GHIT Fund
ANNUAL REPORT
2014

Acceleration & Expansion

"The GHIT Fund, a new model of funding for global health research and development, was established in Tokyo. Technology should benefit the health of all people. My government stands ready to work with the private sector and help other countries to solve these global health challenges to contribute to the sustainable growth of the global economy."

Shinzo Abe, Prime Minister, Government of Japan

"Japan's Strategy for Global Health Diplomacy: Why It Matters," The Lancet, 382, No. 9896 (September 2013): 915–16.

CONTENTS

PICKING UP SPEED

What follows a bold, transformational beginning?

For us, the only possible path after our catalytic first year must be forged by concrete, measurable impact and the steady acceleration and expansion of our progress. Our work is a marathon, not a sprint.

Our first year of operations changed the game for global health R&D with new funding and groundbreaking partnerships between Japanese and international research institutions. This past year, we have only picked up speed: our investments in cutting-edge R&D partnerships doubled; we articulated our transparent impact assessment process, showcasing the tangible R&D progress our work has created and accelerated; we introduced a new early-stage R&D platform in collaboration with Grand Challenges; and we welcomed a major new partner to our Council, expanding our investment capacity. In a little over two years since our inception, the GHIT Fund has delivered notable results despite its novelty and complexity.

Steady progress, an enduring sense of urgency, and a requirement of tangible impact drive our work and our team. The reemergence of Ebola virus disease in West Africa in 2014, coupled with an outbreak of dengue viral infection in Tokyo – the first in 70 years – makes global health R&D investment, innovation, and partnership more urgent than ever. These diseases, together with diseases like malaria, tuberculosis, and neglected tropical diseases (NTDs), overwhelmingly affect the poorest and most marginalized populations in the world. While air travel and urbanization hasten the spread of such devastating diseases, they also create new opportunities for faster collaboration and improved communication. We remain tremendously confident in the promise that new technologies, creative partnership structures, and the increasing global capacity for rapid innovation hold for control and prevention of the diseases that disproportionally affect the poorest of the poor.

Japan's pharmaceutical industry has stepped up to provide a powerful engine for realizing GHIT's mission by making their expertise and assets available for new research. They possess a wealth of chemical compounds and technologies, significant drug and vaccine manufacturing capacities, advanced clinical and preclinical testing capabilities, and decades of experience guiding breakthrough discoveries from basic research to approved products. The GHIT Fund's partnership with these leading companies is emblematic of a broader perspective in Japan, with leaders in both the public and private sectors viewing the country's economic future as firmly tied to conditions in the developing world.

What motivates and propels us? In addition to our fundamental belief in the transformation of global health through innovative R&D partnerships and open innovation, GHIT's success would not be possible without the institutional support and championship of our partners, governors, selection committee, external reviewers and development partners. They inspire us every single day. Their work and leadership consistently remind us of the unwavering commitment and extraordinary expertise, experience, and creativity that propel global health.

We are transforming the future together, catalyzing unparalleled innovation and partnership that will change millions of lives. We are tremendously grateful for such partnership.

Kiyoshi Kurokawa, MD
Board Chair

BT Slingsby, MD, PhD, MPH
Chief Executive Officer

TANGIBLE IMPACT

264,686
Screened Compounds for New Drugs

5,585
Hits Identified for New Drugs

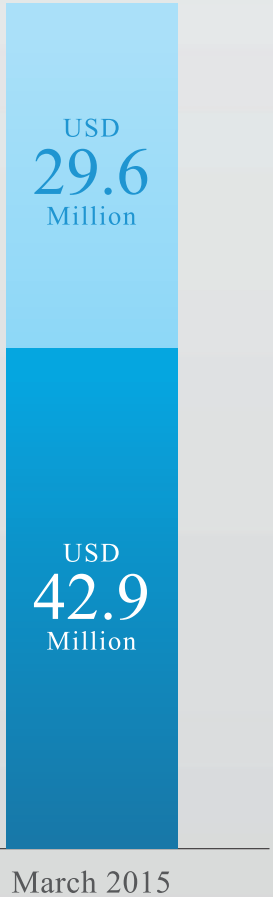
75%
New Molecular Entities (NME) Funded

Achievements in our first two years

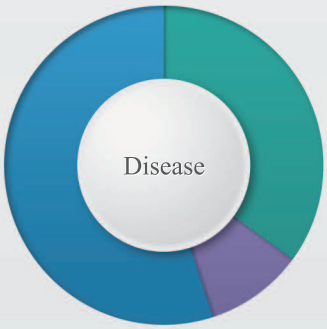
6
Clinical Trials Initiated

17
Potential New Products Funded

39
Funded Partnerships



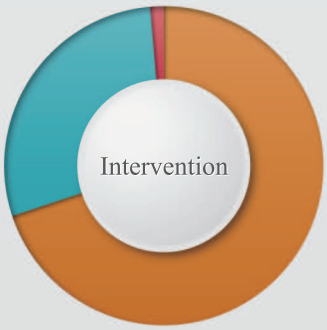
Investments to date
USD 42.9 Million




Malaria 35.6%


Tuberculosis 10.0%

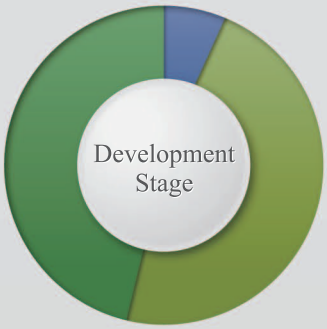

NTDs 54.4%




Drugs 69.8%


Vaccines 28.4%


Diagnostics 1.8%




Discovery 6.9%


Preclinical 46.8%


Clinical 46.3%

The U.S. dollar amounts in this section represent translations of Japanese yen, solely for the reader's convenience, at JPY 100=USD 1.

OUR INVESTMENT PLATFORMS

Our work now spans four game-changing investment platforms, each of which helps fill critical research and funding gaps. R&D conducted under the auspices of these platforms will drive forward the discovery and development of new drugs, vaccines, and diagnostics for global health with Japanese technology and expertise.

Target Research Platform *in partnership with Grand Challenges*

Launched in February 2015, the Target Research Platform in partnership with Grand Challenges (TRP) will invest up to ¥200 million (～US$2 million) annually for early stage development of radically new and improved drugs, vaccines, or diagnostics for malaria, tuberculosis, Chagas disease, and leishmaniasis. These investments will be intentionally broad in scope and will focus on new technologies and novel approaches. Promising projects will then graduate into GHIT's product development platform, which invests in a pipeline of new tools for neglected diseases.

First launched by the Bill & Melinda Gates Foundation 10 years ago, the Grand Challenges contest was created to foster creative and daring global health and development breakthroughs. Bringing Japan's world-renowned basic science research capacity and experience to bear on early stage global health R&D represents a much-needed boost for the field. Japan ranks fourth globally in scientific publication authorship,[1] and the World Economic Forum highlights innovation, capacity to innovate, and world-class research institutions as among Japan's top strengths.[2]

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

"This new platform… will bring together trailblazers with unique and powerful scientific expertise. We welcome Japan's role in using Grand Challenges to catalyze its enormous capacity to tackle neglected diseases that sicken and kill the poorest people in the world."

Peter Singer, CEO, Grand Challenges Canada

"Grand Challenges supports visionary approaches to solving major global health problems. Japan and the GHIT Fund's partnership will amplify impact and innovation."

1. Knowledge, Networks and Nations: Global Scientific Collaboration in the 21st Century," The Royal Society, March 2011, https://royalsociety.org/~/media/Royal_Society_Content/policy/publications/2011/4294976134.pdf
2. Global Competitiveness Report 2013–2014, World Economic Forum, http://www3.weforum.org/docs/WEF_GlobalCompetitivenessReport_2013-14.pdf.

