is essential to making the world a better place. For example, if we could understand the characteristics of malaria larvae as an organism through

detailed basic research, we could figure out when exactly malaria develops resistance to a drug. If we skip that process, we may not be able to prevent or combat resistance as effectively. Attitudes toward and priorities for basic science in Japan seem to have shifted recently, even though basic research does not typically deliver "quick wins."

How have you seen Japanese academia evolve over the last four years?

Basic research itself is not valued unless a paper is written in English and published in an international peer-reviewed journal. This has been a common practice for a long time. However, it has not been common practice for Japanese entities to leverage their research results and do product development with foreign groups. Especially in the field of infectious diseases, there will be more opportunities to win funding from organizations such as GHIT. The mindset of Japanese researchers is rapidly shifting from a domestic to a global viewpoint.

Japanese people are not typically good at self-promotion, but GHIT is an extremely unique system that enables Japanese research to shine in a way that is comfortable for Japanese researchers.

You are Chair of GHIT's Investment Selection Committee. How do applicant interviews with the Selection Committee work?

It is not so easy for those who are not fluent in English to pitch their ideas to and answer questions from the Selection Committee. Japanese



language barrier in the past. However, since English is the accepted global language for science, Japanese researchers must adapt. You must not only explain all scientific components of the research in detail to non-experts, but you must also clearly delineate the pathway from research to productization. Honestly, I think that this is challenging for Japanese academia. In that sense, having Japanese and international research groups form a partnership to write the proposal for product development is important for the globalization of Japanese academia.



researchers have grappled with the

of Biomedical Chemistry at The resident of Japanese Biochemical Society



STAKEHOLDER INTERVIEWS

DEVELOPMENT

STAKEHOLDER INTERVIEWS DEVELOPMENT 01

Mr. Christophe Weber

Representative Director, President and CEO Takeda Pharmaceutical Company Limited

"Japan has a vibrant pharmaceutical industry, which will continue to push on research."



Where do infectious diseases and global health fit into Takeda's vision and core business strategy?

Takeda is active in many countries in the world, both in developed and emerging countries. It is true that in our core research we focus more on non-communicable diseases; however, we see the impact of infectious diseases on lives around the world very clearly. We invest in global health

because it is very important for us. Takeda's vaccines division is especially active in advancing vaccine candidates against diseases such as malaria, dengue, and norovirus, all of which could have great impact on public health, especially in developing countries.

Takeda's commitment to global health manifests through both R&D-driven investments and corporate social

responsibility (CSR) initiatives. How do the two approaches synchronize?

Takeda is engaged in numerous R&D projects with global impact through our vaccines division. And we were an early partner of GHIT, which provides another important way to contribute to global health innovation. In both strategies, Takeda drives to have an impact to improve global health in the world and engages in partnerships that support better access to healthcare.

In what way is GHIT a strategic investment for Takeda?

GHIT is a very innovative model for creating medicines or vaccines against diseases for which there is a lack of R&D funding. I think the model has been very, very successful. Investing in GHIT and contributing to its work makes sense for Takeda not only because of our global health interests but also because of the strong capabilities in Japan that can help make GHIT successful



How is R&D for global health products different from R&D for products with traditional commercial markets?

The R&D process for global health requires engagement from multiple partners across sectors, so the collaboration is slightly different from our core process. However, the overall innovation process is guite similar. You need to design the molecule and the medicine, and you need to do the clinical development. This is where both processes intersect and are complementary. As a pharmaceutical company, we can bring our know-how and combine it with the expertise of partners in the international community to work jointly to progress the critical solutions needed through the R&D pipeline and into the market.

One example is Takeda's partnership with MMV to study antimalarial compounds. This is a noteworthy initiative because Takeda, as a company, does not have strong expertise and experience in malaria. However, Takeda brings in our know-how and capabilities in research and clinical development expertise to

support moving the antimalarial compound into clinical studies. The antimalarial compound utilized in this partnership stems from a collaboration between three different professors from the United States and Australia. This example truly illustrates the global health R&D collaboration model of cross-sectoral partners contributing their core expertise into a partnership to address a global health need.

Looking ahead, in what way do you see Japan continuing to help transform the global health product development process over the next five to ten years?

First, Japan is uniquely positioned



because the level of scientific know-how and knowledge is very dynamic—evident from the total number of Nobel Laureates in Physics, Chemistry, and Physiology or Medicine from Japan. This is a critical foundation. Second, the Government of Japan and its leaders are dedicated to global health officially and personally. They have displayed strong leadership in their support of critical global health commitments from the G8 Summits and the United Nations' initiatives. Third, Japan also has a vibrant pharmaceutical industry, which will continue to push on research. All these components are vital to transforming R&D and product development for global health—and they are all strong and active in Japan. Very few countries possess all three.

STAKEHOLDER INTERVIEWS DEVELOPMENT 02

Mr. Yoshihiko Hatanaka

Representative Director, President and CEO Astellas Pharma Inc.

"I believe that GHIT has catalyzed a mindset shift for the Japanese pharmaceutical industry vis-à-vis global health R&D."

Astellas is a key partner in the Pediatric Praziguantel (PZQ) Consortium. What does the Consortium do?

The Consortium is an international, cross-sector collaboration that aims to deliver drugs with appropriate formulations to children with schistosomiasis, a NTD. PZQ is a standard therapeutic drug with reliable evidence to treat schistosomiasis. The use of the drug was initially limited to adults and school-aged children.

Because PZQ pills were not suitable for infants and preschool-aged children due to their large size and strong bitter taste, there has not been any effective treatment for them.

We decided to participate in the Consortium with the intention of applying our company's expertise in formulation technologies to this problem, to help redesign the drug so that it could also be delivered to infants and preschool-aged children.

What motivated Astellas' management team to engage in this project?

During an academic conference held in Holland in 2011, a member of Astellas' development division happened to be seated next to a representative of Merck KGaA, the company that originally developed PZQ. The Merck KGaA representative's passion for solving the pediatric schistosomiasis challenge resonated with the Astellas scientist. Their interaction catalyzed internal discussions about whether our formulation technologies could be brought to bear.

Why did the management support this initiative? I believe the priority given to access to health in our CSR was the driving factor. Additionally, there is strategic value in the relationships with partner companies we develop through activities like the Consortium—local partnerships and networks inside developing countries, understanding of specific issues faced by developing countries, and relationships with each nation's government.



Why is developing a drug for children particularly challenging?

When developing pediatric PZQ formulations, we first developed mini-tablet with dosage based on patient bodyweight. However, we learned that PZQ was commonly provided through mass drug administration in schools, and altering the number of tablets according to the child's bodyweight was too intricate to conduct on site. Furthermore, there is a risk of asphyxiation when administering multiple tablets to small children. Based on these findings, we started again, developing an orally dispersible tablet.

Has Astellas' engagement in global health R&D delivered any new insights about the product development process?

First, we learned a profound lesson about delivery complexities in the developing world and how they impact R&D. For example, we had to be creative with the administration of the drug while simultaneously reducing production costs, simplifying production techniques, and ensuring stability in the hot and humid conditions of tropical regions. These challenges are not typically major



factors for product development for the developed world settings in which we usually operate. Second, by engaging in drug development for NTDs, we have learned lessons about partnerships across sectors and borders. Open innovation is critical: we have seen how collaboration among multiple interested parties across sectors produces something of greater value. Third, this work has fostered a new culture within the company. Employees are engaging in these activities of their own accord.

How do you think the Japanese pharmaceutical industry's overall engagement in global health R&D has evolved over the past five years?

GHIT has catalyzed a mindset shift for the Japanese pharmaceutical industry and created a mechanism through







Clinical site of Phase 2 trial for pediatric PZQ in Ivory Coast

which companies can combine their R&D expertise and capabilities in cooperation with those of governments, internationa organizations, and non-profits. Furthermore, GHIT catalyzed partnerships between the Japanese pharmaceutical industry and global entities that we would not have been able to create on our own.



