From
the People of Japan

GHIT Fund

Global Health Innovative Technology Fund

UNDP

Empowered lives.
Resilient nations.

Phase 1
Final Report

April 2013–March 2014

GHIT: Research and Development (R&D) of New Global Health Technologies for TB, Malaria, NTDs and Other Diseases for Patients and Citizens of Low- and Middle-Income Countries (LMICs)

Contents

Abbreviations and acronyms

CEO	Chief Executive Officer
DDI	Drug–drug interaction
GHIT	Global Health Innovative Technology
ITA	Intent to Apply
LMIC	Low- and middle-income country
MDG	Millennium Development Goal
Mtb	Mycobacterium tuberculosis
NTD	Neglected tropical disease
PCA	Project Cooperation Agreement
PDP	Product development partnership
R&D	Research and development
RFP	Request for Proposal
SDG	Sustainable Development Goal
TB	Tuberculosis

I. Project summary

Project title	GHIT: Research and Development (R&D) of New Global Health Technologies for TB, Malaria, NTDs and Other Diseases for Patients and Citizens of Low- and Middle-Income Countries (LMICs)
Award ID; Project number	00074638; 00086939
Project duration	12 months (01 April 2013 to 31 March 2014)
Implementing partner(s)	Global Health Innovative Technology (GHIT)
Total budget	US$10,918,165.75
Contribution from Japan	100%
UNDP Strategic Plan Outcome 3	Countries have strengthened institutions to progressively deliver universal access to basic services
UNDP Strategic Plan Output 3.3	National institutions, systems, laws and policies strengthened for equitable, accountable and effective delivery of HIV and related services
Expected project output	The GHIT funding of partnerships between the Japanese research organizations and international entities for the development of new global health technologies for TB, Malaria, NTDs and other diseases for patients and citizens of LMICs
UNDP HQ focal point	Tenu Avafia
UNDP APRC focal point	Cecilia Oh
Report prepared by	Tenu Avafia and Cecilia Oh
Date of report	20 November 2014

II. Context

Tuberculosis (TB), malaria and neglected tropical diseases (NTDs) have an adverse impact on human development. TB accounts for 1.3 million deaths every year, and an estimated 3.3 billion people were at risk of malaria globally, with more than 600,000 deaths occurring in 2012.[1] NTDs disproportionately affect the so-called 'bottom billion'—the 1.4 billion people who live below the US$1.25 per day poverty line. The 17 NTDs listed by the World Health Organization (WHO) are prevalent in 149 countries and share common features. These include their prevalence in poor and disadvantaged populations, and their significant impact on child and maternal health, on global and national economic output, and on progress on the Millennium Development Goals (MDGs) and the post-2015 Sustainable Development Goals (SDGs). The impact of NTDs stretches across multiple development sectors, including water and sanitation, nutrition, maternal and child health, and education. Long-term sustainable development, poverty reduction and improved health outcomes cannot be successfully achieved without simultaneously addressing NTDs.

