A CATALYTIC STARTING LINE

2013 ANNUAL REPORT

BRINGING JAPANESE INNOVATION, INVESTMENT, AND LEADERSHIP TO THE GLOBAL FIGHT AGAINST INFECTIOUS DISEASES

GHIT Fund
Global Health Innovative Technology Fund
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LETTER FROM THE BOARD CHAIR AND CEO

OUR LAUNCHPAD

MILESTONES AND FIRST FRUITS

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The GHIT Fund’s inaugural year was one of significant firsts: our first grant investments, our first groundbreaking partnerships, and the launch of our screening and hit-to-lead platforms designed to jump-start drug discovery. The establishment of the GHIT Fund also represents important firsts for advancing global health and collaboration more broadly:

The first public-private partnership for global health R&D funding.

The first time that a group of pharmaceutical companies has joined together to initiate a major fund—and invested directly—to facilitate and advance global health R&D.

The first time that the Japanese government has significantly invested in global health R&D.

These firsts are exciting, and the promise they hold to transform global health is humbling. Our partners are driven by the conviction that advancing the development of new healthcare technologies is not only a responsibility, but also a long-term investment—one that carries significant returns for Japan’s future. They see that future as firmly tied to the growth of healthy populations and economies in the developing world.

The Japanese government and the country’s leading pharmaceutical companies, together with the Bill & Melinda Gates Foundation and the United National Development Programme (UNDP), have launched something entirely new. Their foresight, personal engagement, and commitment inspire our team as we continue to work toward our goal of achieving the most important firsts: cost-effective healthcare tools to reduce the burden of disease in the world’s poorest countries.

We are honored to share our first annual report of progress with you.

Kiyoshi Kurokawa, MD
Chair of the Board

BT Slingsby, MD, PhD, MPH
Chief Executive Officer
“We welcome the GHIT Fund’s investment and collaboration in the global fight against diseases that disproportionately affect the poorest of the poor.... This commitment of additional resources for R&D moves us a big step closer to the goal of controlling and defeating these neglected diseases and the vast human misery they cause.”

MARGARET CHAN,
DIRECTOR-GENERAL,
WORLD HEALTH ORGANIZATION
A LEGACY OF INNOVATION AND OVERSEAS AID

The GHIT Fund was conceived in 2011 by Japan’s pharmaceutical industry, whose leaders sought to tap into Japan’s legacy of global leadership in drug development, technological innovation, and overseas development assistance (ODA) to create a public-private partnership fund for global health R&D.

While Japan has long been the number three global leader in drug development, and a critical ODA provider, the country had yet to realize its potential in the development of technology specifically for global health.

The pharmaceutical industry recognized that harnessing Japan’s considerable resources, expertise, and innovation in the creation of new medicines, vaccines, and diagnostics for diseases that impact the poorest populations would require global partnerships.

GLOBAL ALIGNMENT TOWARD CRITICAL “FIRSTS” IN GLOBAL HEALTH R&D

Neglected Tropical Diseases (NTDs), along with HIV/AIDS, malaria, and tuberculosis (TB) affect nearly 40% of the world’s population and have the most unmet medical needs. NTDs often result in delayed growth in children; permanent disabilities, such as organ damage and blindness; and even death. Repeated bouts of illness prevent families from working, trapping entire communities in an endless cycle of poverty.

Over the past 60 years, the global health community has aligned through the World Health Organization (WHO), UN agencies, major foundations such as the Bill & Melinda Gates Foundation and the Wellcome Trust, and the establishment of product development partnerships (PDPs) to push forward innovations for these diseases—innovations that are desperately needed but have not been developed due to a lack of commercial investment.