STAKEHOLDER INTERVIEWS DEVELOPMENT 03

Dr. Nathalie Strub Wourgaft

Medical Director Drugs for Neglected Diseases initiative (DNDi)

"It's very clear that no one can do it alone. You need to have partners."

Why do NTDs matter today?

NTDs disproportionately affect the very poor. These diseases have been neglected for decades by pharmaceutical R&D because there is no return on investment to incentivize pharmaceutical companies to find solutions for these patients. The term NTD covers a range of infectious diseases that affect patients living in Africa, Latin America, and Asia. These diseases debilitate, disfigure, blind, or kill. The poorest of the poor particularly women and children—are the hardest hit. The burden of these diseases is significant in terms of morbidity, mortality, lost productivity, and impaired economic growth, engendering a vicious cycle of poverty.

Beyond market failure, what other challenges or opportunities, scientific or otherwise, are notable in the area of drug development for NTDs?

For the diseases that have been neglected by research, there are a lot of guestions that need answers. First is the



question of access to libraries of chemical compounds that could become potential drugs for treatment. One solution is an initiative that was developed by DNDi with the financial support of the GHIT Fund: the NTD Drug Discovery Booster. This has been an incredibly innovative R&D mechanism to expand and enhance research and get access to unique chemical compound libraries.

You also need to be able to categorize and test whether a potential compound will kill whatever infectious agent you want to kill—parasites, for the most part. So there's a need to build screening projects, which we also did in collaboration with Japanese scientists. Then comes the need for improving the chemistry of the compound so that it can become something you can administer to patients. The next step is to test in the

animal models, which will predict human efficacy and safety, where we will also have a big challenge.

Where does research for a new drug for an NTD begin?

We build a project with what we call a target product profile. A target product profile is defined by members who are part of platforms that bring together all the stakeholders, including those that will be using the product in the field: academics, physicians, national programs, ministries of health, nongovernmental organizations, and the pharmaceutical industry. Everyone comes together and asks, "What would be the ideal profile of a drug or treatment for this specific disease? Also, what is acceptable versus ideal? How far can we go to still accept this as bringing a solution?"

Tell us about DNDi's relationship with Japan, and GHIT's impact on that collaboration.

DNDi opened an office in Tokyo in 2004 (a year after our creation). In early 2005, we started collaborating with the Kitasato Institute, looking at screening products and natural products from the institute, for targeting products that would kill the trypanosome parasite for sleeping sickness.

Even before the collaboration with DNDi, Japan had a long history of involvement in infectious diseases. There had been some exchanges between the scientists in the field within Japan and outside of Japan. So that was a natural collaboration.

GHIT has been a catalyzing funding



mechanism that allowed Japanese science to emerge and be available for NTDs more widely. Another unique feature of GHIT is that it allows funding of pre-clinical and discovery work, which bears the higher attrition risk and is not the easiest to fund. Looking at the gaps, that is where we need to start, and without it there's no way we'll find any solutions. For this reason, GHIT is really essential and unique in its scope.







STAKEHOLDER INTERVIEWS





STAKEHOLDER INTERVIEWS ACCESS 01

Dr. Jayasree K. Iyer

Executive Director Access to Medicine Foundation

"Access to medicine is an issue for everybody, a cross-border issue that goes beyond domestic interests."



What is "access to medicine," and why does it matter today?

There are about two billion people globally who do not have access to essential medicines, vaccines, diagnostics, and overall treatment. One of the main issues of access is the need for medicine both to be made available for a lot of different conditions and to be accessible by a lot of different communities. Medicines need to be affordable and of good quality. There is a particular accessibility need for populations in rural areas, in jungles, or on islands. For all these reasons, access to medicine is a critical global health component that needs to be addressed.

What is the Access to Medicine Index? What does the Access to Medicine Foundation do?

The Access to Medicine Foundation was created with the idea that the

pharmaceutical industries could be encouraged to compete with each other against global health social goals, which mainly involve access to medicines. Our primary publication has been the Access to Medicine Index, which is a ranking and evaluation of 20 of the world's largest research-based global pharmaceutical companies and their efforts in access to medicines.

What distinct role can each sector play in improving access?

The private sector, especially the pharmaceutical industry, includes the inventors and the producers of vaccines and medicines, so they need to make sure that medicines are made available and are affordable and of good quality, as well as accessible to people all over the world.

Governments have a key responsibility to ensure that healthcare is prioritized and is available for their people. Nongovernmental organizations play an important role in implementing a lot of programs and gaining acceptance

Access to Medicine



into communities for essential medicines. There is a host of different implementation roles that nongovernmental organizations—and multiple sectors—play. There's also a very important role for people themselves— to seek healthy behavior, health services, and actually get access to medicines.

What is unique about Japan's contributions to improving access?

Japan is well positioned to contribute to access to medicine. It has a strong innovation culture. There's also a very strong recognition that the pharmaceutical industry is part of that innovation culture and some of the solutions in access to medicine. Additionally, there is more trust in the pharmaceutical industry in Japan than you see elsewhere in the world. There also are very strong public-private relationships. Finally, there are many different platforms with the Japan International Cooperation Agency, the GHIT Fund, and the international players that are there, which allow the pharmaceutical industry and various university members to play a role in access to medicine.

What do you see as GHIT's role in improving access?

GHIT plays a role not only in getting the players on board and securing adequate funding but also in leveraging the government, private players, and public players into accelerating the development of medicines and vaccines and other products. We reward companies that participate in GHIT, as we see R&D public-private partnerships as a powerful tool to advance the development of needed health technologies. We also see GHIT involved in antibacterial resistance, and very importantly ensuring that when products are developed, they are very quickly made accessible for people living in low- and middle-income countries, as access plans, like registration, pricing, and intellectual property arrangements, are pre-discussed with their partners.

How do you hope Japan and GHIT will leverage their capacity and leadership in life science innovation to continue to improve access over the next five to ten years?

Several competing contemporary global challenges exist now and will persist in the years to come. So it's important that Japan, GHIT, and the



pharmaceutical industry in Japan play a stronger role in access to medicine. It's important to continue the momentum that's been made in terms of R&D for poverty-related diseases and also try to get more involved in improving non-communicable disease care and access to essential medicines. We also need to improve universal health coverage in low- and middle-income countries. With the innovation culture in Japan, and the momentum that we've had with the Japanese companies playing a role in access to medicine, we've seen the power and potential of Japan to improve targets. I'm hoping to see a stronger role and rapid growth that builds on Japan's momentum to date.

Jayasree Iyer, PhD, is Executive Director of the Access to Medicine Foundation, where she has also been Head of Research. Previously, Dr. Iyer was responsible for creating, negotiating, and managing public–private partnerships in R&D for infectious diseases and oncology. She has worked at nongovernmental organizations, academic institutions, and think tanks and co-founded the European Solutions Enterprise for Neglected Diseases.



STAKEHOLDER INTERVIEWS ACCESS 02

Mr. Tetsuo Kondo

Director United Nations Development Programme (UNDP) Representation Office in Tokyo

"We are clearing the path to promote effective introduction and scale-up of the new health technologies that are emerging from GHIT's pipeline."

How does UNDP help improve access to health care?

Specifically, we focus on improving affordability and ensuring availability of health services and health technologies.

Managing access to healthcare is normally the responsibility of each country's government. However, many government agencies do not have sufficient capacity to respond to the

day-to-day health needs of their populations and ensure that all citizens have access to medical care. Supporting countries to build resilient health systems is one of the important facets of UNDP's work.

What role does UNDP play as a strategic partner to the GHIT Fund?