Screening Platform

Our Screening Platform enables the screening of tens of thousands of drug candidates for potential new treatments for neglected diseases by opening the door to the vast, advanced compound libraries of Japan's private and academic sectors. These libraries were previously closed to the global health community. Japan's unique chemical compounds bring new resources, chemistry, and promise to the fight against infectious disease. Within just two years, the GHIT has financed and facilitated the screening of over a quarter million compounds for target diseases and assessing their impact on parasites and bacteria of focus.

Melvin Spigelman, President & CEO, TB Alliance

"GHIT has made numerous new opportunities available to the global health and product development partnership communities..., almost immediate access to Japan's leading pharmaceutical companies' chemical compounds libraries..., multiple additional partnerships have very quickly materialized."

Tachi Yamada, Chief Medical & Scientific Officer
and Executive Vice President,
Takeda Pharmaceuticals International, Inc.

"GHIT's cross-border, cross-sector partnerships are transforming global health R&D, and in the process catalyzing open innovation, transparency, and improved access."

TAKING ON BIG RISKS: Our Focus on New Molecular Entities

The mechanisms of action in 75% of the drugs in our pipeline are novel. New Molecular Entities (NMEs), drugs or chemicals that are without precedent among currently regulated and approved products. Such innovation is particularly exciting for diseases in which new drugs have not been seen in 80 years,[4] whose existing treatments face drug resistance, and for diseases that lack any effective treatment or prevention tools at all.

NMEs breathe new life into global health R&D by illustrating new pathways and mechanisms of action where deadly pathogens are vulnerable. Such cutting-edge innovation is rare for infectious diseases and NTDs. A Lancet study showed that of the NMEs approved between 2000 and 2011 only 1% were for neglected diseases[5]. Why so few? Namely, cost and risk. R&D for new drugs and vaccines typically costs a pharmaceutical company around $1 billion and takes 10-15 years. Additionally, when it comes to NMEs, the

Hit-to-Lead Platform

Our Hit-to-Lead Platform (HTLP) is designed to leverage active platforms for neglected diseases in partnership with Japanese companies, research institutions and academic organizations that have relevant compounds, facilitating access to the chemical diversity in Japanese research organizations and medicinal chemistry expertise. HTLP projects focus on the aspect of the drug discovery and development process that progresses hits, identified through compound library screening, into lead compounds that can then be optimized into drug candidates. This platform provides a bridge from early drug discovery to our product development platform that begins with the lead-optimization step. This lead-generation step is critical as it is the earliest point at which knowledge-driven decisions about compounds can be made. An early, rigorous assessment can focus resources on the most promising lead series and projects. Currently three partnerships are conducting lead generation and evaluation of drugs for malaria, Chagas disease and visceral leishmaniasis.

Tim Wells, Chief Scientific Officer, Medicines for Malaria Venture

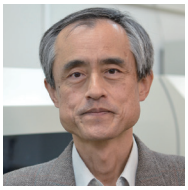
"GHIT has helped open the door to extremely fruitful new collaborations in Japan, which is critically important given Japanese companies' strong history in the discovery and development of new medicines to combat infection."

Yasuko Mori, Professor, Kobe University Graduate School of Medicine

"The product development process is highly complex, and one consequence is a frequent disconnect between what academics are doing and think is valuable versus what life-science companies prioritize. GHIT works across the sectors to help provide a bridge between those critical perspectives."

Product Development Platform

Drawing on Japan's position as a technology and R&D leader (number two in the number of new patents and fourth in R&D expenditure[3]) our Product Development Platform invests in R&D activities ranging from preclinical research (post-lead optimization), through clinical development (including clinical trials and manufacturing scale-up), to licensure and WHO prequalification. Our goal is to develop new drugs, vaccines, and diagnostics for infectious diseases that are prevalent in the developing world, and to make those products accessible where they are needed most. Through this platform, in its first two years, GHIT has invested in more than 20 innovative technologies for malaria, tuberculosis, and NTDs.



Takafumi Tsuboi, Professor, Malaria Research Division, Proteo-Science Center, Ehime University

"Ehime University represents the research, and our partner, MVI PATH, excels at the product development. With GHIT's investment, we are able to join forces and accelerate progress towards a new, effective malaria vaccine."

Mahima Datla, Managing Director, Biological E. Limited

"The GHIT Fund's research platforms expand the drug and vaccine pipeline for deadly infectious and parasitic diseases by making new collaboration and engagement between key global health stakeholders possible."

3. Patents: Resident utility patent filings per 1 million population and per $1 million of R&D spent; utility patents granted as a percentage of world total. R&D spending: expenditure as a percentage of GDP. The Bloomberg Innovation Index (2015), http://www.bloomberg.com/graphics/2015-innovative-countries/.

probability of success is only one in 10,000.[6] Such risks, coupled with the market failure surrounding these diseases, make investments in NMEs very difficult for any institution, government, or company to shoulder on its own.

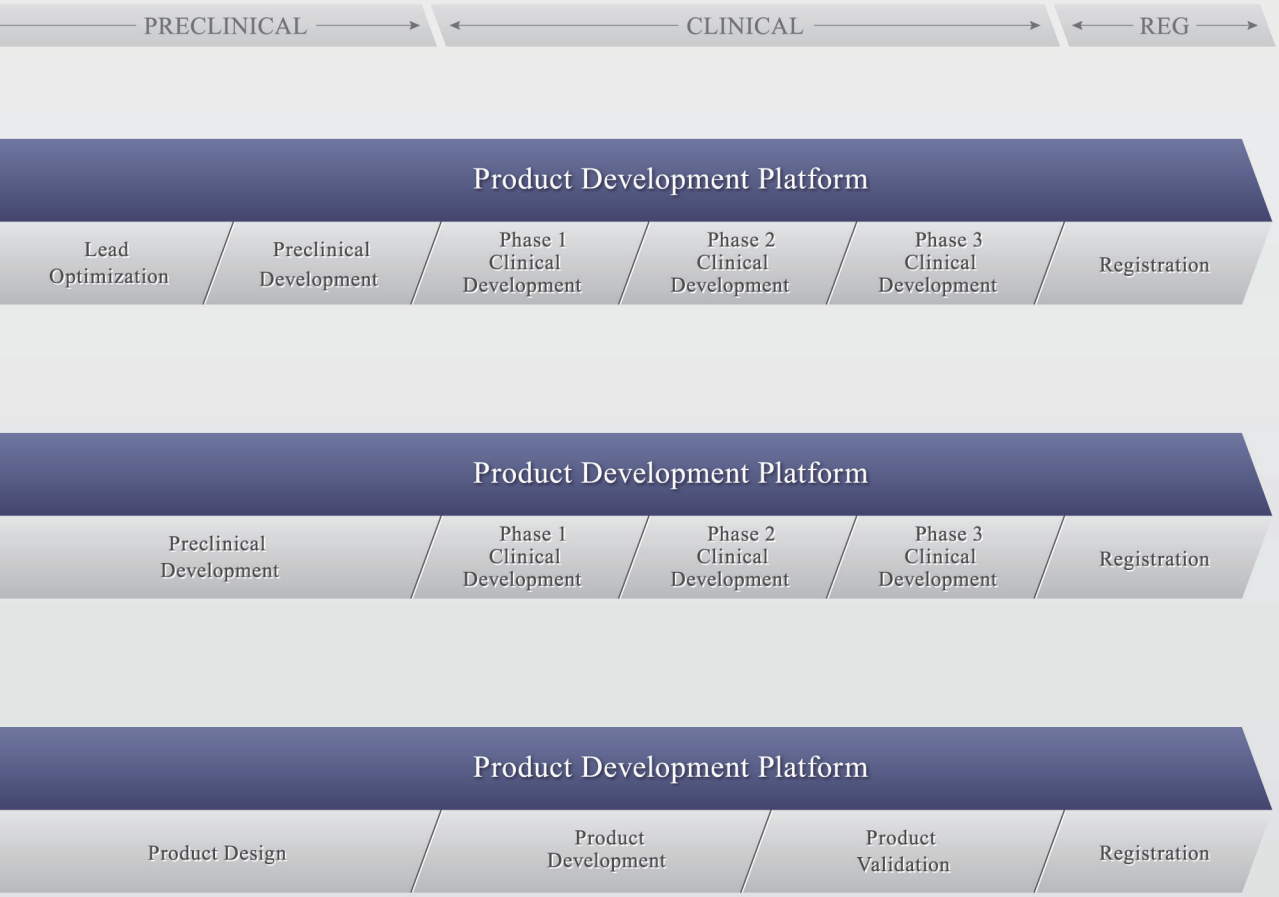
GHIT recognizes the value of taking on these big risks and works with partners to make it easier for them to engage. The previously untapped potential of Japan's chemical compound libraries offers enormous innovation potential, as well as hope for the millions of people worldwide who suffer from and live in fear of devastating infectious diseases.