Overall funding for NTDs has remained static since 2009. In cases where tools are available, they are in very short supply. The GHIT Fund injects critical new funding and new technology into global health R&D.
Japan deeply appreciates the importance of working in solidarity to address the world’s global health challenges. In post-war Japan, disease epidemics, undernutrition, and poverty were part of daily life. Malaria, TB, and NTDs were endemic. But a nationwide community-based program resulted in the effective elimination and subsequent eradication of these diseases in Japan. Transformational health gains led to enormous economic development. In less than 35 years, the country became the number two economy in the world and home to myriad multinational corporations, technology innovators, and political leaders. In that same period of time, Japan—for which TB had been a “national scourge”—became the nation with the highest global life expectancy. Today, the public health programs of postwar Japan form the basis of many WHO disease elimination strategies.
In 2013, the Japanese government made global health a central component of its foreign policy and domestic economic revitalization strategy, demonstrating its recognition of global health as not only an ODA target but also a critical factor in national human security. This policy shift serves as a milestone in a years-long intensification of efforts to more effectively support R&D and leverage the country’s deep well of technology and innovation in order to maximize the value of its foreign aid.

The Japanese government’s investment in the GHIT Fund is a direct realization of the country’s 2013 Strategy on Global Health Diplomacy, which encourages strategic collaborations with international partners and the use of domestic R&D capabilities in continued support of achieving the UN’s Millenium Development Goals (MDGs). This strategy is linked tightly with Japan’s Healthcare and Medical Strategy, also launched in 2013.

Policy engagement in global health at the highest levels of the Japanese government complement the country’s legacy of important investments in health: Japan helped establish the Global Fund and put health on the G8 agenda, and the country has contributed to the achievement of MDGs for years. The formalization of foreign policy focused on combating the most devastating diseases of the developing world has been under way since the mid-1990s, along with an increasing recognition of the overwhelming toll that infectious diseases take on the communities and economies Japan’s ODA supports.
• US$5,450,975 (¥560,469,256) invested for six grants for partnerships working on drugs and vaccines against malaria, TB, and Chagas’ disease
• 2nd call for proposals for screening partnerships announced

Hit-to-Lead Platform launched

• US$12,107,156 (¥1,244,857,831) invested for four grants to speed the development of innovative drugs for schistosomiasis, Chagas’ disease, and parasitic roundworms, as well as research on a novel TB vaccine candidate
First Fruits
The GHI T Fund has facilitated over 20 R&D partnerships to advance product development using Japanese innovation. Highlights of three such partnerships and our screening platform include the following:

Pediatric Formulation of the Gold Standard Drug for Schistosomiasis

Astellas Pharma’s innovative pharmaceutical technologies in drug formulation and clinical development for children enables this partnership to create a pediatric formulation for praziquantel, the gold standard drug co-developed by Merck KGaA and Bayer in the mid-1970s. Leveraging the Swiss Tropical and Public Health’s expertise on drug effectiveness and efficiency in endemic regions, the fruits of this collaboration will change the game dramatically for schistosomiasis treatment.

The partnership has already produced test batches of two new pediatric drug formulations, which will be tested first in adults, followed by taste tests for children. Support from the GHI T Fund not only accelerates this project’s progress, but it also helps the partnership prepare for Phase II studies with the new formulation selected for further development.

With the standard recommended treatment, younger children run a significant risk of choking because of the size and bitter taste of the oral tablets. A pediatric formulation is urgently needed to increase safety, acceptability, and overall access.

"The Consortium, with its 6 partners, is committed to contribute to the elimination of the second-most prevalent tropical disease in Africa through Astellas’ expertise in advanced formulation technology and development. We believe the partnership with GHI T is the key for success to accelerate and expand our activities in delivering treatment to the very young children suffering from schistosomiasis."

Yoshihiko Hatanaka, Representative Director, President and CEO, Astellas Pharma Inc.

Schistosomiasis
Schistosomiasis (or bilharzia) spreads through parasitic worms and can lead to anemia, stunting, reduced learning ability, and death. Endemic in 78 countries, it affects more than 240 million people (40% of them children), making it second only to malaria in impact of a parasitic disease. Annual global economic losses due to schistosomiasis are estimated at more than US$640 million.
A Novel TB Vaccine

“Early research shows tremendous potential for the rhPIV2 platform. This partnership helps to bring the global health community closer to the ultimate goal of establishing a new vaccine strategy for the prevention of TB.”