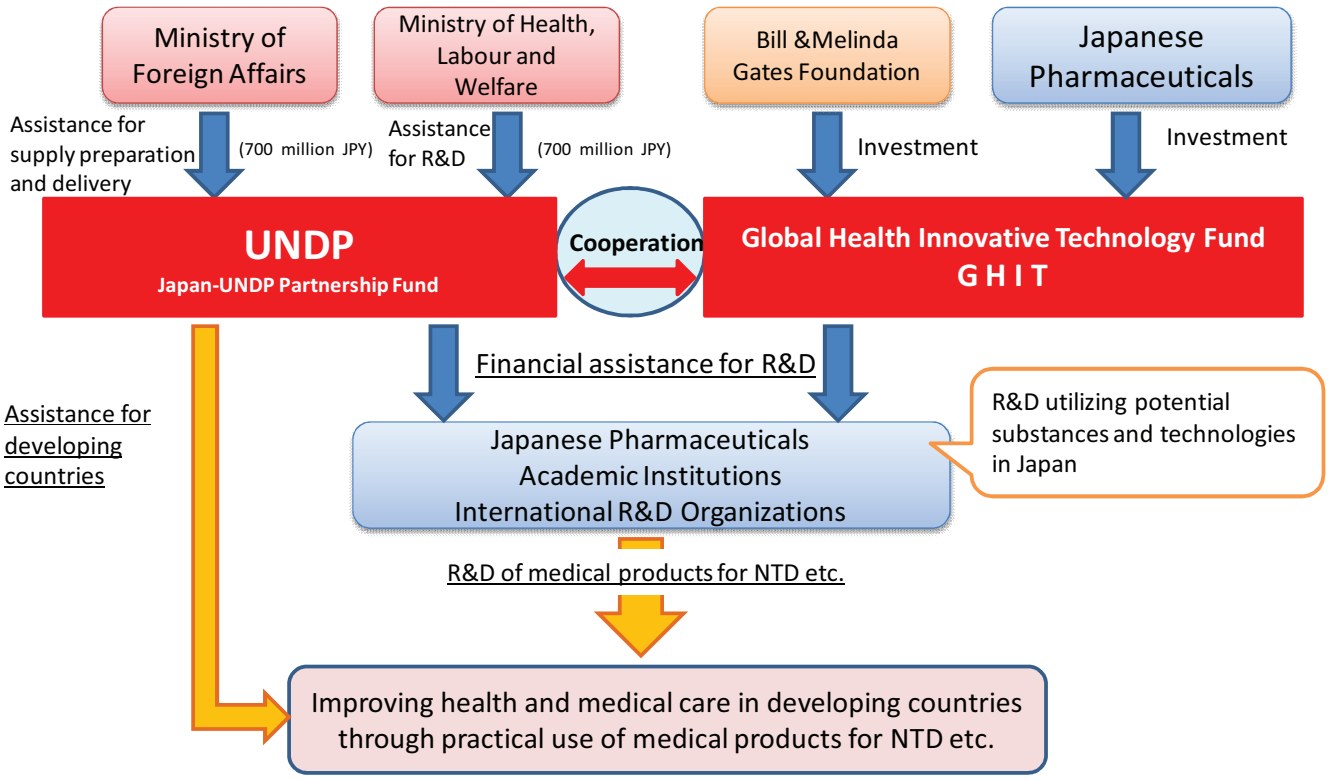
In addition to being diseases of poverty and inequality, TB, malaria and NTDs are disproportionately neglected by research-based pharmaceutical companies and share an urgent need for increased innovation for health technologies. Of the 1556 new medicines approved between 1975 and 2004, only 1.3 percent were specifically developed for tropical diseases and TB.[2] Furthermore, evidence suggests that capacity in low- and middle-income countries (LMICs) to absorb, deliver and provide access to vaccines, diagnostics and medicines to treat TB, malaria and NTDs is weak.[3] While the number of new health technologies coming to market for TB, malaria and NTDs is increasing, a public health impact will come only after the adoption of health technologies in the health systems of LMICs.[4]

The need for sustainable capacity to deliver new global health technologies is also indicated in MDG8.E: "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries". To indicate success against MDG8.E, countries must show "proportion of population with access to affordable essential drugs on a sustainable basis". This indicator of sustainability denotes that countries must have, or develop, the capacity for access to and delivery of new global health technologies. Ongoing discussions of the health goal of the post-2015 SDGs continue to reflect the importance of NTDs and the commitment to addressing the related needs as a critical part of sustainable development efforts.

1. TDR, Global Report for Research on Infectious Diseases and Poverty, TDR, Geneva, 2012.
2. W. Wells and A. Brooks, PDP Support of Country Decision Making: A Discussion paper, TB Alliance and PATH, New York, 2012.
3. Oxfam, Ending the R&D crisis in Public Health: Promoting pro-poor medical innovation, Oxfam Briefing Paper, Oxfam, Oxford, 2008; W. Wells and A. Brooks, PDP Support of Country Decision Making: A Discussion paper, TB Alliance and PATH, New York, 2012.
4. W. Wells and A. Brooks, PDP Support of Country Decision Making: A Discussion paper, TB Alliance and PATH, New York, 2012.