4. The only TB vaccine available today (BCG) was developed more than 80 years ago and provides insufficient protection to teenagers and adults, who carry the highest TB burden.
5. Belen Pedrique et al., "The Drug and Vaccine Landscape for Neglected Diseases (2000–11): A Systematic Assessment," The Lancet Global Health, 1, No.6 (December 2013): 371–79.
6. Ish Khanna, "Drug Discovery in Pharmaceutical Industry: Productivity Challenges and Trends," Drug Discovery Today, 17, Nos. 19/20 (October 2012): 1088 –1102.

TRACKING PROGRESS

To measure the impact of its investments, GHIT has established a monitoring and evaluation (M&E) process that requires partners to submit semi-annual progress reports coupled with interactive conferences for each GHIT-funded project. This is done within each of four investment platforms from discovery to product registration, regardless of whether the technology is a drug, vaccine, or diagnostic. We do this through M&E or the tracking of over 10 Stage-Gates and 30 Milestones.

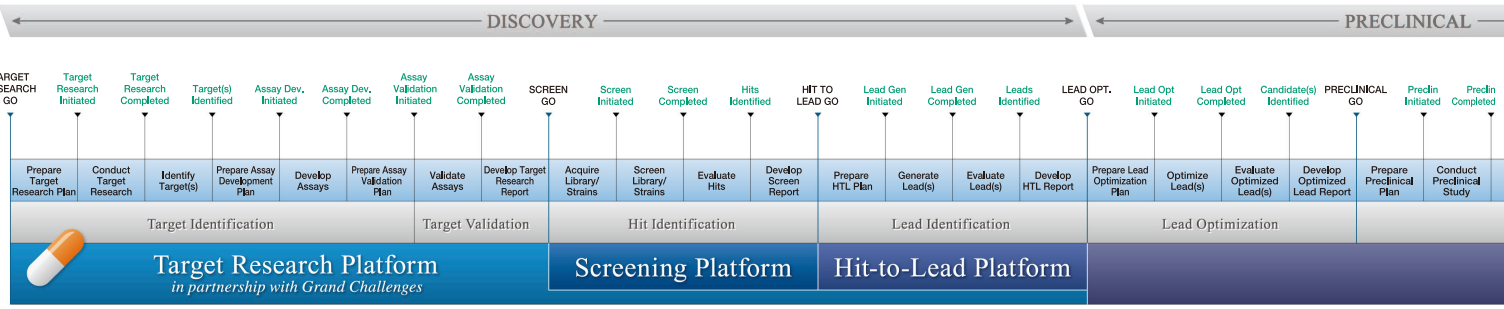
Because GHIT invests in product candidate development from discovery to the registration of drugs, vaccines and diagnostics — each unique in its path of development and for multiple diseases — GHIT has implemented broadly applicable stage-gates and milestones based on standards as defined in the pharmaceutical and biotechnology sectors.



EVALUATION OF STAGE-GATES AND MILESTONES

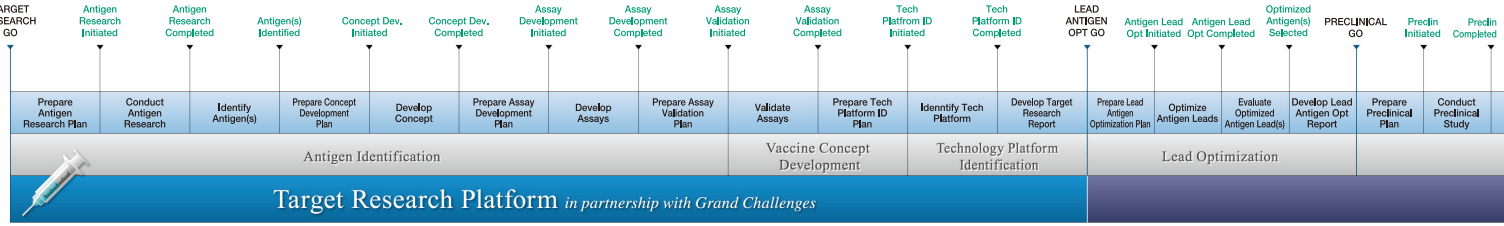
GHIT defines Stage-Gates as the go/no go decision points the R&D process (e.g., compound screening go/no go, IND-filing go/no go, Phase 2 development go/no go). They are segmented by the Fund's investment platforms. The Target Research Platform encompasses all discovery research-based activities, including those associated with the Fund's Drug Screening Platform and Drug Hit-to-Lead Platform. The Product Development Platform encompasses all of the product development-based activities, including Preclinical Development, Clinical Development, and Regulatory Approval. For Milestones, GHIT has defined them as the measurable steps that occur between Stage-Gates (e.g., Phase 2 Go: first patient in, last patient in, last patient out, data lock and analysis, Phase 3 go/no go). In the GHIT system, a Stage-Gate is counted as both a stage-gate and a milestone.

DRUG DEVELOPMENT



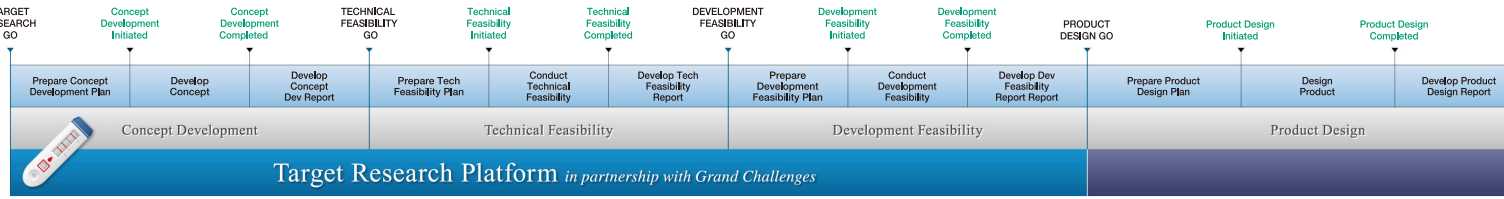
Collaboration Partners	Target Disease	Investment Amount (USD)	Project Awarded RFP
Company A PDP B	Malaria	1.9 Million	PD RFP 2013-001
Company C University D	Chagas	1.4 Million	HTL RFP 2014-002

VACCINE DEVELOPMENT



Collaboration Partners	Target Disease	Investment Amount (USD)	Project Awarded RFP
PDP E University F	Malaria	1.0 Million	PD RFP 2013-002
PDP G Research Institute H	Dengue	2.5 Million	PD RFP 2014-001