Yasuhiro Yasutomi, Director, Tsukuba Primate Research Center, NIBIO

This collaboration—made possible by GHIT support—combines advanced science and technology created in Japan with translational R&D expertise from Create Vaccine (a joint venture between Dainippon Sumitomo Pharma and Japan BCG Laboratory) and Aeras. The partnership will advance vaccine candidates based on the rhPIV2 technology created by the Tsukuba Primate Research Center at NIBIO through preclinical stages, with the goal of advancing to safety and immunogenicity testing in clinical trials.

Partners are establishing development criteria, including characterizing new vaccine constructs with a variety of antigens, the conduct of immunology studies to identify the most promising novel vaccines, and the establishment of good manufacturing practices.

Tuberculosis

According to the WHO, in 2012, 8.6 million people fell ill with TB and 1.3 million died from TB. TB takes the greatest toll on individuals during their most productive years (ages 15 to 44). Annual global costs for TB treatment and care are estimated at US$8 billion. The global emergence and spread of multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) impose enormous human and economic costs—more than 200 times the cost of treating drug-susceptible TB.
Accelerating the Development of Novel Drugs for Malaria

"It is an honor to partner with Takeda. This collaboration provides MMV with access to novel Japanese compounds, expertise, and support, which we hope will open the door to new breakthrough malaria medicines to help stop unnecessary loss of life due to the disease and pave the way for malaria elimination and eradication."

David Reddy, CEO, MMV

Emerging resistance to the few widely used antimalarial drugs in our arsenal has resulted in increasingly complicated treatment challenges. With no new drug class yet on the market, the gains made thus far in controlling and eliminating malaria are being severely threatened.

This partnership—catalyzed by the GHIT Fund—brings Takeda’s unique chemistry expertise and know-how in clinical testing together with promising MMV compounds to advance new antimalarial drug candidates. One drug is DSM265, which kills the malaria parasite through inhibition of an essential enzyme and has already entered Phase I studies. It has so far shown a good safety profile, and the compound’s long duration of action creates the potential for DSM265 to be part of a single-dose cure.

Another drug is ELQ300, a preclinical antimalarial prophylactic quinolone derivative. This antimalarial compound is in earlier stages of development, and research to date indicates that ELQ300 has the potential to be given once a month to treat and prevent malarial infections, which would make it an important tool for low-dose cures or prophylaxis of the disease. However, some additional work related to its formulation is needed before it can be tested in patients. Here, Takeda is contributing critical chemistry, manufacturing, and controls expertise for the development of a solid oral dose form development.

Malaria

Malaria causes more than 200 million cases and approximately 650,000 deaths annually, 86% of them among children. In some endemic countries, the disease accounts for up to 40% of public health expenditures, 30-50% of inpatient hospital admissions, and up to 60 percent of outpatient health clinic visits. This disease costs Africa between US$12-30 billion in lost GDP every year.
WHY PARTNERSHIPS FOR PRODUCT DEVELOPMENT?

Global health challenges are too great for one pharmaceutical company, research institution, or nation to confront alone.

Consider a billion people who are in desperate need of new drugs, vaccines, and diagnostics, but they can’t pay—or can pay only pennies. Now reflect on the fact that the creation of these tools requires massive investments of capital, time, and complex R&D. Combine scientific complexity and enormous risk with uncertainty around the adoption and uptake of these tools due to poor infrastructure in the communities that need them most, and we have the equation for the dearth of new drugs for the diseases that affect the world’s poorest.

Partnerships for product development are indispensible to the discovery and development of new technologies for diseases that have little or no commercial market. These partnerships often take place between the public sector, industry, academia, and international agencies—leveraging each organization’s strengths while acknowledging and addressing their needs and constraints. Similar to the GHIT Fund, partnerships for product development often use public and philanthropic funds to reduce or remove risk for companies and research institutions undertaking the R&D. The results of these partnerships: quicker, less costly development of badly needed, affordable health tools with game-changing global health benefits.
URGENCY

The early-stage drug pipeline for malaria, TB, leishmaniasis, and Chagas’ disease is nowhere near as robust as it should be, considering the health and economic burdens these diseases carry, as well as the number of products that the global community is trying to develop. To secure a stable pipeline, new chemical entities and novel compounds are critical.
Drug Discovery Screening Platform

Expanding the drug pipeline for neglected diseases

Japan’s pharmaceutical sector is a long-established global innovator in new chemical entities—the essence of what makes drugs effective. Countless chemical entities with enormous potential for developing new tools to combat the major diseases of the developing world sit on the shelves of Japan’s public and private research institutions.