Public–private partnerships (PPPs) offer a new means to address this gap in the global health sector by combining the work of the private sector's capability of drug development, with the public sector's work in health policy and ability to build capacity in developing countries. The Government of Japan's leadership and commitment to addressing the challenges related to innovation and access to and delivery of new health technologies for NTDs are highly appreciated by the United Nations Development Programme (UNDP) and other partners. The collaboration between the Government of Japan and UNDP focuses on the promotion of research and development (R&D) and on increasing access to and delivery of health technologies used to address TB, malaria and NTDs mainly through two projects—'Global Health Innovative Technology (GHIT) Fund' and 'Building Capacity for Access and Delivery of New Global Health Technologies for Tuberculosis (TB), Malaria, Neglected Tropical Diseases (NTDs) and Other Diseases in LMICs' (Access and Delivery Partnership) (see Figure 1).

FIGURE 1. Collaboration between the Government of Japan and UNDP



This innovative partnership between the Government of Japan and UNDP is in line with the approach of the UNDP Strategic Plan 2014–2017. Outcome 3 of the Strategic Plan focuses on the capacity of institutions to lead the development process and deliver justice, security and other basic services to all women and men, including the most marginalized. In particular, Output 3.3 aims to strengthen national institutions, systems, laws and policies for equitable, accountable and effective delivery of HIV and related services which are applicable to other diseases such as TB, malaria and NTDs.

In this context, the GHIT Fund aims to promote R&D in technologies for treatment and control of TB, malaria and NTDs through the provision of grants to partnerships of Japanese pharmaceutical companies with international entities (see Annex 3 for more details). The GHIT Fund was established for the purpose "to engage exclusively in activities for the promotion and support of scientific research in the public interest and specifically for the research and development of medical products and technology for developing countries, and through these activities, to deliver Japanese technologies to the patients and citizens of developing countries…".[5]

Recognizing the capacity gaps in LMICs to effectively access and deliver needed new health technologies, the Access and Delivery Partnership brings together UNDP, the Special Programme for Research and Training in Tropical Diseases at WHO (WHO/TDR) and PATH to support countries to strengthen their capacities to address bottlenecks in this area. The ADP thus complements the work of the GHIT Fund by bridging the chasm between R&D and access and delivery in LMICs.

In this Annual Report to the Government of Japan, UNDP highlights the first year's achievements of the GHIT Fund project from the period between 1 April 2013 and 31 March 2014.

5. General Incorporated Association [Global Health Innovative Technology Fund (Global Health Gijyutsu Shinkou Kikin)] Articles of Incorporation. Chapter 1—General Rules: Article 3 (Purpose).

III. Performance review

i. Achievements

ACTIVITY 1: Develop governance and management structures for the GHIT Fund

Establishment of governance and management structures

The GHIT Fund and UNDP signed the Project Cooperation Agreement (PCA) on 5 April 2013 and set out to implement a governance and management structure that represents key stakeholders and ensures efficiency and quality in the product development grant-making process. The governance framework—including Council, Board of Directors, Selection Committee, Advisory Panel and Management Team—and systems for operations, finance and reporting were put in place, including cooperation and communication modalities between the UNDP and the GHIT Fund Management Team (see Annex 1). The Articles of Incorporation and organizational rules outlining the roles and responsibilities of each function were finalized (see Table 1).

TABLE 1. GHIT Fund Articles of Incorporation and organizational rules

Structure	Roles and responsibilities
Council	• Oversight of the Board of Directors • Advocacy for the Fund's mission • Amendment of the Articles of Incorporation, determination of the terms of the Board and approval of financial statements
Board of Directors	• Governance and oversight for the Selection Committees • Set policy • Assess the Fund's overall performance
Selection Committee	• Evaluate grant proposals and reports from grantees • Recommend provision of grants to the Board of Directors • Ensure independence, accountability and transparency of grant review and recommendations
Advisory Panel	• Provide strategic advice to the Chair of the Board and the Chief Executive Officer (CEO)
Management Team	• Daily operations, proposal of midterm strategies and annual plans to the Board of Directors • Proposal of selection criteria and priorities to Selection Committee to the Council • Reporting of financial statements to the Council and donors

A management team was recruited by the GHIT Fund, comprising a CEO, Director of Operations, Director of Strategy, Director of Communication Design, Programme Manager: Operations, Programme Manager: Communication Design, CEO Office Manager and Programme Associate: Operations.

