



GHIT^{ON} THE GROUND INNOVATION & IMPACT

EVENT REPORT

June 7, 2016 14:00-16:30
Tower Hall at Roppongi Academyhills 49F
Tokyo, Japan

GHIT Fund

Global Health Innovative Technology Fund





*We Are Expanding.
We are On the Ground.
We Will Deliver.*

On June 7, the GHIT Fund held its third Annual Partners Meeting to discuss the impact on the ground and the value that GHIT's expanding partnership network brings to global health R&D.

The running theme throughout the event was the remarkable forward momentum of GHIT in terms of its work and progress since it was established just three years ago. This momentum is evidenced by the May 20th pledge by the Government of Japan to contribute \$130 million to GHIT's replenishment, and by the announcement of 10 new GHIT partners on June 6.

In his opening remarks, GHIT's CEO and Executive Director BT Slingsby set the tone for the day by delivering three key messages about the Fund's forward momentum.

We are expanding: As a public-private partnership of 10 organizations launched just three years ago, GHIT now counts 26 partners and

sponsors. In addition, the GHIT's network of product development partners has grown to 75 organizations around the world. "Each individual partner is driving forward Japanese innovation for global health," said Dr. Slingsby.

We are on the ground: GHIT-funded projects are now under way in Uganda, Tanzania, Burkina Faso, Ivory Coast, Peru, and Bolivia, in partnership with local community hospitals, companies, and governments. Dr. Slingsby lauded the enormous efforts local partners are putting forth to advance clinical trials in developing country settings.

We will deliver: GHIT's pipeline is advancing rapidly, and the Fund expects its first products to reach the market within the next few years, potentially including a malaria vaccine and a pediatric formulation of Praziquantel for schistosomiasis. "Just imagine," Dr. Slingsby said, "in just a few years a GHIT-funded product will positively affect millions, if not billions, throughout

the world. This is Japanese innovation having a direct impact on people's daily lives."

Dr. Slingsby also reminded participants that it takes a community to realize the dream of global health R&D innovation: "As a collective group of empowered and passionate people, empowered and passionate organizations, we can deliver Japanese innovation for global health.

We can do it right, we can do it with passion, and we can do it with joy."

All three messages, as well as the theme of joy and passion, echoed throughout the day's discussions.



Dr. BT Slingsby

Panel 1: GHIT on the Ground: Innovation and Impact

The first of the day's interactive sessions, moderated by Dr. Naoko Yamamoto, Assistant Minister for Global Health at the Ministry of Health, Labour and Welfare and GHIT Council member, showcased two GHIT-funded clinical trials currently underway in the developing world, the significance and impact of the tools being developed, and how Japanese innovation is helping to drive progress forward. Speakers included clinical trial leaders from GHIT's development partners in Africa and their Japanese counterparts.

Dr. Sodiomon Bienvenu Sirima, Executive Director at the Centre National de Recherche et de Formation sur le Paludisme, Burkina Faso, and Dr. Toshihiro Horii, Professor of Molecular Protozoology at Osaka University's Research Institute for Microbial Diseases, explained the significance and impact of the BK-SE36 malaria vaccine candidate, originally developed at Osaka University and currently undergoing a Phase I trial in Burkina Faso. Dr. Muhidin Kassim Mahende, Clinical Research Officer at Tanzania's Ifakara Health Institute, and Dr. Hiroyuki Kojima, Research Fellow at Astellas Pharma Inc.'s Pharmaceutical Research and Technology Labs, provided insight into the development and clinical trials of a new pediatric formulation of Praziquantel—the gold standard treatment for schistosomiasis. The Phase I trial was conducted in Tanzania and the Phase II trial has also been conducted in Ivory Coast.



From left: Dr. Naoko Yamamoto, Dr. Hiroyuki Kojima, Dr. Muhidin Kassim Mahende, Dr. Toshihiro Horii, Dr. Sodiomon Bienvenu Sirima

Dr. Sirima outlined the urgent global need for a malaria vaccine. Worldwide, over 200 million suffer from malaria each year, resulting in roughly 500,000 deaths. In Burkina Faso alone, eight million (44% of the population) are affected, mostly children. One million malaria patients occupy one-third of the country's hospital beds—a significant burden on the national health system. Further, mosquitoes that carry the malaria parasite are resistant to insecticide, and the parasite itself is also becoming resistant to treatment. “The availability of an affordable, effective malaria vaccine will not only help individuals stay healthy,” Dr. Sirima noted, “but also have a profound, positive effect on Burkina Faso's healthcare system and the economy.”



Recent trials among children aged 1-5 years in Burkina Faso showed no severe side effects; if ongoing monitoring

demonstrates symptomatic protection, the partnership will proceed to large-scale Phase III trials and eventually seek U.S. FDA approval.

Such promising achievements do not come easily. Dr. Horii reminded participants that prior attempts to develop malaria vaccines have not been effective, as the antibodies they induce can only bind one of several forms of the malaria antigen. BK-S36 can bind all malarial structures, and is highly immunogenic and thermostable.