In June 2013, for the first time, Japan’s private and academic sectors opened the doors of their vast, advanced compound libraries to PDPs through the GHIT Fund’s Drug Discovery Screening Platform. These PDPs are focused on drug discovery for TB, malaria, leishmaniasis, and Chagas’ disease. This will enable the screening of tens of thousands of drug candidates for potential new treatments. Initial partnerships have already begun screening chemical compounds from Japanese partner libraries with assays for target diseases and assessing their impact on parasites and bacteria of focus.

In February 2014, the GHIT Fund launched its Hit-to-Lead Platform with the goal of converting drug “hits” identified through the Screening Platform into “lead compounds”—chemicals that show promise as anti-infectives but likely require further chemical modification before they can be tested as human drugs. This new program will help researchers find promising drug compounds that can fight deadly and debilitating infectious diseases.

The Partners

ALLIANCE FOR TB DRUG DEVELOPMENT
DRUGS FOR NEGLECTED DISEASES INITIATIVE (DNDI)
MMV

The Libraries

Private
ASTELLAS PHARMA
DAIICHI SANKYO
EISAI
SHIONOGI
TAKEDA

Academic
INSTITUTE OF MICROBIAL CHEMISTRY
KITASATO INSTITUTE
To the Board of Directors, Global Health Innovative Technology Fund:

We have audited the accompanying financial statements, which comprise the balance sheet, the statement of income, the notes to the financial statements, and the related supplementary schedules of the General Incorporated Association Global Health Innovative Technology Fund (“the Organization”) applicable to the second fiscal year from April 1, 2013, through March 31, 2014. We conducted our audit in accordance with the rules and regulations concerning General Incorporated Associations and General Incorporated Foundations in Japan, under Item 1 in Paragraph 2 of Article 124.

Directors’ Responsibility for the Financial Statements and the Related Supplementary Schedules

Directors need to ensure that the financial statements and related supplementary schedules were prepared and fairly presented in accordance with accounting principles generally accepted in Japan. Among others, directors are responsible for designing and operating such internal control as directors determine is necessary to enable the preparation and fair presentation of the financial statements and the related supplementary schedules that are free from material misstatement, whether due to fraud or error.

Auditor’s Responsibility

Our responsibility is to express an opinion on these financial statements and the related supplementary schedules based on our audit. We conducted our audit in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements and the related supplementary schedules are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements and the related supplementary schedules. The procedures selected depend on the auditor’s judgment, including the assessment of the risks of material misstatement of the financial statements and the related supplementary schedules, whether due to fraud or error. The purpose of an audit of the financial statements is not to express an opinion on the effectiveness of the Organization’s internal control, but in making these risk assessments, the auditor considers internal controls relevant to the Organization’s preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate for the circumstances. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by directors, as well as evaluating the overall presentation of the financial statements and the related supplementary schedules.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements and the related supplementary schedules referred to above present fairly, in all material respects, the financial position and results of operations of the Organization applicable to the second fiscal year ended March 31, 2014, in conformity with accounting principles generally accepted in Japan for Public Interest Incorporated Associations (equivalent to a 501(c)(3) in the United States).

Conflicts of Interest

We have no interest in the Organization which should be disclosed in compliance with the Certified Public Accountants Act.