DIAGNOSTIC DEVELOPMENT

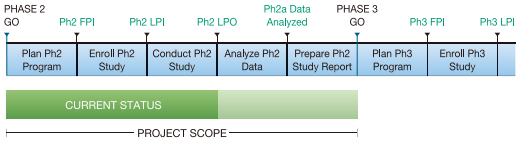


Collaboration Partners	Target Disease	Investment Amount (USD)	Project Awarded RFP
PDP I Company J	Tuberculosis	2.0 Million	PD RFP 2014-002
Company K University L	Shistosomiasis	0.7 Million	TR RFP 2015-001

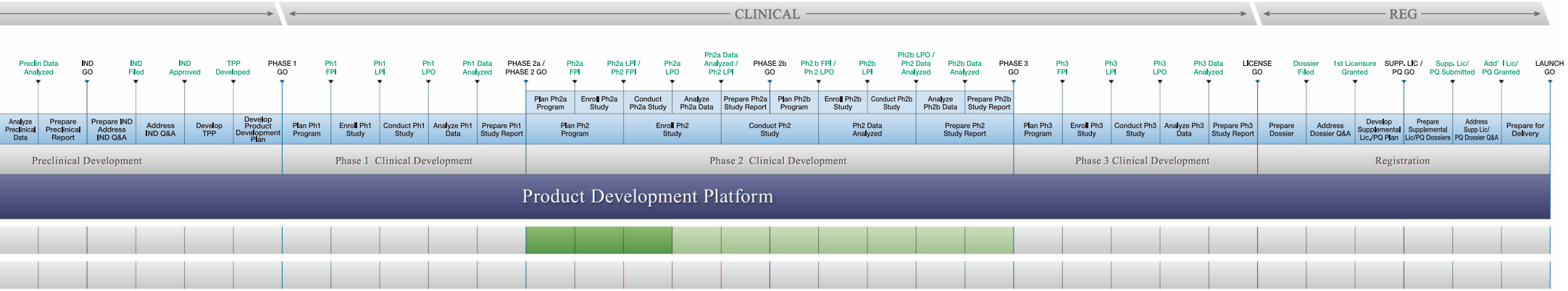
Drug and vaccine candidate stage-gates and milestones tend to be quite similar once a product has entered the product development portion of the R&D process, but they differ during the research phase. Diagnostic product candidates differ significantly from drugs and vaccines in both the research and product development phases of the R&D process. For Chemistry, Manufacturing and Controls (CMC) and Good Manufacturing Practices (GMP), GHIT also monitors and evaluates such in a similar mechanism.

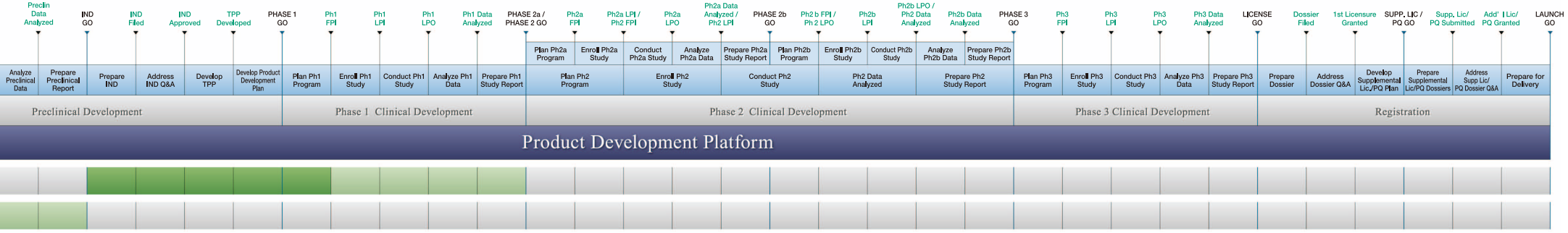
Project Scope vs Current Reporting Period Status

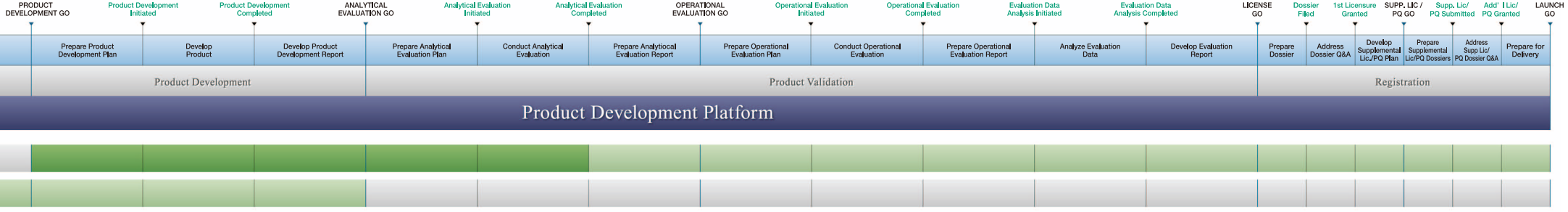
For example, a successful investment in a Phase 2 clinical trial would yield one Stage-Gate and five Milestone advancements. For the semi-annual progress report, partners designate the current state of the project by specifying the project's current activity. An example would be completing the study portion of the Phase 2 clinical trial by the second reporting period would credit the project with one Stage-Gate and four Milestone advancements.



■ STAGE-GATE ■ MILESTONE STAGE ACTIVITY







NOVEL DRUG DISCOVERY FOR CHAGAS DISEASE AND VISCERAL LEISHMANIASIS

EISAI CO., LTD. / SHIONOGI & CO., LTD. / TAKEDA PHARMACEUTICAL COMPANY LIMITED
DRUGS FOR NEGLECTED DISEASES *initiative* (DND*i*)

Prevalence

Chagas disease and visceral leishmaniasis (VL) are insect-borne parasitic diseases that typically affect the poorest people in low-income countries. There are an estimated 6 to 7 million cases of Chagas disease worldwide[7], with 50,000 new cases per year.[8] Approximately 12,000 people die from the disease every year and 65 million people in the Americas alone are at risk of contracting this disease.[9] VL is another neglected disease that is becoming a global challenge, causing 20,000 deaths and leading to 300,000 new infections annually. An estimated 310 million people are at risk for contracting VL.[10]

Socioeconomic Costs

Once infected with Chagas disease, a mother-to-be can spread it to her infant, who will have less than a 50% chance of surviving past the age of two.[11] Sometimes manifesting a decade or more after infection, the disease causes cardiac disorders, enlargement of the esophagus or colon, or neurological disorders.[12] Equally as distressing, VL is fatal within two years after infection if left untreated, and often after causing irregular bouts of fever, weight loss, enlargement of the spleen and liver, and anemia. Both diseases inflict devastating tolls on the economies of regions they affect. The global cost of Chagas disease, for example, is estimated at $7 billion annually.[13] The majority of this cost burden stems from losses in workforce productivity. In the case of VL, a recent analysis for one of the worst affected regions in India showed that 7 months of an infected individual's income was spent on treatments for the disease.[14]

Innovation Opportunity

The few existing treatments for both Chagas disease and VL are expensive, inefficient, and cause serious side effects. The most effective existing VL therapy is unstable at the high temperatures in regions affected by the disease, and is given by painful injection—both limiting patient access and compliance. The two existing drugs for Chagas disease are effective when given soon after infection, but their efficacy decreases significantly as the disease progresses from the acute to the

chronic phase. Because the majority of infected individuals do not show symptoms in the early stages of the disease, the effectiveness of these drugs has been limited. These drugs also cause side effects that lead to discontinuation of treatment in more than 30% of patients.[15] Moreover, these treatments require multiple doses over a prolonged duration, which results in poor patient adherence.