GHIT's work in developing drugs, vaccines, and diagnostics, utilizing Japan's highly advanced

technologies, is extremely important. Unfortunately, the public health systems of low- and middle-income countries are still weak, and uptake of new technologies, however useful, is not always straightforward or immediate. For this reason, UNDP is helping to lay the groundwork for country adoption and integration of critically needed new drugs, vaccines, and diagnostics like those being developed by GHIT. To achieve this, UNDP supports health system strengthening. In other words, we are clearing the path to promote effective introduction and scale-up of the new health technologies that are emerging from GHIT's pipeline.

pharmaceutical capabilities and

What is the Access and Delivery Partnership (ADP)?

The ADP is led by UNDP's HIV, Health and Development Group. It seeks to help improve access to and delivery of new health technologies. This program started in 2013 as a joint effort with the Special Programme for Research and



Training in Tropical Diseases and a health nongovernmental organizations called PATH. Examples of past initiatives include supporting Ghana in developing the National Medicines Policy and assisting Indonesia in the introduction of bedaquiline, a new treatment for multidrug-resistant tuberculosis. Furthermore, the ADP supported Indonesia's Ministry of Health in institutionalizing the Health Technology Assessment approach. In Africa, we helped to develop the African Union Model Law for Medical Products. While GHIT supports product development, UNDP's strength (particularly through the ADP) is to help create a system that enables effective delivery of new health technologies to patients in need.

We work in multiple countries to strengthen government capacity for policies, systems, and technical capabilities across multiple sectors to promote effective introduction and scale-up of new health technologies. This work is important, and we still have a long way to go. For example, in 2014 only 27% of the 10.8 million people who needed preventive chemotherapy for schistosomiasis in Tanzania were able to receive it through government measures.

GHIT is currently promoting the development of a new pediatric formulation for the gold standard treatment for this disease; UNDP's effort in strengthening the public health system will help ensure the effective delivery of the new pediatric formulation once it becomes available.

What do you see as GHIT's major successes to date?

GHIT's very existence is an important accomplishment in and of itself-one that contributes to universal health coverage, for which Japan has been advocating repeatedly. GHIT has also been remarkably successful in increasing the opportunities for Japanese technology to be applied to global health R&D.





Furthermore, GHIT's work has also increased the willingness of the Japanese government to engage more deeply in global health. For example, the Japanese government's decision to become involved in the Coalition for Epidemic Preparedness Innovations is largely due to the important role that the GHIT has been playing in increasing awareness from and engagement with government agencies, pharmaceutical companies, and politicians.

STAKEHOLDER INTERVIEWS ACCESS 03

Dr. Aya Yajima

Technical Officer Malaria, Other Vectorborne and Parasitic Diseases Unit Division of Communicable Diseases World Health Organization Western Pacific Regional Office

"Through GHIT, I believe Japan strengthened its commitment to eradicate, eliminate, and control NTDs for the common goal of a healthier world."

What are NTDs?

NTDs describes 21 infectious diseases. Currently, more than one billion people in 149 countries and territories are estimated to be affected by NTDs, with a resulting economic loss of billions of dollars each year.

NTDs typically cause severe physical deformities and other permanent disabilities. As a result, affected individuals might not be able to work or get married. They might suffer from discrimination and prejudice and carry psychological burdens. Some NTDs also affect physical and cognitive development in children.

How are Japan and the international community addressing NTDs?

World Health Assembly resolutions calling for global efforts to eradicate or eliminate some NTDs date back to the 1950s. At the G8 Summit in Denver in 1997, Japan's then–Prime Minister Ryutaro Hashimoto indicated that parasitic diseases represent one of the



major causes of poverty globally and called for global efforts to combat them. This triggered increased interest and response from the global community and led the World Health Organization (WHO) to officially redefine the group of diseases as NTDs and establish the Department of Control of NTDs in 2005.

In 2007, WHO held the first Global Partners Meeting on NTDs. In 2012, WHO launched a roadmap, which set targets for 2020 and a public–private partnership of an unprecedented scale (commonly known as the London Declaration) was launched towards achievement of that roadmap. The GHIT Fund was founded in 2013, through which Japan also increased its commitment to NTD elimination and control. Please tell us about the efforts of the World Health Organization Western Pacific Regional Office's NTD work and its elimination of lymphatic filariasis.

Fourteen NTDs are endemic in 28 countries and territories in the WHO Western Pacific Region. Our greatest advancement has been in elimination of lymphatic filariasis. The Global Programme to Eliminate Lymphatic Filariasis was launched in 2000, preceded by the Pacific Programme to Eliminate Lymphatic Filariasis (PacELF).

Mass drug administration has proved effective in the Western Pacific Region where six countries have validated by WHO as having eliminated lymphatic filariasis as a public health problem over the past two years. Five of them are Pacific Island countries under the PacELF. We believe that most of the countries in the Western Pacific Region are on track for elimination of lymphatic filariasis by the 2020 global target.

Is mass drug administration an important strategy for all NTDs?

While mass drug administration alone can be effective as a primary strategy



for elimination of some NTDs, there are many other NTDs for which a combination of multiple strategies is required. For example, schistosomiasis, which is currently widespread in China and the Philippines, infects both humans and other mammals, such as buffalo and cattle. In such case, mass drug administration targeting humans alone is insufficient.

What weapons does the future fight against NTDs require?

Even in countries that have achieved elimination status, the job is not over. For example, patients in these countries suffering from lymphedema and hydrocele will remain and continue to live with this residual morbidity for the rest of their lives. We need to make sure that the health system provides a minimum package of care for such patients, and that such care is sustained over a long period.

Another issue is post-elimination surveillance. Lymphatic filariasis is endemic in both Bangladesh and the Philippines. There is theoretically a risk of reemergence of transmission if many infected individuals migrate from these countries to some of the Pacific Island countries that have achieved elimination.

As new challenges arise, we must join forces with a wide range of stakeholders to identify the most effective and feasible systems/measures to address them. We are continuously building and refining our evidence base to establish the best strategies and guidance for countries. We would like to continue pursuing such pioneering efforts with a hope that the lessons learned in our region can help other disease elimination and control efforts globally in the future.

Aya Yajima, PhD, is Technical Officer in the Malaria, Other Vectorborne and Parasitic Diseases Unit within the World Health Organization Western Pacific Regional Office's Division of Communicable Diseases. Previously, she was Technical Officer at the Department of Control of NTDs at WHO Headquarters, where she supported development of various technical guidelines and tools to facilitate and monitor implementation of preventive chemotherapy interventions.



STAKEHOLDER INTERVIEWS





STAKEHOLDER INTERVIEWS POLICY 01

Dr. Mark Dybul

Former Executive Director The Global Fund to Fight AIDS, Tuberculosis and Malaria

"When we all come together and look at the world in a positive way and look at what is possible, we can achieve extraordinary things."



What is the Global Fund's relationship with Japan?

Japan has played a tremendous role in the Global Fund from the beginning, including the G8 Summit in Okinawa, where we were born. Japan has been one of the largest funders of the Global Fund. But it's not just the origins and the money that have been important. From the beginning, Japan has been an intellectual leader. The country's academic community,

nongovernmental organizations and advocacy community, and the Japanese government—regardless of which party is in power-and a cross-party group of Parliamentary members, have all strongly supported the Global Fund.

What role does the Japanese private sector play in the Global Fund's work?

Japan has contributed its know-how and brain power on productivity and commodities since 2009. Between 2009

and 2016, the Global Fund purchased USD 440 million worth of commodities from companies in Japan. One of the best and most effective drugs against multidrug-resistant tuberculosis is produced by Otsuka. We see new and innovative products that are coming forward from Japan's private sector as incredibly important. And Japanese pharmaceutical companies, namely Takeda, give resources to the Global Fund.

Why is innovation in drugs, vaccines, and diagnostics for HIV, malaria, and tuberculosis important?

We need new and effective vaccines if we are truly going to accelerate the end of these epidemics. We have vaccines for malaria and HIV, but they are not particularly effective. We do not have a modern-day vaccine for tuberculosis. Theoretically, we can get to the elimination of tuberculosis and malaria with the current available products, but drug resistance is a real risk, and it is inevitable when you treat so many people. If drug resistance is

not contained, we could lose our first-line products, as they will no longer work.