Ernst & Young ShinNihon LLC
May 7, 2014
### 2013 Financial Summary (audited, $USD)

#### SOURCES OF REVENUE

- **52.1%** Governments, NGOs, multilateral organizations
- **24.2%** Foundations
- **23.7%** Corporations

#### EXPENSE ALLOCATION

- **97.4%** Program services
- **2.6%** Support services

#### REVENUE (in thousands)

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<thead>
<tr>
<th>Source</th>
<th>Revenue (in thousands)</th>
</tr>
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<tbody>
<tr>
<td>Governments, NGOs, multilateral</td>
<td>$10,693</td>
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<tr>
<td>organizations</td>
<td></td>
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<tr>
<td>Foundations</td>
<td>4,970</td>
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<tr>
<td>Corporations</td>
<td>4,863</td>
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<tr>
<td><strong>TOTAL REVENUE</strong></td>
<td><strong>$20,526</strong></td>
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</table>

#### EXPENSES (in thousands)

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<thead>
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<th>Expense</th>
<th>Expenses (in thousands)</th>
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<td>Program services</td>
<td>$18,074</td>
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<tr>
<td>Support services</td>
<td>483</td>
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<tr>
<td><strong>TOTAL EXPENSES</strong></td>
<td><strong>$18,557</strong></td>
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#### Assets, Liabilities, and Net Assets

<table>
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<tr>
<th>Asset</th>
<th>Assets (in thousands)</th>
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<tbody>
<tr>
<td>Cash and cash equivalents</td>
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<tr>
<td>Fixed assets</td>
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<td><strong>TOTAL ASSETS</strong></td>
<td><strong>$10,621</strong></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Liability and Net Asset</th>
<th>Liabilities and Net Assets (in thousands)</th>
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</thead>
<tbody>
<tr>
<td>Total Liabilities</td>
<td>$8,364</td>
</tr>
<tr>
<td>Net Assets</td>
<td>2,257</td>
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<tr>
<td><strong>TOTAL LIABILITIES AND NET ASSETS</strong></td>
<td><strong>$10,621</strong></td>
</tr>
</tbody>
</table>

#### GRANT INVESTMENTS (in $USD)

- **BY DISEASE**
  - MALARIA: $4,283,887
  - TB: $6,175,472
  - NTDs: $7,098,773

- **BY INTERVENTION**
  - DRUGS: $10,112,580
  - VACCINES: $7,445,552

- **BY RESEARCH STAGE**
  - PRE-CLINICAL: $8,844,761
  - CLINICAL: $8,713,371

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The U.S. dollar amounts in this report represent translations of Japanese yen, solely for the reader’s convenience, at ¥102.82=US$1, the approximate exchange rate on March 31, 2014.

This financial summary is an excerpt from the GHIT Fund’s audited financial statements, which are audited by Ernst & Young ShinNihon LLC. The GHIT Fund is a General Incorporated Association and is registered in Japan.
Leadership

Council

Members of the Council provide oversight for the Board of Directors and serve as advocates for the GHIT Fund’s mission. Our private sector Council members are not involved in organizational or funding decisions. Funding from the GHIT Fund need not go to the same private companies represented on our Council. In fact, it may be directed to a partnership with any institution in Japan. All GHIT Fund grant investments support partnerships between Japanese entities and non-Japanese entities.

Takehiro Kagawa, Director-General, Global Issues, Ministry of Foreign Affairs, Government of Japan

Mitsuhiro Ushio, MD, Deputy Director-General for Global Health, Minister’s Secretariat, Ministry of Health, Labour and Welfare, Government of Japan

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

Astellas Pharma Inc.: Yoshihiko Hatanaka, Representative Director, President and CEO

Daiichi Sankyo Company Ltd.: George Nakayama, Representative Corporate Officer, President and CEO

Eisai Co. Ltd.: Haruo Naito, President and CEO

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

Takeda Pharmaceutical Company Ltd.: Yasuchika Hasegawa, President and CEO
Board of Directors

The global health experts on the GHIT Fund’s Board of Directors provide governance and fiduciary oversight for the Selection Committee, set policy, and assess the GHIT Fund’s overall performance.