Partnership in Action

Committed to finding effective treatments against these neglected diseases, the GHIT drug discovery partnership between DND*i* and pharmaceutical companies Eisai Co. Ltd., Shionogi & Co. Ltd., and Takeda Pharmaceutical Company Limited provides DND*i* with access to the drug discovery portfolios and scientific expertise of the Japanese pharmaceutical companies for the purpose of finding new treatments for both diseases. GHIT's Hit-to-Lead Platform — a drug discovery approach that allows for rapid screening of compounds to find those most promising for treatment — forms the heart of the partnerships, which is expected to identify at least four potential drug candidates for each disease within the next two years. Hopes are high that these "hits" will provide at least one lead drug candidate for each disease, which can then be advanced through more detailed safety and effectiveness studies during development.

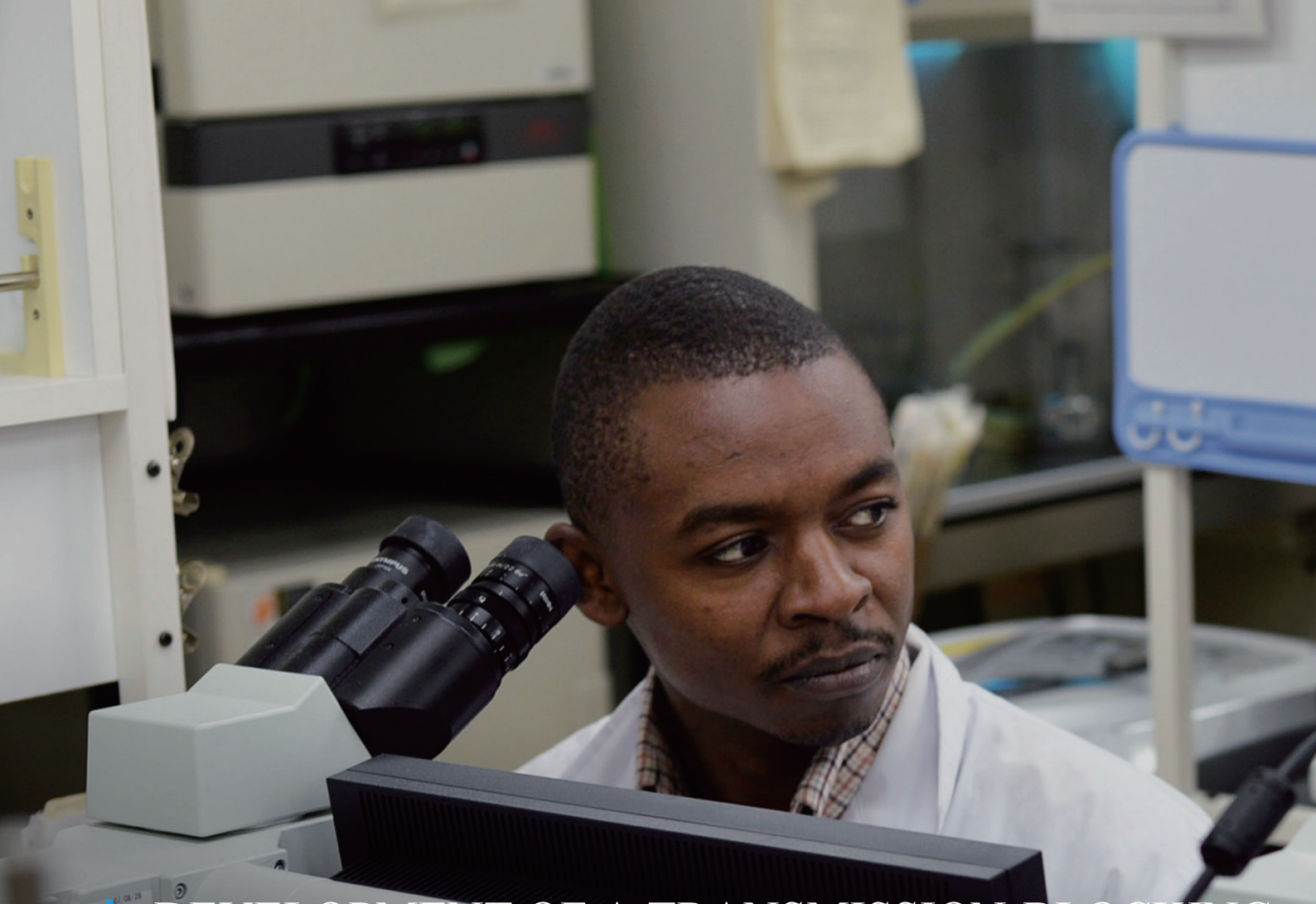
7. "WHO: Chagas Disease (American trypanosomiasis)," World Health Organization, updated February 2015; accessed February 24, 2015, http://www.who.int/mediacentre/factsheets/fs340/en/.
8. "Research Priorities for Chagas Disease, HAT and Leishmaniasis," World Health Organization (2012), accessed February 24, 2015, http://www.who.int/iris/bitstream/10665/77472/1/WHO_TRS_975_eng.pdf.
9. "Chagas disease – PAHO/WHO,." Pan American Health Organization, accessed February 15, 2015, http://www.paho.org/hq/index.php?option=com_topics&view=article&id=10&Itemid=40743.
10. "WHO | Leishmaniasis." Updated January 2004. Accessed February 15, 2015, http://www.who.int/leishmaniasis/en/.
11. Joseph A. McFalls Jr, and Marguerite Harvey McFalls, "Disease and Fertility," (Academic Press, 1984).
12. "Chagas disease Symptoms - Diseases and Conditions ..." 2014. Accessed February 15, 2015, http://www.mayoclinic.org/diseases-conditions/chagas-disease/basics/symptoms/con-20030854.
13. Bruce Y Lee et al. "Global Economic Burden of Chagas Disease: A Computational Simulation Model." The Lancet Infectious Diseases, 13.4 (2013): 342–48.
14. Rhonda Sarnoff et al. "The Economic Impact of Visceral Leishmaniasis on Rural Households in One Endemic District of Bihar, India," Tropical Medicine & International Health 15.s2 (2010): 42–49.
15. Gilberto Marcelo Sperandio Da Silva et al., "A Clinical Adverse Drug Reaction Prediction Model for Patients with Chagas Disease Treated with Benznidazole." Antimicrobial Agents and Chemotherapy 58.11 (2014): 6371–377.

Dr. Isao Teshirogi

President & CEO, Shionogi & Co., Ltd.

"Global health has never before been better positioned to join forces across sectors to innovate for neglected diseases."

Photo Credit : Benoit Marquet / DND*i*



DEVELOPMENT OF A TRANSMISSION-BLOCKING VACCINE FOR MALARIA

EHIME UNIVERSITY
PATH MALARIA VACCINE INITIATIVE (PATH MVI)

Prevalence

The pervasiveness of malaria can be traced to infectious parasites spread by mosquitos. In 2013, malaria caused 584,000 people deaths globally –78% of which were in children under the age of five.[16] That same year, about 198 million cases of the disease existed[17] and approximately 44% of people worldwide were at risk of being infected. Most of the deaths occur in Sub-Saharan Africa and India, where mosquitos breed in crowded and impoverished areas, but the disease affects populations in at least 97 tropical and sub-tropical countries.