Establishment of review and grant-making mechanism

The GHIT Fund Management Team developed a grant-making and review process by conducting research on different grant-making processes that were outcome driven. The resulting process (see Box 1), which was approved by the Board of Directors, reflects the strategic goals of the programme and the needs of key stakeholders, including the Foundation, and ensures a transparent system of review and selection of grants with health impact as the foremost criterion. Grants made by GHIT Fund contain global access commitments in line with GHIT's grant-making mechanism as approved by the Board and its Data Access Plan and Grant Modules. Grant applications, selection process and contractual agreements were also developed by the Management Team. The GHIT Fund also successfully introduced the electronic reviewing system using Editorial Manager, which resulted in a more valid and efficient review.

BOX 1: The 10 steps of the GHIT Fund grant-making process

1. Applicants submit an Intent to Apply (ITA) form in response to a Request for Proposal (RFP) within a specified time-frame.
2. The GHIT Fund Management Team performs an initial partnership and scope eligibility assessment.
3. The successful applicants submit full proposals using the second proposal templates by the specific deadline.
4. The GHIT Fund Management Team reviews the submitted full proposals based on the following criteria: 1) the partnership meets the GHIT Fund's eligibility criteria; 2) project objectives are aligned with the scope specified in the RFP; and 3) the proposal is complete and addresses all required content.
5. The GHIT Fund Management Team notifies the applicants whether or not they are eligible for proposal evaluation by external reviewers.
6. Three external reviewers, who are experts in the discovery and development of global health technologies and have the experience to objectively evaluate the proposal content, review each eligible proposal.
7. Once the external reviews are complete, the GHIT Fund Management Team aggregates scores for each proposal and then ranks them. All evaluation documentation is compiled and distributed to the Selection Committee for review and evaluation.
8. The Selection Committee members review and prioritize the proposals for funding based on the external review evaluations.
9. The proposals selected by the Selection Committee are passed to the GHIT Board of Directors to review and approve the award decision.
10. For proposals approved by the Board of Directors, the grant agreement is contracted between the applicants and the GHIT Fund. Once the grant agreement is signed, the GHIT Fund will process the first payment to the designated grantee.

To fast-track proposals and projects with early results and achievements, the GHIT Fund developed the contract-based Drug Discovery Screening Platform, designed specifically to connect product development partnerships' (PDP) active screening platform for TB, malaria and NTDs in partnership with Japanese companies or academic organizations that have relevant compound libraries. The Screening Platform enables the screening of tens of thousands of drug candidates for potential new treatments. In June 2013, Japan's private and academic sectors made their advanced compound libraries accessible to PDPs through the Screening Platform. Initial

partnerships—focused on drug discovery for TB, malaria, Leishmaniasis and Chagas disease—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.

Subsequently, 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 but are likely to require further chemical modification before they can be tested as human drugs. This new programme helps researchers find promising drug compounds that can fight infectious diseases.

ACTIVITY 2: Identify and initiate potential collaborations between Japanese companies/universities and global health R&D organizations in Year 1

Ten grants awarded

During the first year of the project, GHIT successfully identified potential collaborations for the discovery, development and delivery of global health technologies between Japanese companies or universities and capable international organizations involved in the R&D of global health technologies. The GHIT Fund has to date facilitated 10 partnerships and funded eight of them to discover and develop new global health technologies for TB, malaria, Chagas disease, schistosomiasis and parasitic roundworms at the clinical or pre-clinical stage. Investments in dissemination and communication were made to ensure high visibility of the project through a dedicated website, multiple international events and proactive introduction of GHIT to potential applicants.

The GHIT Fund announced **the first funding award opportunity (GHIT Fund RFP 2013-001)** in early May 2013. A total of 39 ITA forms were received, out of which 36 applications qualified for submission of a full proposal. GHIT received 28 full proposals by the deadline of 15 June 2013, of which 25 were deemed eligible by the external reviewers.