Shifting to the session's second case study, Dr. Mahende explained that schistosomiasis also represents a significant health burden. Affecting over 200 million worldwide each year, the disease does not kill, but causes serious and permanent liver and spleen complications if left untreated. Over half of the Tanzania's population are infected, mostly children and youth. While the treatment drug Praziquantel has been available since the 1970s, the tablet is too large and bitter for children to swallow, leaving them untreated during the crucial period following infection. “If there are no appropriate dosage forms, that means no access to the medicine for some patients, even though the active ingredients are very promising and effective,” said Dr. Kojima. Trials among Tanzanian children confirmed that the new pediatric formulation under development will be more palatable and appropriately sized for

“If there are no appropriate dosage forms, that means no access to the medicine for some patients, even though the active ingredients are very promising and effective.”



children. “We observed that the new ODT tablets (Oral Dispersible Tablets) work very well,” said Dr. Mahende.

The Praziquantel (PZQ) Consortium provides an excellent example of how GHIT-funded projects allow partners to contribute unique expertise to a common goal. In this case, Merck contributed its PZQ expertise, while clinical trial experiences came from Swiss TPH; Lygature provided project management, and Astellas offered its expertise in developing pediatric drug formulations. Farmanguinhos brought unique expertise to produce the new pediatric formulation candidates. Simcyp built and validated a pharmacokinetic model to allow better prediction of appropriate dosage regimens in pediatric clinical trials. It is precisely this kind of collaboration that the GHIT seeks to enable through its investments.

Dr. Kojima added another important reason for why Astella joined the consortium: “Our team members showed very strong interest in doing something for African children. Our top management accepted our proposal in consideration of the importance of this program.” In short, passion was the driving force; the major motivation was doing right; and an important result: joy.

The pediatric PZQ formulation journey, like that of BK-S36, has not been without challenges. Initial efforts were made to develop smaller tablets, called “mini tablets,” but they were so small

that they posed a choking hazard. The current ODT tablets are sufficiently small in size for children, dissolvable in water for infants, thermostable, and affordable.

Speakers also discussed broader challenges for partnerships across sectors and continents. Ann Veneman, former Executive Director of UNICEF and current GHIT Board member, noted from the audience, “particularly when you try to put the NGO community together with the private sector, oftentimes the cultures are so different that it’s difficult to actually get people to work together, particularly those on the ground.” However, she added that passion, mutual respect, cultural

are key words for how the GHIT Fund cultivates and nourishes its product development partnerships.”

Panel 2: Partner Expansion

Building on the partnership theme, the second session of the day showcased GHIT’s expanding network and passion for its mission.

Dr. Nobuo Hanai, Executive Director of the Board, President, and CEO of Kyowa Hakko Kirin Co., Ltd. explained that the guiding principles of the GHIT Fund and Kyowa Hakko Kirin Co., Ltd. align



From left: Mr. Ko-Yung Tung, Mr. Gen Miyazawa, Mr. Shuichi Fujimura, Dr. Ann Mills-Duggan, Dr. Nobuo Hanai

flexibility, and transparent communication can overcome such challenges.

In the words of Dr. Horii, “Each partner has a diverse cultural background and customs. Africa and Japan are very far from each other. To be good partners, we have to be flexible and appreciate each other’s cultural differences. The benefits are numerous: important strides for global health R&D, important friendships and mutual learning, and the joy that results.” Underscoring this theme, Dr. Yamamoto added, “passion, joyfulness, and solidarity

towards a common goal: “Partnership with GHIT will help us realize our company philosophy of contributing to the health and well-being of people around the world.”

A natural alignment of missions also inspired the involvement of the Wellcome Trust in the GHIT. “We want to improve health for everyone by helping good ideas to thrive, ... and good ideas can come from anywhere,” said Dr. Ann Mills-Duggan, Head of Seeding Drug Discovery Fund, Business Development

and Innovations, Wellcome Trust. She lauded the Wellcome Trust's partnership with GHIT as a "very synergistic interaction," where each side is heard and actively benefits from the other's networks and expertise.

The panel also demonstrated that non-health organizations have a critical role to play in global health. "The airline industry," explained Mr. Shuichi Fujimura, Executive Vice President, International Affairs, Alliances and Purchasing, All Nippon Airways Co., Ltd. (ANA), "is very vulnerable to social events, political issues, economic issues, terrorism, and epidemics. We have seen the negative impact that SARS, MERS, Ebola, and Zika have on our industry." ANA supports GHIT activities in kind with the provision of airfare to and from Japan.