Socioeconomic Costs

In children, malaria causes severe anemia, respiratory distress, or cerebral distress that can lead to brain damage and even coma. Pregnant women infected with the diseases face increased risk of miscarriage, maternal death, severe anemia, and transmitting the disease to their unborn children. Additionally, malaria diminishes worker productivity and increases healthcare costs, which can lower a nation's gross domestic product by as much as 6%.[18] In Africa alone, malaria costs $12 billion a year in lost productivity and can cut household income by 25%.[19] Social impacts are most notable in education: malaria keeps more children out of school than any other disease, which translates into higher failure rates, repeated school years, and more drop-outs.[20] A recent study estimates that $208.6 billion in economic gains could be realized between 2013 and 2035 if malaria were reduced and eliminated from the world.[21]

Innovation Opportunity

Drugs, bed nets, and insecticide treatments have made great strides toward managing malaria, but they do not offer a robust promise for elimination. One potential solution is a vaccine that disrupts the malaria transmission cycle between mosquitoes and humans. A transmission-blocking vaccine for malaria would not prevent a human from developing the disease; rather, it prevents the transmission of parasites from

infected humans to others. An effective malaria elimination campaign would involve the use of both vaccine types. Transmission-blocking vaccines are also used for diseases like malaria where the parasites have complex life cycles, making infection-preventing vaccines difficult to develop.

Partnership in Action

The GHIT Fund has forged a partnership between Ehime University in Japan and the PATH Malaria Vaccine Initiative (PATH MVI) in the United States to create a transmission-blocking vaccine that aims to prevent the spread of the parasites responsible for malaria. Both partners bring unique expertise in vaccine development; Ehime has the proprietary manufacturing platform to produce components of the vaccine, while PATH MVI identifies and accelerates malaria vaccine candidates through the development process. If proven to be safe and effective in humans, the vaccine will be combined with current interventions and other vaccines to reduce the global impact of malaria.

16. "World Malaria Report 2014," World Health Organization (2014).
17. Ibid.
18. World Economic Forum Global Health Initiative in cooperation with Harvard School of Public Health, "Business and Malaria: A Neglected Threat?" (World Economic Forum, June 2006).
19. The Abuja Declaration, The African Summit on Roll Back Malaria, African Heads of State and Government, 25 April 2000, Abuja, Nigeria.
20. C. Leighton and R. Foster , "Economic Impact of Malaria in Kenya and Nigeria, " Bethesda: Abt Associates (1994). See also: Malaria No More Website, accessed February 16, 2015, https://www.malarianomore.org/.
21. M. Purdy, M. Robinson , K. Wei , and D. Rublin, "The Economic Case for Combating Malaria," American Journal of Tropical Medicine and Hygiene, 89, No. 5 (November 2013):819–23.

Dr. Ashley J. Birkett

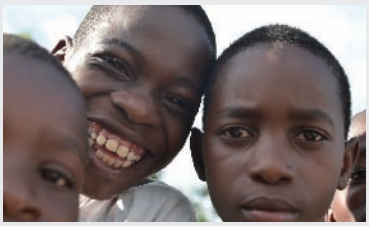
Director, PATH MVI

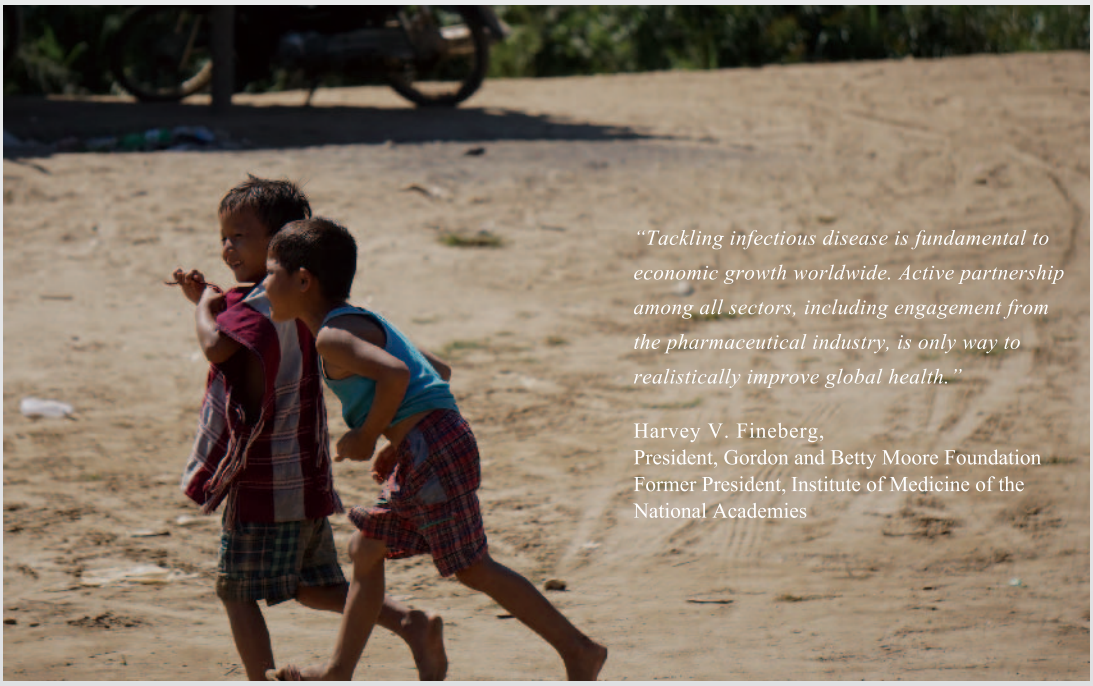
"This partnership is critical to our pursuit of next-generation vaccines to support the malaria eradication effort, as it brings to bear Japanese know-how and investment in the global fight against infectious diseases."

Photo Credit : Taihei

A VIEW FROM THE FIELD

Tanzania / Thailand / Peru





"Tackling infectious disease is fundamental to economic growth worldwide. Active partnership among all sectors, including engagement from the pharmaceutical industry, is only way to realistically improve global health."

Harvey V. Fineberg,
President, Gordon and Betty Moore Foundation
Former President, Institute of Medicine of the National Academies

FINANCES

For Translation Purposes Only

Independent Auditor's Report

To the Board of Directors, Global Health Innovative Technology Fund:

<Audit of the Financial Statements>

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 Public Interest Incorporated Association Global Health Innovative Technology Fund ("the Organization") applicable to the third fiscal year from April 1, 2014, through March 31, 2015. We conducted our audit in accordance with the rules and regulations concerning the Act on the Authorization, etc. of Public Interest Incorporated Associations and Public Interest Incorporated Foundations in Japan, under Article 23.

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 third fiscal year ended March 31, 2015, in conformity with accounting principles generally accepted in Japan for Public Interest Incorporated Associations (equivalent to a 501(c)(3) in the United States).

<Opinion on the List of Assets and Liabilities>

We have audited the accompanying list of assets and liabilities for the third fiscal year of the Public Interest Incorporated Association Global Health Innovative Technology Fund at March 31, 2015. We conducted our audit in accordance with the rules and regulations concerning the Act on the Authorization, etc. of Public Interest Incorporated Associations and Public Interest Incorporated Foundations in Japan, under Article 23.

Directors' Responsibility for the List of Assets and Liabilities

Directors need to ensure that the list of assets and liabilities was prepared and fairly presented in accordance with accounting principles generally accepted in Japan and also in conformity with the public-interest certification documents.

Auditor's Responsibility

For Translation Purposes Only

Our responsibility is to express an opinion on the said list of assets and liabilities which was prepared and fairly presented in accordance with auditing standards generally accepted in Japan and also in conformity with the public-interest certification documents.

Opinion

In our opinion, the list of assets and liabilities referred to above present fairly, in all material respects, in accordance with auditing standards generally accepted in Japan and also in conformity with the public-interest certification documents.

<Emphasis of Matter>

As stated in the Notes to Financial Statement, the Organization became certified as a Public Interest Incorporated Association on June 1, 2014. The financial statements for the period between April 1st, 2014 and May 31st, 2014 were prepared as a General Incorporated Association. Our opinion is not affected by this matter.