To maximize the use of public funds and donations and to guarantee transparency, fairness and accountability, a double peer review process was put into effect through which the Selection Committee processes grant proposals for final review and approval by the Board of Directors. The Selection Committee meeting was held in Tokyo on 1 July 2013 and culminated in a recommendation to fund a total of seven proposals for a total budget of JPY610,469,256. The recommendation was then submitted to the Board of Directors. All the grant agreements were duly signed by the GHIT Fund[6] and the grantees by November 2013. Using UNDP's phase 1 fund, the GHIT Fund disbursed the total amount of $4,369,734.35 (see Annex 3).

The GHIT Fund announced the **second funding award opportunity (GHIT Fund RFP 2013-002)** in August 2013. A total of 24 ITA forms and 23 grant proposals were received by the deadline of 31 October 2013. Of these, 18 proposals were qualified to proceed to review by the external reviewers (see Annex 2). Following the Selection Committee's meeting in Tokyo on 22 January 2014, four proposals were recommended to the Board of Directors. On 5 February 2014, the Board approved all the recommended proposals.[7]

6. https://www.ghitfund.org/about/mediacenter/pressdetail/detail/41/en.

7. https://www.ghitfund.org/about/mediacenter/pressdetail/detail/79/en.

By mid-March 2014, all the grant agreements were finalized and duly signed by the GHIT Fund and the grantees. On 28 March 2014, two grants were disbursed for the total amount of US$1,601,875, including $499,246.87 for 'New Drug Compounds against Wolbachia Bacteria' and $1,102,628.13 for 'Paediatric Formulation of Gold Standard Drug for Schistosomiasis'.

Approval of 'Development of rhPIV2 as a Potential New TB Vaccine Candidate' was awarded contingent on the achievement and positive assessment of the two milestones for the grant awarded in November 2013 (phase 1). Milestone 1 requires demonstrating that boosting gene-deficient and multiple-antigen constructs significantly enhances protective immunity against Mycobacterium tuberculosis (Mtb). Nasal vaccination of the optimized rhPIV2 construct in combination with BCG- or rBCG-priming should significantly reduce Mtb bacterial load, especially in lungs in the mouse aerosol challenge model. Milestone 2 entails demonstrating that the rhPIV2 vaccine works in an animal model of wild type PIV2 infection. Achievement of the milestones required for the second award towards 'Development of rhPIV2 as a Potential New TB Vaccine Candidate' was planned for October 2014. However, the completion of the milestones has been further delayed, and the grantees have requested that the milestones' evaluation criteria be reviewed. It is expected that the Selection Committee will consider this request in January 2015.

Regarding the second grant, 'A New Treatment for Chagas Disease', the support from GHIT will enable the grantees to develop a combination therapy consisting of benznidazole and an experimental triazole compound known as E1224. Proceeding to phase 2, a proof-of-concept study of the efficacy and safety of the combination, is contingent on the thorough evaluation of the data obtained during the initial drug–drug interaction (DDI) study. A third-party consultant and the GHIT Fund's Selection Committee are required to review the data compiled before granting approval and financial support to proceed to phase 2, and subsequently, a phase 3 multi-country study. The in-depth review of data obtained during the course of the DDI study did not take place as planned by February 2014, due to delays in the study and submission of data. In September 2014, DNDi and Eisai, the two grantees, indicated that the project had been delayed further. The Management Team expects that the decision regarding the next outstanding disbursement will be taken by the Steering Committee in January 2015.

Annex 3 provides a brief overview of all the grants awarded under RFP 2013-001 and -002.

ii. Funding statement

In April 2013, UNDP received the total contribution amount of US$10,918,165.75 from the Government of Japan (Japan–UNDP Partnership Fund) for GHIT's grant-making activities (see Annex 4). As of 27 October 2014, total expenditures amounted to US$5,971,609.35, and interest accumulated by the GHIT Fund amounted to $173.52. Therefore, the closing balance is US$4,946,729.92. It is intended that the unspent funds will be carried over to the budget of the next four years' grant-making activities as outlined in the approved project document, 'GHIT: Research and Development (R&D) of New Global Health Technologies for TB, Malaria, NTDs and Other Diseases for Patients and Citizens of Low- and Middle-Income Countries (LMICs).'