According to Mr. Gen Miyazawa, Executive Corporate Officer, Executive Vice President and President of the Media & Marketing Solutions Group at Yahoo Japan Corporation, media companies with access to large audiences also have a role to play in support of GHIT's vision by helping the public "understand the world's bigger challenges and social issues through the power of the Internet." Through a special dedicated website, Yahoo! Japan has taken on the challenge of helping to inform Japanese audiences about global health through articles based on interviews with GHIT-recommended experts. In addition to educating the public, "the platform also raises domestic

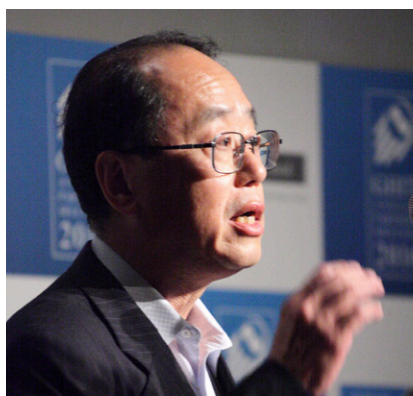
“ GHIT has made steady progress, including the facilitation and support of over 60 R&D projects between Japanese and international institutions. We take pride that R&D innovation originating in Japan contributes meaningfully to global health and to moving us closer towards the goal of eradicating infectious diseases rampant in developing countries. ”

awareness about the success of Japanese researchers in the world of infectious diseases,” added Mr. Miyazawa.

Mr. Ko-Yung Tung, Senior Counselor at Morrison & Foerster LLP and Member of GHIT's Board of Directors, issued a challenge at the session's close to all industry leaders: "No matter what sector you're in, there is a role that you can play. The recently launched Sustainable Development Goals require the engagement not just of member countries, but also the engagement of all sectors in member countries."

Japan's Continued Leadership in Global Health

Next, Professor Peter Piot, Director of the London School of Hygiene and Tropical Medicine and Member of the GHIT Board, introduced a very special guest: Dr. Hiroto Izumi, Special Advisor to Prime Minister Abe. Dr. Izumi reminded the audience of Japan's legacy of leadership in global health, including the recent G7 Communiqué from the Government of



Dr. Hiroto Izumi

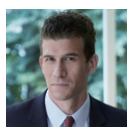


Dr. Kiyoshi Kurokawa

Japan announcing its \$130 million contribution to GHIT's replenishment and an overall \$1.1 billion allocation to global health initiatives. "Since its establishment in 2013," said Dr. Izumi, "GHIT has made steady progress, including the facilitation and support of over 60 R&D projects between Japanese and international institutions. We take pride that R&D innovation originating in Japan contributes meaningfully to global health and to moving us closer towards the goal of eradicating infectious diseases rampant in developing countries."

But of course, no nation is insulated from the threat of infectious diseases, Dr. Kiyoshi Kurokawa, Chairman of the GHIT Fund, pointed out in his closing remarks, detailing the example of tuberculosis that required travelers to present chest x-rays. He reiterated Dr. Izumi's recounting of Japan's leadership in global health and GHIT's remarkable progress in bringing Japanese innovation to infectious disease R&D on the ground in record time. Dr. Kurokawa expressed his delight in seeing GHIT's partner network expand so rapidly. In sum, he concluded, GHIT is expanding; it is on the ground; and it is delivering tangible results. Potential products are within reach by leveraging Japanese innovation.

Opening Remarks



BT Slingsby, MD, PhD, MPH
Chief Executive Officer,
Global Health Innovative Technology Fund

Panel Session 1. GHIT on the Ground: Innovation & Impact

Panelists

Clinical development of the BK-SE36 malaria vaccine candidate



Sodiomon Bienvenu Sirima, MD, PhD
Executive Director, Centre National de
Recherche et de Formation sur le
Paludisme (CNRFP), Burkina Faso



Toshihiro Horii, PhD
Professor, Research Institute for Microbial Diseases,
Osaka University

Development of a new praziquantel pediatric formulation for the treatment of schistosomiasis



Muhidin Kassim Mahende, MD
Clinical Research Officer,
Ifakara Health Institute,
Tanzania



Hiroyuki Kojima, PhD
Research Fellow,
Pharmaceutical Research and Technology Labs,
Astellas Pharma Inc.

Moderator



Naoko Yamamoto, MD, PhD, MPH
Assistant Minister for Global Health,
Minister's Secretariat,
Ministry of Health, Labour and Welfare

Panel Session 2. Partner Expansion

Panelists



Nobuo Hanai, PhD
President and Chief Executive Officer,
Kyowa Hakko Kirin Co., Ltd.



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



Shuichi Fujimura
Executive Vice President, International Affairs,
Alliances and Purchasing,
All Nippon Airways Co., Ltd.



Gen Miyazawa
Executive Corporate Officer Executive Vice President,
President of Media & Marketing Solutions Group,
Yahoo Japan Corporation

Moderator



Ko-Yung Tung, JD
Senior Counselor, Morrison & Foerster
Former Senior Vice President
and General Counsel of the World Bank

Special Remarks



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



Hiroto Izumi, PhD
Special Advisor to the
Prime Minister of Japan

Closing Remarks



Kiyoshi Kurokawa, MD
Chair of the Board, Global Health Innovative Technology Fund
Adjunct Professor, National Graduate Institute for Policy Studies
Chairman, Health and Global Policy Institute