What new innovations do you find particularly exciting?

A few years ago, the first new tuberculosis drugs in 50 years became available. There is also innovation occurring to have antiretrovirals in injectable form, that will last three months and allow us to provide prevention, as well as treatment, in a much more efficient and effective way. New preventative technologies are also emerging, along with very exciting things happening with gene therapy that could, for example, make a mosquito incapable of transmitting malaria.

What makes public-private partnerships successful?

One is political leadership. Additionally, full engagement of the private sector and a true understanding that companies need to be responsive to shareholders, and provided with incentives to engage, are hugely important.

That's what GHIT was designed to do, to see the incentives that were possible to open up marketplaces because of the political leadership, but also because of the partnership and relationships that Japan has through the Global Fund, Gavi, Untied Nations system, academic, and nonprofit organizations. There is a marketplace out there. Companies have to tell their shareholders that what they're investing in makes a difference.

What are your hopes for how Japanese entities will help transform global health policy in the near future?

If Japan does over the next 15 years what it has contributed over the last 15 years, we'll be in great shape. This includes continuing their financial contributions. Prime Minister Abe made a very large commitment to global health as part of last year's G7 Ise-Shima Summit. Japan has also shown tremendous leadership around the Sustainable Development Goals in the government's Universal Health Coverage commitment. In addition to the 2016 G7 Summit, the Sixth Tokyo International Conference of Africa's Development was held in Africa for the



first time.

But this is not just about financial resources. The resources support the ideas that came from Japan, including universal health coverage and human security, and then link them to the private sector. Japan has always participated in the ideas and the resourcing, as well as the private sector providing innovative commodities, and looking to the future and continuing to stimulate those ideas.

was Co-Director of the Global Health Law O'Neill Institute for National and Global Health Law. He was also the founding Plan for AIDS Relief. He has served as US Global AIDS Coordinator and worked at

STAKEHOLDER INTERVIEWS POLICY 02

Dr. Seth Berkley

CEO Gavi, the Vaccine Alliance

"I think it is important to create this type of shared value partnership, which will help eliminate as many barriers to entry as possible."

Please share brief background on Gavi, the Vaccine Alliance, for a lay audience.

Gavi, the Vaccine Alliance, is a public–private partnership with a mission to save children's lives and protect human health by increasing equitable use of vaccines in lower-income countries. Since 2000, Gavi has helped to immunize over half a billion children against deadly diseases, and our work with vaccine manufacturers has reduced the price of vaccines by 90%. Gavi now purchases vaccines for 60% of the world's children in nearly 70 of the world's poorest

Gavi's new five-year strategy means we will continue to roll out new vaccines but also focus on reaching the "fifth child"—the 20% of children of worldwide who are still not getting basic vaccines.

countries.

Why are new and improved vaccines critical today?

With changing trends in human and animal migration, increasing urbanization, the density of mega-cities, the rise in antimicrobial resistance, and climate change, the threat of a major new disease outbreak is growing larger and larger. New vaccines are critical to help us counter this threat.

What is Japan's role in the Gavi Alliance today, and why is it important?

Japan began to contribute to Gavi in 2011, providing USD 53.7 million between 2011 and 2015. At our last replenishment conference in 2015 Japan doubled its contribution. The Japanese government has also given Gavi strong political backing, for instance by making a reference to Gavi in the G7 Leaders' Declaration.

The Japanese pharmaceutical industry could play an even greater role—not just in manufacturing vaccines, but also



producing medical devices such as syringes and cold chain equipment to support the Gavi model.

What has been Japan's role in global health leadership over the past ten years?

Japan's focus on universal health coverage has also been important. For me, one of the critical issues in trying to get our vaccines out is that we are trying to reach everybody in the world. The people that are not being reached with vaccines are the ones who have no access to health services. Therefore, efforts to deliver vaccines and Japan's priority on universal health coverage are key to individuals' ultimately being able to access other health services as well.

In your experience, what is the most important factor for a successful global health R&D partnership?

Prior to Gavi, I ran an organization called the International AIDS Vaccine Initiative. We worked with Japanese scientists to move forward a vaccine for HIV. There were some challenges, including a language barrier, but what made the partnership successful was its focus on bringing together a group of people with shared values and interest in moving forward together. I think it is important to create this type of shared value partnership, which will help eliminate as many barriers to entry as possible. To me, this will allow Japan to contribute even more to global health R&D than it already has, especially Japanese companies.





Seth Berkley, MD, is CEO of Gavi, the Vaccine Alliance. Previously, he founded the International AIDS Vaccine Initiative. Prior to that, he was an officer of the Health Sciences Division at The Rockefeller Foundation. He has worked for the Centers for Infectious Diseases of the US Centers for Disease Control and Prevention, the Massachusetts Department of Public Health, and the Carter Center, where he played a key role in Uganda's national HIV sero-survey and helped develop its National AIDS Control Program. He was recognized by TIME magazine as one of the "100 Most Influential People in the World" and by Wired Magazine as among "The Wired 25." He sits on many international steering committees and boards, including those of Gilead Sciences, the New York Academy of Sciences, and the Acumen Fund

STAKEHOLDER INTERVIEWS POLICY 03

Hon. Prof. Keizo Takemi

Member of the House of Councillors of Japan Chairman, Special Committee on Global Health Strategy of the Liberal Democratic Party's Policy

"I believe that having global public–private partnerships from the very beginning has been a key factor in the GHIT Fund's success to date."

What is the history of Japan's leadership in global health policy and strategy?

Japan put infectious diseases on the agenda for the first time at the 2000 G8 Summit in Kyushu and Okinawa, where the government announced the Okinawa Infectious Diseases Initiative. Japan's leadership led to the establishment of The Global Fund to Fight AIDS, Tuberculosis and Malaria.

In 2008, Japan hosted the Hokkaido Toyako G8 Summit, emphasizing the need for health systems strengthening. Japan played a pivotal role in making this new theme mainstream in global health. At the Ise-Shima G7 Summit in 2016, Japan proposed reinforcing the global health architecture to strengthen responses to public health emergencies in peacetime based on the recent outbreaks of infectious diseases such as Ebola and Zika. Moreover, Japan appealed for a collaborative international framework to help create a more robust and sustainable health system in each



country. The end goal is universal health coverage, another critical health theme that Japan has been promoting.

More recently, Japan has also aggressively engaged in global health R&D, helping to create new innovations by leveraging Japan's cutting-edge pharmaceutical technology and capability. The GHIT Fund has played a catalytic role in launching and accelerating these activities. What is the rationale for Japan's leadership in global health?

The first reason is philosophical. During the Obuchi Cabinet of the 1990s, Japan revised its Official Development Assistance charter. Human security was included as one of Japan's fundamental foreign policies.

The second reason is to leverage Japan's strengths for the global public good. Life expectancy in Japan is



among the highest in the world, and our health, medical, and long-term care policies and systems are among the best and most progressive. Leveraging these strengths for health and medical issues at the global level has become an important pillar of the country's international contributions.

The third reason is our contribution to low- and middle-income countries. In addition to Japan, many other countries are rapidly aging. Asian countries are expected to have a massive aging population prior to achieving universal insurance and health care coverage systems. To help address these problems now, Japan must make major, comprehensive contributions to these other countries in Asia.

What role did you play in GHIT's establishment?

I worked with the Government of Japan to help facilitate its involvement in GHIT from the very beginning. It was important for us to make sure GHIT had an innovation delivery support function from the outset, so that people in lowand middle-income countries could actually use our products. In other words, the goal was not simply to create innovation, but also to ensure access to and appropriate use of that innovation.

Realizing GHIT's vision required the Ministry of Health, Labour and Welfare and the Ministry of Foreign Affairs both to provide funds—this represented the first time two ministries funded a project jointly.

What do you see as GHIT's progress to date? What challenges and opportunities do you see in GHIT's future?