<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, 2015

End-of-Document

独立監査人の監査報告書

平成２７年５月７日

公益社団法人　グローバルヘルス技術振興基金
理　事　会　御　中

新日本有限責任監査法人

指定有限責任社員
業務執行社員　公認会計士　矢崎弘直

＜財務諸表監査＞
当監査法人は、公益社団法人及び公益財団法人の認定等に関する法律第２３条の規定に基づき、公益社団法人グローバルヘルス技術振興基金の平成２６年４月１日から平成２７年３月３１日までの第３期の貸借対照表及び損益計算書（公益認定等ガイドライン１－５(1)の定めによる「正味財産増減計算書」をいう。）並びにその附属明細書並びに財務諸表に対する注記について監査し、併せて、正味財産増減計算書内訳表（以下、これらの監査の対象書類を「財務諸表等」という。）について監査を行った。

財務諸表等に対する理事者の責任
理事者の責任は、我が国において一般に公正妥当と認められる公益法人会計の基準に準拠して財務諸表等を作成し適正に表示することにある。これには、不正又は誤謬による重要な虚偽表示のない財務諸表等を作成し適正に表示するために理事者が必要と判断した内部統制を整備及び運用することが含まれる。

監査人の責任
当監査法人の責任は、当監査法人が実施した監査に基づいて、独立の立場から財務諸表等に対する意見を表明することにある。当監査法人は、我が国において一般に公正妥当と認められる監査の基準に準拠して監査を行った。監査の基準は、当監査法人に財務諸表等に重要な虚偽表示がないかどうかについて合理的な保証を得るために、監査計画を策定し、これに基づき監査を実施することを求めている。
監査においては、財務諸表等の金額及び開示について監査証拠を入手するための手続が実施される。監査手続は、当監査法人の判断により、不正又は誤謬による財務諸表等の重要な虚偽表示のリスクの評価に基づいて選択及び適用される。財務諸表監査の目的は、内部統制の有効性について意見表明するためのものではないが、当監査法人は、リスク評価の実施に際して、状況に応じた適切な監査手続を立案するために、財務諸表等の作成と適正な表示に関連する内部統制を検討する。また、監査には、理事者が採用した会計方針及びその適用方法並びに理事者によって行われた見積りの評価も含め全体としての財務諸表等の表示を検討することが含まれる。
当監査法人は、意見表明の基礎となる十分かつ適切な監査証拠を入手したと判断している。

監査意見
当監査法人は、上記の財務諸表等が、我が国において一般に公正妥当と認められる公益法人会計の基準に準拠して、当該財務諸表等に係る期間の財産及び損益（正味財産増減）の状況をすべての重要な点において適正に表示しているものと認める。

＜財産目録に対する意見＞
当監査法人は、公益社団法人及び公益財団法人の認定等に関する法律第２３条の規定に基づき、公益社団法人グローバルヘルス技術振興基金の平成２７年３月３１日現在の第３期の財産目録（「貸借対照表科目」、「金額」及び「使用目的等」の欄に限る。以下同じ。）について監査を行った。

財産目録に対する理事者の責任
理事者の責任は、財産目録を、我が国において一般に公正妥当と認められる公益法人会計の基準に準拠するとともに、公益認定関係書類と整合して作成することにある。

監査人の責任
当監査法人の責任は、財産目録が、我が国において一般に公正妥当と認められる公益法人会計の基準に準拠しており、公益認定関係書類と整合して作成されているかについて意見を表明することにある。

財産目録に対する監査意見
当監査法人は、上記の財産目録が、我が国において一般に公正妥当と認められる公益法人会計の基準に準拠しており、公益認定関係書類と整合して作成されているものと認める。

＜強調事項＞
財務諸表に対する注記の冒頭にあるとおり、法人は平成２６年６月１日付で、公益社団法人となった。平成２６年４月１日から平成２６年５月３１日の会計区分は公益認定前の区分である。
当該事項は、当監査法人の意見に影響を及ぼすものではない。

＜利害関係＞
公益社団法人グローバルヘルス技術振興基金と当監査法人又は業務執行社員との間には、公認会計士法の規定により記載すべき利害関係はない。

以　上

2014 Financial Summary (audited)

ASSETS, LIABILITIES, AND NET ASSETS

ASSETS	Millions of Yen	Millions of U.S. dollars
Cash and Cash Equivalents	¥486.9	$4.0
Fixed Assets	1,272.7	10.6
TOTAL ASSETS	¥1,759.6	$14.6

LIABILITIES AND NET ASSETS	Millions of Yen	Millions of U.S. dollars
Total Liabilities	¥520.9	$4.3
Net Assets	1,238.7	10.3
TOTAL LIABILITIES AND NET ASSETS	¥1,759.6	$14.6

FUNDS RECEIVED	Millions of Yen	Millions of U.S. dollars
Governments, NGOs, Multilateral Organizations	¥1,255.5	$10.4
Foundations	697.4	5.8
Corporations	1,055.7	8.8
TOTAL FUNDS RECEIVED	¥3,008.6	$25.0

FUNDS RECEIVED

41.7% Governments, NGOs, Multilateral Organizations

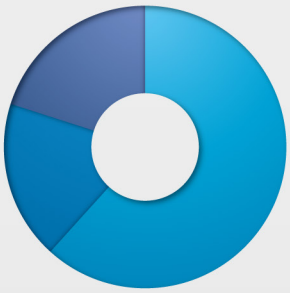
23.2% Foundations

35.1% Corporations

NET ASSETS VARIATION STATEMENT

ALLOCATED REVENUE	Millions of Yen	Millions of U.S. dollars
Governments, NGOs, Multilateral Organizations	¥1,381.3	$11.5
Foundations	375.8	3.1
Corporations	440.2	3.7
TOTAL ALLOCATED REVENUE	¥2,197.3	$18.3
CARRY-OVER FROM PRIOR YEAR	¥14.8	$0.1

EXPENSES	Millions of Yen	Millions of U.S. dollars
Program Services	¥2,108.1	$17.5
Support Services	104.0	0.9
TOTAL EXPENSES	¥2,212.1	$18.4

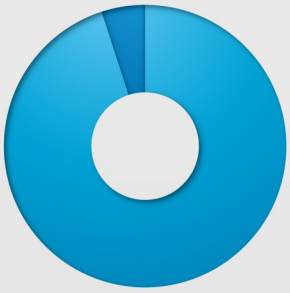


SOURCES OF ALLOCATED REVENUE

62.9% Governments, NGOs, Multilateral Organizations

17.1% Foundations

20.0% Corporations



EXPENSE ALLOCATION

95.3% Program Services

4.7% Support Services

The U.S. dollar amounts in this section represent translations of Japanese yen, solely for the reader's convenience, at JPY 120.15=USD 1, the approximate exchange rate at March 31, 2015.

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 Public Interest Incorporated Association and is registered in Japan.

LEADERSHIP

Our governance structure is designed to structurally transcend potential conflicts of interest that can arise when a company may be both a benefactor and a beneficiary of the Fund. The reason for this is simple: national institutes and universities are critical research partners, but we need companies to champion the development and delivery of products to patients. Companies commit non-dilutive capital to the GHIT Fund but then relinquish all decision-making for investments and portfolio management to a Board and Management Team that excludes private sector representation.