Chair & Representative Director

Kiyoshi Kurokawa, MD, Academic Fellow, National Graduate Institute for Policy Studies; Chairman, Health and Global Policy Institute

Executive Director

BT Slingsby, MD, PhD, MPH, CEO, Global Health Innovative Technology Fund

Members

Peter Piot, MD, PhD, Director, London School of Hygiene & Tropical Medicine, Former Executive Director of UNAIDS

Ann M. Veneman, Former Executive Director, UNICEF

Kazushi Yamauchi, MD, PhD, MPH, Director, International Cooperation Office, International Affairs Division, Minister’s Secretariat, Ministry of Health, Labour and Welfare, Government of Japan

Hiroyuki Yamaya, Director, Global Health Policy Division, International Cooperation Bureau, Ministry of Foreign Affairs, Government of Japan

Advisors

Hikaru Ishiguro, LLM, Board Member and President, Health and Global Policy Institute

Ko-Yung Tung, JD, Senior Counselor, Morrison & Foerster LLP

Ex-Officio

Kim C. Bush, Director of Life Sciences Partnerships, Bill & Melinda Gates Foundation
Members of the GHIT Fund’s Selection Committee evaluate grant proposals and reports from grantees, recommend the provision of grants to Board of Directors, and ensure independence, accountability and transparency of the grant review and recommendation process. The Selection Committee is free of large pharma representatives to avoid any conflicts of interest between our backers and grantees.

**Selection Committee**

Mahima Datla, Managing Director, Biological E. Ltd.

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

Penny M. Heaton, MD, MPH, Director, Vaccine Development and Surveillance, Bill & Melinda Gates Foundation

Kiyoshi Kita, PhD, Professor and Chair, Department of Biomedical Chemistry, Graduate School of Medicine, The University of Tokyo

Alex Matter, MD, CEO, Experimental Therapeutics Centre and D3, A*STAR, Singapore

Yasuko Mori, MD, PhD, Professor, Division of Clinical Virology, Center for Infectious Diseases, Kobe University Graduate School of Medicine

Dennis Schmatz, PhD, Former head of Infectious Diseases Research, Merck Research Labs, USA

Former Head of Research, MSD-Japan

**Advisory Panel**

Members provide strategic advice to the Chair of the Board and the CEO.

Peter Agre, MD, Director, Johns Hopkins Malaria Research Institute

Harvey V. Fineberg, MD, PhD, President, Institute of Medicine of the National Academies

Dai Hozumi, MD, MSM, MPH, Senior Advisor for Health Systems and Policy, PATH

Calestous Juma, PhD, Professor, Practice of International Development and Director, Science, Technology, and Globalization Project, Harvard Kennedy School

Michael R. Reich, PhD, Taro Takemi Professor of International Health Policy, Harvard School of Public Health

Kumi Sato, President and CEO, Cosmo Public Relations Corporation

Peter Singer, MD, MPH, FRCPC, CEO, Grand Challenges Canada and Director, Sandra Rotman Centre
The work of the GHIT community could not progress without vital support from these experts and their institutions worldwide.

**EXTERNAL REVIEWERS**

Dr. Richard Adegbola
Dr. Yukihiro Akeda
Dr. Pedro Alonso
Dr. Peter Andersen
Dr. W. Ripley Ballou
Dr. Clif Barry
Dr. Marleen Boelart
Dr. Maria Elena Bottazzi
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Dr. Kaoru Terashima
Dr. Katsushi Tokunaga
Dr. Nadia G. Tornieporth
Dr. Bruno Travi
Dr. Takačumi Tsuboi
Dr. Moriya Tsuji
Dr. Mickey Urdea
Dr. Stephen Ward
Dr. Tim Wells
Dr. John Westwick
Dr. Bruce G. Weniger
Dr. Judith Wilber
Dr. Elizabeth Winzeler
Dr. Michael Witty
Dr. Paul Wyatt
Dr. Donato Zipeto
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Japanese Ministry of Health, Labour and Welfare
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Eisai Co. Ltd.
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Takeda Pharmaceutical Company Ltd.
Bill & Melinda Gates Foundation
United Nations Development Programme

**Sponsors**
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ACCELERATE HEALTH INNOVATION

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Global Health Innovative Technology Fund

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