I believe that having global public-private partnerships from the





very beginning has been a key factor in the GHIT Fund's success to date. The drug development pipeline is progressing steadily, even with relatively limited funding. Our scope of activity will also further expand. However, we are coming to a critical moment. It is important that we reach our initial goal, which is to produce and ensure the delivery of drugs and vaccines to low- and middle-income countries.

Keizo Takemi, LLM, is a Member of Japan's House of Councillors and Chairman of the Special Mission Committee on Global Health Strategy for Japan's Liberal Democratic Party. He is also Senior Fellow at the Japan International Exchange Center and Visiting Professor at Keio University, Nagasaki University, and Minobusan University. Previously, he was Senior Vice-Minister of Health, Labour and Welfare in the Government of Japan, where he has also been Parliamentary Secretary for Foreign Affairs. He has also been a Professor in the School of Political Science and Economics at Tokai University, a Visiting Fellow at Harvard University's School of Public Health, and a television anchor in Japan.



ANA HOLDINGS INC.





salesforce.com Co.,Ltd.

Senior Manager Corporate Brand & CSR, Corporate Communications ANA HOLDINGS INC.

Natsuki Uota



Morrison & Foerster



Hisateru Goda Partner

Kenji Hosokawa Partner

SPONSOR INTERVIEWS

Our shared vision drives creative partnerships for global health innovation



MORRISON FOERSTER



Yahoo Japan Corporation



Gen Miyazawa Executive Corporate Officer EVP, President of Media Group Yahoo Japan Corporation

> Non Profit Sales Account Executive

Rie Endo Director Salesforce.org

Lead Solution Engineer Solution Engineering

Keisuke Ueda Toshikazu Watanabe Service Cloud Specialist Solution Engineering

> Ken Wakamatsu Product Management Director

Mori Building Co., Ltd.



Shun Hirano Office Leasing Unit 1, Office Business Department

Midori Aoyama Office Leasing Unit 1, Office Business Department



Natsuki Uota

Senior Manager Corporate Brand & CSR, Corporate Communications ANA HOLDINGS INC.

"We can support product development by gathering innovation catalysts."

An airline's role in the fight against infectious diseases

ANA handles air shipping operations for a range of industries. We are fully aware that global issues such as infectious diseases directly affect our business. We have seen outbreaks of severe acute respiratory syndrome, influenza, Ebola, and other emerging diseases, and in each case have made exhaustive efforts to minimize their impact on both business and human health. We have done this through compliance with airline-related safety policies and through airport quarantines. Meanwhile, we are always wondering, as a corporation, what else we can do.

In 2014, we learned about the GHIT Fund. When we heard that sponsorship was possible, we thought, "it is imperative that we join forces."

The core of our business is to deliver customers and goods safely and on time. When outbreaks occur, customers and employees certainly feel uneasy. For us, it makes sense to halt non-essential movement or transit of people and goods whenever threats to safety are present. Our customers' justified discomfort with participating in air travel during such times certainly makes a significant impact on our bottom line. We as an individual airline cannot control an outbreak of infectious diseases by ourselves, but we can implement countermeasures in support of broader efforts. Therefore, we are honored to tackle the problem of infectious diseases, both directly and indirectly, with GHIT.

Sponsoring in-person connections

As a sponsor, we support travel to and from Japan for GHIT's overseas researchers and Selection Committee members. Many of these experts hail from across North America, South America, Asia, Europe, and Africa.

We appreciate that information technology has made cross-border communication easy. Nevertheless, we do believe that certain discussions should happen in person. We are very pleased that we can advance unique





relationships between [experts] from different countries, regions, and affiliated organizations.

ANA cannot create drugs or vaccines, but we can support the ecosystem for their creation by gathering those who can tangibly foster innovation and advance product development.

Shared urgency

We cannot predict exactly which infectious disease epidemics will hit, when, but we know more epidemics will come. We strongly identify with GHIT's sense of urgency in executing on its mission and vision.



Gen Miyazawa

Executive Corporate Officer EVP, President of Media Group

"After all, people cannot address problems of which they are unaware."

A responsible news source

Every day, Yahoo! Japan receives over 4,000 articles from various media sources. Over the past few years the number of both daily readers and news articles has rapidly increased, and Yahoo! News is now firmly established across the globe as a credible news source. As our role as a news source grows, we feel a responsibility to leverage our reach and diverse audience to make important social matters not traditionally considered "mainstream" more accessible for the general public.

Our sponsorship of GHIT fits perfectly with this trajectory. Our goal is to inform our diverse audience of the challenges and opportunities that exist today-to raise awareness in Japan.

Partnering to raise awareness

The first initiative Yahoo! Japan undertook in partnership with GHIT was to interview five Japanese researchers who have made transformational contributions to global health research. The impact of this partnership has already borne fruit. The articles about Nobel Laureate Professor Satoshi Omura and other researchers were widely read.

Our role in helping to draw attention to

this research and these wonderful professors resonated deeply. Before our special features were published, these researchers had not often been highlighted in Japan's mainstream media.

Internal enthusiasm

The team that undertook the interview project with GHIT was a highly motivated group of individuals. I did not request volunteers; rather, many people proactively sought a role in the project. In their role as representatives of a "problem-solving engine," it is important that our employees take individual initiative to identify social challenges.





Without awareness there can be no action

By partnering with GHIT, Yahoo! Japan can create opportunities for many people to learn about GHIT's efforts and global health. Awareness-raising is critical. After all, people cannot address problems of which they are unaware. We also appreciate that awareness-raising goes hand-in-hand with creating opportunities for action.

Tangible global health solutions like the tools GHIT is developing require a great deal of time to create. During this process, we can continue to keep people updated about progress and why such work continues to be important.



SPONSOR INTERVIEWS

salesforce.com Co.,Ltd.

Keisuke Ueda

Toshikazu Watanabe

Rie Endo

Masahiro Ishijima

Ken Wakamatsu

"It is a great honor that our technology can help address social problems."

A two-track approach: core business and social contribution

Ken Wakamatsu: Salesforce was

established in San Francisco in 1999, and the Japanese subsidiary was founded in 2000. We offer cloud-based customer relationship management services that leverage social, mobile, and artificial intelligence technologies, enabling personalized engagement and communication to help companies effectively connect with their customers.

Rie Endo: We launched Salesforce.org, the philanthropic arm of Salesforce, in 1999 and have been taking a two-track approach to grow and enhance both our business and our broader contribution to society. Our employees contribute 1% of their working hours to social contribution activities. Such activities include volunteer activities and the provision of our technology and strategic financial investment to other nonprofit organizations. Our activities vary from organization to organization, including educational



support, support for the elderly, and provision of solutions to address environmental problems.

Keisuke Ueda: In the case of the GHIT. Wakamatsu provides product development expertise, and Ishijima and Watanabe have helped GHIT conduct a major core system analysis to increase operational efficiency and lay the groundwork for institutional expansion

Institutional growth through pro bono work

Endo: Our pro bono works give us opportunities to see and think about our products from a more intimate customer perspective. This helps us continuously improve our services and communicate more effectively with our business partners.

Toshikazu Watanabe: Salesforce actively encourages us to engage in pro bono activities, and I have had many opportunities to try different things. I am pleased to be able to support nonprofit organizations as a pro bono volunteer by making full use of my technical expertise, such as system implementation and operational methods.

Masahiro Ishijima: Many of our customers are large corporations whose indirect contributions to society



as taxpayers and employers are critically important. Nonprofit organizations often make a more direct impact on society; through our work with them we can also make a direct contribution—with our technology and our experience.



Salesforce × GHIT

Wakamatsu: There are many areas in which we can work to make the current GHIT data management system better. We believe that we can help the organization grow further by using our technology to organize information and processes more efficiently, and we are looking forward to that.

Ueda: I personally would be truly happy if the organizations can expand their activities by using various products and platforms comprehensively and effectively. As their trusted partner, we would like more people to get involved in our pro bono activities and achieve success by working with us.