COUNCIL

[Roles and Function] Appoint and dismiss members of the Council and Board/ Amend Articles of Incorporation/ Determine Board terms/ Serve as advocates for the Fund/ Approve financial statements

Atsuyuki Oike
Director-General for Global Issues,
Ministry of Foreign Affairs

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

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

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

Chugai Pharmaceutical Co., Ltd.
Osamu Nagayama
Representative Director,
Chairman and CEO

Daiichi Sankyo Company, Limited
George Nakayama
Representative Director,
President and CEO

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

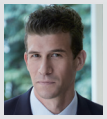
Shionogi & Co., Ltd.
Isao Teshirogi, PhD
President and CEO

Takeda Pharmaceutical Company Limited
Yasuchika Hasegawa
Representative Director,
Chairman of the Board

BOARD OF DIRECTORS

[Roles and Function] Approve midterm strategies/ Approve annual plans and budget/ Appoint and dismiss Selection Committee members/ Approve selection criteria and priorities for the Selection Committee/ Approve investment recommendations from the Selection Committee

Representative Director and Chair
Kiyoshi Kurokawa, MD
Adjunct Professor,
National Graduate Institute for
Policy Studies & Chairman,
Health and Global Policy Institute

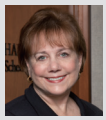


Executive Director
BT Slingsby, MD, PhD, MPH
CEO,
Global Health Innovative Technology Fund

Member
Mahima Datla
Managing Director,
Biological E. Limited

Member
Eiji Hinoshita, MD, PhD
Director, Office of International Cooperation,
International Affairs Division,
Minister's Secretariat,
Ministry of Health, Labour and Welfare

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



Member
Ann M. Veneman, JD
Former Executive Director, UNICEF
Former Secretary,
United States Department of Agriculture

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

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

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

Ex-Officio Observer
Kim C. Bush
Director, Life Sciences Partnerships,
Bill & Melinda Gates Foundation

Ex-Officio Observer
Richard Seabrook, PhD, MBA
Head, Business Development, Innovations,
Wellcome Trust

SELECTION COMMITTEE

[Roles and Function] Review and evaluate investment proposals and progress reports from development partners/ Recommend provision of investments to the Board based on their evaluations/ Ensure independence, accountability, and transparency of investment recommendations

Member

Ann Mills-Duggan, PhD

Head, Seeding Drug Discovery Fund,
Business Development, Innovations,
Wellcome Trust

Member

Ken Duncan, PhD

Deputy Director,
Discovery & Translational Sciences,
Bill & Melinda Gates Foundation

Member

Kouji Hattori, PhD

Project Professor, United Centers for
Advanced Research and Translational Medicine,
Tohoku University Graduate School of Medicine

Member

Penny M. Heaton, MD, MPH

Director, Vaccine Development
and Surveillance,
Bill & Melinda Gates Foundation

Member

Kiyoshi Kita, PhD

Professor,
Department of Biomedical Chemistry
Graduate School of Medicine,
The University of Tokyo

Member

Alex Matter, MD

CEO,
Experimental Therapeutics Centre and D3,
A*STAR, Singapore

Member

Yasuko Mori, MD, PhD

Professor, Division of Clinical Virology,
Center for Infectious Diseases,
Kobe University Graduate
School of Medicine

Member

Dennis Schmatz, PhD

Former Head, Infectious Diseases Research,
Merck Research Labs, USA,
Former Head, Research, MSD-Japan

ADVISORY PANEL

[Roles and Function] Provide strategic advice to the Fund's Board Chair, CEO, and Management Team

Member

Awa Marie Coll Seck, MD, PhD

Minister of Health, Republic of Senegal
Former Executive Director,
Roll Back Malaria Partnership

Member

Harvey V. Fineberg, MD, PhD

President, Gordon and Betty Moore Foundation
Former President,
Institute of Medicine of the National Academies

Member

Dai Hozumi, MD, MSM, MPH

Senior Advisor,
Health Systems and Policy, PATH

Member

Michael R. Reich, PhD

Taro Takemi Professor,
International Health Policy,
Harvard School of Public Health

Member

Kumi Sato

President and CEO,
Cosmo Public Relations Corporation

Member

Lorenzo Savioli, MD, DTM&H, MSc

Former Director, Department of
Neglected Tropical Diseases, WHO

Member

Peter Singer, MD, MPH, FRCPC

CEO,
Grand Challenges Canada

EXTERNAL REVIEWERS

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

Richard Adegbola
Yukihiro Akeda
Peter Andersen
Rip Ballou
Clifton E Barry
Marleen Boelaert
Maria Elena Bottazzi
Nancy Le Cam Bouveret
Walter Brandt
Tom Brewer
Ami Shah Brown
David Brown
Simon Campbell
Shing Chang
Eric Chatelain
Simon Croft
Carol Dahl
Peter Dailey
Christine Debouck
Thomas Dick
Carter Diggs
Boro Dropulic
Filip Dubovsky
Hiroyoshi Endo
Alan Fairlamb
Herman Feldmeier
David Fiddock
Michael Free
Nisha Garg
Birgitte Giersing
Ann Ginsberg
Pantaleo Giuseppe
Glenda Gray
Brian Greenwood
Sanjay Gurunathan
Kip Guy
Lee Hall
Yoshihisa Hashiguchi
Christopher Hentschel
Gray Heppner
Toshihiro Horii
Sanjay Jain
Takushi Kaneko
Niranjan Kanesa-thasan
Shigeyuki Kano
Subhash Kapre
Naoto Keicho
David Kelso
Kent Kester
Akinori Kimura
Sue Kinn
Somei Kojima
Hidehito Kotani
Michael Kurilla
Dennis Kyle
James Le Duc
John Mansfiled
Carol Marzetta
Greg Matlashewski
James McCarthey
James McKerrow
Carl Mendel
Charles Mgone
Melinda Moree
Koichi Morita
Charles Mowbray
Peter Myler
Daniel Neafsey
Christian Ockenhouse
Giuseppe Pantaleo
David Persing
Meg Phillips
David Pompliano
Regina Rabinovich
Rino Rappuoli
Zarifah Reed
Yves Ribeill
Rebecca Richards Kortum
Paul Roepe
Polly Roy
Peter Ruminski
Philip Russell
Judy Sakanari
Hing Sham
KJ Singh
Peter Smith
Lynn Soong
Dan Stinchcomb
Nathalie Strub-Wourgaft
Marcel Tanner
Kaoru Terashima
Katsushi Tokunaga
Nadia Tornieporth
Bruno Travi
Takafumi Tsuboi
Moriya Tsuji
Mickey Urdea
Stephen Ward
Timothy Wells
Bruce G. Weniger
John Westwick
Judith Wilber
Elizabeth Winzeler
Michael Witty
Paul Wyatt
Donato Zipeto

PARTNERS

Funders

外務省 MOFA Japan

ひと、くらし、みらいのために 厚生労働省 Ministry of Health, Labour and Welfare

UNDP

astellas Leading Light for Life

CHUGAI Roche ロシュ グループ

Daiichi-Sankyo

Eisai

SHIONOGI

sysmex

Takeda

BILL & MELINDA GATES foundation

wellcome trust

= Founding Partner

Sponsors

ANA

MORI

MORRISON FOERSTER

YAHOO! JAPAN

"Japan's ODA has long been used in ways which bring together a diverse range of partners – traditional donors, South-South partners, multilateral organizations, the private sector, and civil society organizations…. [An] example is Japan's Global Health Innovative Technology Fund (GHIT), through which the public and private sectors have come together to help bring new health technologies to the world's poorest people. UNDP is very pleased to be a partner in GHIT."

Helen Clark, Administrator, UNDP

Keynote speech, Event celebrating Japan's 60th Anniversary of Official Developmental Assistance, Tokyo, Japan, November 17, 2014. Available at: http://www.undp.org/content/undp/en/home/presscenter/speeches/2014/11/17/helen-clark-keynote-speech-at-event-celebrating-japan-s-60th-anniversary-of-official-developmental-assistance-tokyo-japan.html.

Partner with Japan, Accelerate Health Innovation.

GHIT Fund

Global Health Innovative Technology Fund

Ark Hills Sengokuyama Mori Tower 25F,
1-9-10 Roppongi, Minato-ku,
Tokyo 106-0032 Japan
TEL:+81-36441-2032 FAX:+81-36441-2031
www.ghitfund.org