Morrison & Foerster

Hisateru Goda

Kenji Hosokawa

well as in Europe and Asia. This year marks the 30th anniversary of the opening of our Tokyo office.

Our partnership with and sponsorship of GHIT began when Mr. Ko-Yung Tung, our Senior Counselor, became a GHIT Supervisory Board member.

The relationship between Morrison &

Hisateru Goda: Morrison & Foerster is

an international law firm founded 130

years ago in San Francisco, California.

Currently, it has offices along the West

and East Coasts of the United States, as

Foerster and GHIT: origins

Preparing legal documents essential to GHIT's activities

Goda: The majority of our work for GHIT has consisted of reviewing contracts. Certain contracts may be written in English, but they are governed by Japanese law.

Kenji Hosokawa: Our first project with GHIT was the development of a framework and template for its investment agreement with product development partners. Having developed the template, we now assist GHIT in negotiating the investment agreement for each grant, which requires us to move more quickly.

Leveraging legal expertise in activities to support the social good

Goda: Morrison & Foerster is originally an American law firm. In the United States, lawyers are expected to engage in public service and are encouraged to do pro bono work that leverages their expertise. I remember being told at my last interview when registering myself as a New York attorney, "Now that you are a lawyer, be sure to do pro bono work." The Pro Bono Committee set up within our firm determines which pro bono matters we take on. Examples include supporting an organization that protects minority rights, an environmental conservation organization, an organization working to improve education or address poverty, and an organization providing care for post-disaster psychological traumas.



MORRISON FOERSTER

"GHIT's success lies in the strong foundation of its backers."

Through our work with GHIT, we are able to see contracts that we would not normally see in our daily work, which increases our awareness of the variety of contracts that exist. They give us opportunities to think thoroughly about technical legal issues we would not normally think about in other transactions, such as governing law. Such opportunities to think theoretically about legal issues are rare and invaluable.

Working with a new type of organization

Hosokawa: I think that GHIT is an organization set up with a great deal of consideration. There are many ways to tackle global problems; GHIT is building a new form of public-private partnership to improve global health. This in and of itself is extremely valuable.

SPONSOR INTERVIEWS

Mori Building Co., Ltd.

Shun Hirano

Office Leasing Unit I, Office Business Department Office Leasing Office Business D

Midori Aoyama

"GHIT's pioneering partnership model complements our concept of open-minded cities."

Urban development and global health

Shun Hirano: As shown by our ARK Hills and Roppongi Hills projects, we have engaged in long-term urban development while continuously promoting dialogue with local residents for many years. From a global perspective, we see the promotion of urban development and attracting people, dynamic businesses, and capital from around the world as essential to Tokyo and Japan's future. The Mori Building Company's corporate climate is pretty unconventional, strongly embracing individual contributions and creativity. We hope to maximize the potential of "open-minded" cities where people from around the world can connect in new and inspirational ways.

GHIT links organizations in Japan and overseas to develop new drugs; in other words, it harnesses creative partnerships to accelerate critical innovation. In doing so, GHIT has introduced new value in the global health field and the overall function of public-private partnerships across sectors and borders. This complements our concept of open-minded cities. This is why our urban development company become a sponsor of GHIT.

Midori Aoyama: Since its establishment, GHIT has been headquartered in the Sengokuyama Mori Tower within our ARK Hills complex. In addition to using our offices, GHIT has held several Annual Partners Meetings and other public events at our Roppongi Academy Hills forum facility.

The 2016 Annual Partners Meeting left a particularly strong impression on me. One of the speakers was a clinician from Africa who brought to life the problem of local infectious diseases in his region. It was shocking to hear that infectious diseases that are almost unheard of in Japan are damaging the health and taking the lives of so many children. At the same time, as a citizen of Japan, I felt proud that experts from Africa, which is far away from Japan, and Japanese researchers were collaborating to develop vaccines and drugs using Japanese technology and





A new lens for Japan's influence

expertise. It also meant a lot to see Japan leading and participating in global initiatives.

Accelerating urbanization, and countermeasures for infectious diseases

Hirano: Globalization and urbanization are 21st century facts of life. The rapid movement of people in and out of Tokyo and other cities around the world is likely to pick up speed. Therefore, we need to keep the risk of infectious diseases top of mind. As was the case with the dengue fever outbreak in Tokyo a few years ago, once an infectious disease spreads throughout an urban area, it greatly affects the daily life of all people. Considering the fact that the Tokyo 2020 Olympic and Paralympic Games will result in even more people from within and outside Japan visiting the city, we may be able to take special action from the security and safety points of view.



STAFF STORY

Four staff members, each of whom has been with the team from the time of GHIT's launch, discuss their passion for global health, perspectives on partnership, visions for the future, and reflections on their work over the past five years.

Toshie Ando

Vice President Finance & Operations

Bumpei Tamamura, MPH

Senior Director Brand Communications External Affairs

Saho Kitawaki

Senior Manager External Relations External Affairs

Kei Katsuno, MD, MPH

Director Investment Strategy & Development Government Affairs

Saho Kitawaki: I joined GHIT at the true start of the organization (long

starting from scratch

before its official launch in April 2013). There were only two of us at the time — Dr. BT Slingsby and me. We were starting from scratch, preparing the articles of incorporation and hiring new staff.

A global health R&D challenge:



Small temporary office in January 2013

The launch committee set up to build GHIT went beyond individual companies and organizations. thought that the way in which each member went about his or her tasks with such determination was truly impressive. Even now, I vividly remember everyone's solidarity, which increased every time we met. am sincerely grateful to those who have been involved and have supported us since our inception. It



Clinical site visit in Tanzania: clinical trial of pediatric PZQ formulation for the treatment of schiste



is because of these people that we were able to establish GHIT, which is now a high-functioning organization.

Becoming a team on the global stage

Toshie Ando: One of GHIT's major roles is to increase Japan's presence on the international stage. We always think about what kind of spaces would enable Japanese people to demonstrate their capabilities. believe that creating such a space is one of my, and GHIT's, roles — so I'm very happy when we are appreciated for "providing a space" where people find strategic partners. How GHIT responds to the increasing expectations from those around us will be both challenging and interesting.



Kei Katsuno: GHIT's business model makes it unique: contributing to global health as a public-private partnership specializing in product development. GHIT's success also illustrates that it is possible to help resolve societal problems with strategic fundraising and product development through global partnerships. If GHIT can steadily build up its track record, then similar organizations could emerge across various disciplines, not just domestically, but internationally as well.

Kitawaki: I believe that one of the key roles GHIT plays is to create a successful example of how cooperation between the public and private sectors can contribute to global health. It's a contribution with great importance for both Japan and the world, so even just the creation of a new model was significant. But the real work begins now. Our true mission is realized only when a drug in which GHIT invests is approved and starts benefitting people in developing nations. That is the real meaning of success.

A small team with a big impact

Ando: GHIT's appeal is in the strength of heart of our chairman, Dr. Kiyoshi Kurokawa; our CEO, Dr. BT Slingsby; and our partners, funders, and staff. Working with experienced, highly motivated people often causes people to notice things that they had not perceived before. I am deeply thankful for an environment where I can work under the direction of visionary leaders and see things from a high-level perspective, which I think is one of

Bumpei Tamamura: Since GHIT is a small organization of less than 20 people, demands for speed, quality, and workload on staff are high. GHIT is a nonprofit organization, but we are very similar to a company in how

GHIT's advantages.

we work. I would like us to be an organization that can continue to make a large impact with a small team. However, our ability to have an impact with these select few is only possible because we are supported by many people at home and abroad. We could not have made it this far without assistance from the people supporting GHIT day and night, not only with investment but





An unprecedented organization

Kitawaki: GHIT has been moving at top speed over the last five years, with growth always in mind. Constant evolution has been our natural state. GHIT is gaining more recognition globally, and we will need to continue to evolve to be a truly international organization.

Tamamura: By repeatedly taking on new challenges, failing fast, and immediately improving our processes, the staff has gained significant confidence. I have been able to grow individually, too. GHIT is a relatively young organization, but



we have mobility, creativity, and passion. The career histories of our team are diverse, and the range of things that the team can do is expanding. Because these teams are led by directors, a selection committee, and advisors who provide strategy and governance, I think we can be confident about the next five years.



GHIT Board meeting held at Wellcome Trust in London in July 2017



Katsuno: Recognition of the GHIT Fund is increasing. When I travel overseas, I am often asked about how GHIT was formed and how it continues to operate. I appreciate that other players want to make the GHIT Fund a model for public-private partnerships and fundraising mechanisms. I would like to help lead this model, contributing from Japan on an even broader scope.

*This article combines and condenses content from interviews conducted with each individual staff member in August 2017. Full content for each individual interviews is available on GHIT's 5th Anniversary Website: http://5th.ghitfund.org/staffstory/en The titles and affiliations listed in this article represent staff members' titles and affiliations at that time.



A Conversation with Our Chair and CEO

World's First Global Health **R&D** Fund

Kiyoshi Kurokawa: Five years have passed since GHIT's establishment. Before, there were only a few Japanese companies, universities, and research institutes engaged in global health R&D. Now, more than 40 Japanese institutions have participated in GHIT's investment platforms, which is very exciting. In fact, an even bigger number of Japanese institutions have applied for investment from GHIT. This level of interest and engagement has surpassed our expectations. It means a lot to me to see this transformative change in Japan's

engagement in global health R&D over the past five years.

BT Slingsby: Indeed, when considering that Japan ranks third in the world for new drug development, its pharmaceutical sector was not engaged in global health R&D before GHIT. Now Japan's pharmaceutical companies are some of the most engaged entities worldwide. This truly underlines the leadership of these companies and the passion of their scientists. Each and every one of our

investments is in a global partnership between Japanese and non-Japanese entities resulting in a model of open innovation realized and driven by GHIT

Kurokawa: Historically speaking, Japan has shown great leadership potential in the global health. At the Okinawa G8 Summit in 2000, Japan put global health on the agenda and led the inception of The Global Fund to Fight AIDS, Tuberculosis and Malaria. In addition, Japan hosted the Toyako G8 Summit in 2008 and the Ise-Shima G7 Summit in 2016, prioritizing global health as a key agenda item requiring global attention, which increased commitment from G7/G8 countries. Moreover, building on Japan's legacy of global health leadership, GHIT has demonstrated the strength of Japanese R&D as a key global health accelerator.

GHIT's steady progress over the past 5 years is attributed to several factors: first, proactive efforts by Japanese institutions; second, a financial partnership between the Bill & Melinda Gates Foundation, the Wellcome Trust, the Government of Japan, and Japan's leading pharmaceutical companies; and third, R&D partnerships with PDPs. From a brief glance at our highly diverse leadership in the Council, Board of Directors, Selection Committee, and Advisory Panel, it is clear that GHIT is the only true "international" Japanese public interest incorporated association. GHIT's leadership has elevated and maintained the guality and level of our business operations.

Slingsby: I am glad you pointed this out. Very few realize the disruptive innovation that GHIT has created for the non-profit sector in Japan. As Japan's first public interest incorporated association governed and managed as a global institution, this was challenging at first. Anywhere from our Articles of Incorporation to our delineation of governance and management are based on an international approach that take into account norms in North America, Europe, and Japan, collectively. This is a first for a public interest incorporated association in Japan and we hope this leads to a more

Kurokawa: Developing new medicines is not something that can be done overnight. Industry data suggests that it takes almost a billion dollars over the span ten years plus to develop a single new drug. GHIT is trying to accomplish this with less time and money through unique partnerships between Japanese and overseas entities. We understand that this is very ambitious, but our passion resonates from the unmet needs of patients. We should emphasize that collective, cross-sectoral and global collaborations by government, foundations, industry, research institutions, and universities are truly valuable. Finally, BT and I would like to express our gratitude for the support from all our partners. We look forward to further collaborations in the second phase as we aim to accelerate global health R&D.

Board Chair

Japan-based "global" non-profits in the future. We came up with this vision in the GHIT Launch Committee, back in the summer of 2012. This committee, comprised of GHIT's founding partners, worked with me to lay the roots of what now is a growing global organization in Japan.

Toward GHIT Fund 2.0

Slingsby: During GHIT 1.0, spanning from FY 2013 to FY 2017, we were able to build a robust portfolio of investments using Japan-based technologies, capacities, and capabilities. For GHIT 2.0, beginning in FY 2018, our goal is to move these products through the pipeline and look to see that they affect patients' lives —this is what we must achieve. More collaboration is needed among partners here in Japan and on a global stage as well; we will need to ensure strategic investment and stringent portfolio management.

Kinovlij Kunokama 25

Kivoshi Kurokawa. MD

BT Slingsby, MD, PhD, MPH Chief Executive Officer

GHIT Fund History

Timeline of key milestones

2011

September 2011

Matching funds raised by the Government of Japan, Japanese pharmaceutical companies, and the Bill & Melinda Gates Foundation



2012 July 2012 GHIT Fund Launch Committee established

2013

April 2013

GHIT Fund, the world's first public-private global health R&D fund launches. Government of Japan (Ministry of Foreign Affiars and Ministry of Health, Labour and Welfare), UNDP, Bill & Melinda Gates Foundation, Astellas, Daiichi Sankyo, Eisai, Shionogi and Takeda are GHIT's founding partners



May 2013 Japan develops the Strategy for Global Health Diplomacy

June 2013 Japan develops the Revitalization Strategy

June 2013

GHIT press conference at The Fifth Tokyo International Conference on African Development in Yokohama



2014 March 2014

Cumulative investment USD 19.1 million



Cumulative number of invested partnerships



April 2014

Development and registration of a new PZQ pediatric formulation for the treatment of schistosomiasis (Phase 1 began)



June 2014 GHIT certified as a Public Interest Incorporated Association



July 2014 Japan develops the Healthcare and Medical Strategy

December 2014 Chugai Pharmaceutical joins GHIT as funder



2015

January 2015 Development of DSM265 as a long-acting antimalarial compound (Phase 2 began)



March 2015 Cumulative investment USD 46.1 million

USD 46.1 Million

Cumulative number of invested partnerships



*Continuation projects included

June 2015 Wellcome Trust, Sysmex Corporation join as new funders: ANA, Morrison & Foerster, and Yahoo! Japan join as new sponsors







July 2015

Clinical development of the BK-SE36 malaria vaccine candidate (Phase 1 began)



October 2015

Japanese scientist Satoshi Omura receives Nobel Prize in Physiology or Medicine for discoveries concerning a novel therapy against infections caused by roundworm parasite



2016

February 2016 DAR-901 whole cell booster vaccine to prevent tuberculosis infection in adolescents (Phase 2 began)



March 2016 Cumulative investment USD 63.7 million

USD 63.7 Million





April 2016





June 2016 Development and registration of a new PZQ pediatric formulation for the treatment of schistosomiasis (Phase 2 began)



June 2016

FUJIFILM, Otsuka, GSK, Johnson & Johnson, Kyowa Hakko Kirin, Merck, Mitsubishi Tanabe, Nipro, Sumitomo Dainippon Pharma join as funders; Salesforce.com joins as sponsor

FUJIFILM

KYOWA KIRIN





Preclinical and clinical development of (+)-SJ000557733, a novel inhibitor of Plasmodium ATP4 (Phase 1 began)

Government of Japan announces decision to contribute USD 130 million to GHIT Fund/UNDP replenishment at the G7















October 2016

A new treatment for Chagas disease (Phase 2 began)



2017

June 2017

GHIT Fund announces its replenishment with a USD 200 million commitment for the next five years (FY2018-FY2022)



October 2017 Cumulative investment USD 115.3 million



Cumulative number of invested partnerships



December 2017 GHIT Fund 2.0 Strategic Plan published





Clockwise from left: Yoshihiko Hatanaka (Representative Director, President and CEO, Astellas Pharma Inc.), Tatsuro Kosaka (President & COO, Chugai Pharmaceutical Co., Ltd.), George Nakayama (Representative Director, Chairman and CEO, Daiichi Sankyo Company, Limited), Haruo Naito (Representative Corporate Officer and CEO, Eisai Co., Ltd.), Isao Teshirogi (President and CEO, Shionogi & Co., Ltd.), Christophe Weber (Representative Director, President and CEO, Takeda Pharmaceutical Company Limited), Stephen Caddick (Director, Innovations Division, Wellcome Trust), Eiji Hinoshita (Director, Global Health Policy Division, International Cooperation Bureau, Ministry of Foreign Affairs), Kiyoshi Kurokawa (Representative Director and Chair, GHIT Fund), BT Slingsby (CEO, GHIT Fund), Naoko Yamamoto (Assistant Minister for Global Health, Minister's Secretariat, Ministry of Health, Labour and Welfare), Andrin Oswald (Director, Life Sciences Partnerships, Bill & Melinda Gates Foundation) *As of June 1, 2017.





Global Health Innovative Technology Fund

75

Global Health Innovative Technology Fund

The GHIT Fund held a press conference at the Kioi conference center in Tokyo on June 1, 2017, announcing its replenishment with a USD 200 million commitment for the next five years (FY2018–FY2022) from its funding partners. The following GHIT Council members participated: Government of Japan (Ministry of Foreign Affairs and Ministry of Health, Labour and Welfare), Japanese pharmaceutical companies (Astellas Pharma Inc.; Chugai Pharmaceutical Co., Ltd.; Daiichi Sankyo Company, Limited; Eisai Co., Ltd.; Shionogi & Co., Ltd.; and Takeda Pharmaceutical Company Limited), and foundations (Bill & Melinda Gates Foundation and Wellcome Trust).

GHIT Fund CEO Dr. BT Slingsby opened the press conference by revisiting GHIT's inception, when the Japanese government, Japanese pharmaceutical companies, and the Bill & Melinda Gates Foundation collaborated to create a matching fund to promote product development for infectious diseases by using Japan's untapped pharmaceutical technology and capabilities. He shared key activities and investments to date

illustrating how, in just four years, Japan's innovations have made a critical impact on global health R&D.

Dr. BT Slingsby also described six GHIT-funded clinical trials that are currently taking place in Africa and South America. He noted how replenishment funds will be used to accelerate these trials and other product development in order to move products to market. The USD 200 million replenishment amount effectively doubles the size of the GHIT Fund. "In our second phase, it is imperative for us to accelerate product development further and deliver those products to patients. We will build a delivery strategy in partnership with domestic and overseas organizations," Slingsby mentioned.

Additionally, Dr. Isao Teshirogi, President and CEO of Shionogi & Co., Ltd., gave a keynote lecture on behalf of the Council of the GHIT Fund, entitled "Accelerating Japan's Innovation for Global Health." Dr. Teshirogi discussed key global health issues, such as threats of emerging and reemerging infectious diseases on the



global scale, the impact of NTDs, and access to medicines and healthcare. He also emphasized Japan's responsibility and role in tackling these issues. First, Japan is one of the world's leading drug discovery countries and has a responsibility to address unmet medical needs. Second, from the perspective of national security, it is important to protect the health of Japanese citizens against infectious diseases beyond national borders. Third, Japanese pharmaceutical companies can contribute to creating a new market in low- and middle-income countries by supporting and improving public health in the global health arena.



Dr. Isao Teshirogi (President and CEO, Shionogi & Co., Ltd.)

Dr. Teshirogi emphasized that the GHIT Fund is a successful case of public-private partnership. "All Council members here today are seriously committed to the GHIT Fund for doing the right thing. It is very rare for CEOs of pharmaceutical companies to get together, but all CEOs here have been strongly committed to and passionate about the GHIT Fund for a long time and for a specific mission. I do not know of any other public-private partnership like this successful case." He



"I do not know of any other public-private partnership like this successful case."



Prof. Stephen Caddick (Director, Innovations Division, Wellcome Trust)

Teshirogi went on to describe the solidarity and unity between the GHIT Fund and its stakeholders and expressed hope for further changes in attitudes towards global health R&D, including among the Japanese government, companies, and academia. Dr. Teshirogi

concluded by indicating that "Continuing this momentum reinforces Japan's leadership and international presence."

In the Q&A session, journalists asked about the impact of government changes in Europe and the United States on health-related budgets, and the expected role of private companies and foundations in this environment. Council members provided such responses as "We are now living in an uncertain time, but there is nevertheless an opportunity to demonstrate our leadership" and "The field of global health has always experienced significant funding gaps, therefore we should work together by utilizing the strengths of public-private partnerships and leveraging knowledge, funds, and resources in order to deliver products to those who need them the most."

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

> Dr. Kiyoshi Kurokawa, Chair of the GHIT Fund, concluded that it is essential to further strengthen and improve governance and management capabilities in the GHIT Fund in order to meet expectations in the institution's second phase.



Dr. Kiyoshi Kurokawa (Representative Director and Chair, GHIT Fund)

MESSAGES FROM PARTNERS ON GHIT FUND REPLENISHMENT



Wellcome Trust

"Japan has an outstanding science base for the rapid advancement of new ways to people around the world who need them



Yoshihiko Hatanaka

"GHIT catalyzed a mindset shift for the health issues by combining their R&D



Koichi Aiboshi

"Japan has a long history in global inclusion of infectious diseases to the G8 agenda, and during the most recent summit, the first G7 summit after the adoption of the Sustainable Development Goals, global health was highlighted. I am Summit outcome document as a well-coordinated public-private partnership for R&D. Our investment in clear signal that Japan has a sustained commitment to global health."



Naoko Yamamoto

"By leveraging GHIT's new platform, we and abroad that Japanese pharmaceutical to the nation's health, but to global health as well. Based on these successful companies and research organizations in Japan become motivated to help address the challenges of global health, and this global health R&D."



Trevor Mundel Bill & Melinda Gates Foundation

commitment to transforming the global greatest burdens of disease in low- and



George Nakayama

resources to bring to bear on global leverage our technologies for global



Haruo Naito

to deliver those medicines to all the malaria, and tuberculosis, which are a medicines and improve access through Fund's new endeavors on this front. Eisai



Osamu Nagayama

"In order for the global society to develop" further, the realization of global health Fund is the world's first public-private aiming for global health and engages in a critical mission. Chugai will contribute to human health around the world with its



Isao Teshirogi

innovators and producers of lifesaving medicines, vaccines, and diagnostics. We these medicines and improve overall



Christophe Weber Takeda Pharmaceutical Company Limited



Magdy Martínez-Solimán Assistant Administrator and Director

is proud to partner with Japan and GHIT, including through its Access and Delivery bottlenecks within their health systems so



Shigetaka Komori

"Partnering with the GHIT Fund has





Nobuo Hanai

treatments. Partnering with GHIT, which



Tatsuo Higuchi

in the creation of delamanid, one of the half a century. Our partnership with the GHIT Fund enables us to further contribute to new drug development for



Hisashi Ietsugu

Fund, we will accelerate the creation of infectious diseases."



Kihito Takahashi Development and Medical Affairs Division GlaxoSmithKline K.K.

innovative medicines and vaccines to save member of GHIT Fund and of supporting the same mission to overcome global



Masayuki Mitsuka President & Representative Director Mitsubishi Tanabe Pharma Corporation

and creating new treatments for the infectious diseases that burden the



Masayo Tada

people not only in Japan but also around how we can utilize our innovative drug disease fields in which there are significant unmet medical needs, thereby



Belén Garijo Merck KGaA

Praziquantel Donation Program. Our

GHIT Fund 5th Anniversary