IV. Project management

iii. Project implementation modality

This project is being implemented under an NGO implementation modality. GHIT is the non-governmental organization responsible for the overall accountability, management and administration of the project and the implementation of project activities, based on the PCA signed between UNDP and GHIT. The project's main management principle is results-based management based on agreed indicators and required capacities, practical and targeted coordination and UNDP's prevailing rules and regulations.

iv. Roles and responsibilities of the Project Board

The establishment of the GHIT Project Board is planned for phase 2 of the project. The Project Board has been conceptualized to provide policy guidance and to monitor performance of the project, ensure the completion of milestones, review progress against project results and benefits on a periodic basis, approve progress reports and the final completion report and manage risks. It will be composed of (additional members may be invited at the discretion of the Board):

- a representative from the BPPS HIV, Health and Development Group, UNDP (Chair);
- a representative from BERA/RPC, UNDP;
- a representative from a UNDP Regional Bureau, which will be responsible for the programme countries of the access and delivery project;
- representatives from the Ministry of Foreign Affairs of Japan/Permanent Mission of Japan to the United Nations (as the donor for the project); and
- a GHIT Programme Advisor (ex officio).

The Project Board will meet virtually at least once per year and review and appraise the Annual Work Plans and reports and commission evaluations, and make revisions as necessary. For the purposes of cooperation with GHIT, the BPPS representative will serve as Chair. The Regional Bureaux—which are responsible for programme countries for the other related project, 'Building Capacity for Access and Delivery of New Global Health Technologies for TB, Malaria, NTDs and Other Diseases in LMICs'—and BERA (responsible for the Japan–UNDP Partnership Fund) will participate in the Project Board as project stakeholders from UNDP. The GHIT Programme Advisor will act as secretariat and will be responsible for convening the meetings, preparing the agenda, overseeing preparation of meeting materials and preparing and distributing minutes of the meetings. If the virtual Project Board meeting does not take place, the Programme Advisor will ensure that consultation is carried out with Project Board members individually.

V. Communications and visibility

The GHIT project has successfully highlighted the important contribution made by the Government of Japan towards improving access to medicines for NTDs. The fifth Tokyo Conference on African Development (TICAD V), hosted by the Government of Japan, provided a good opportunity to bring attention to the initiative it has taken. A press conference during the conference showcased the unique approach taken by GHIT, bringing together the private sector, with the Gates Foundation, UNDP and the Government of Japan.[8]

8. See: https://www.ghitfund.org/about/mediacenter/eventsdetail/detail/27.

VI. Implementation challenges

Over the course of the first year of partnership between the GHIT Fund and UNDP, a few operational complexities were encountered. UNDP's rules and regulations for advance payment of implementing partners enable disbursements on a quarterly basis (following an initial instalment upon signature of the grant agreement) following receipt of a financial report and agreed documentation showing satisfactory management and a minimum of 80 percent disbursement of advanced resources, while GHIT makes awards twice a year. The difference in payment cycles between UNDP and GHIT's grant awards presented an initial challenge for the timely disbursement of funds from UNDP to GHIT. The PCA for phase 2 (covering 1 April 2014 to 31 March 2018) was able to address this challenge, as UNDP has secured approval for an annual disbursement schedule going forward.

Two grant disbursements by GHIT were delayed, as grantees did not meet the conditions for award imposed by the GHIT Fund's Selection Committee on 5 January 2014. GHIT was, therefore, restricted to disbursing the payments according to the original schedule, which were to be completed by the end of March 2014. This resulted in an unspent balance at the end of year 1. GHIT encountered some delays in submitting a no-cost extension in a timely manner, which led to the expiration of the PCA between UNDP and the GHIT Fund. The amendment of the PCA for phase 2, which is currently under review by the UNDP Legal Support Office, will incorporate the outstanding payment of $4.9 million from year 1 for disbursement in the future.

The issue of intellectual property rights on GHIT products is still under discussion, but some progress has been made towards reaching an agreement between UNDP and GHIT. It is anticipated that the discussion will continue and be resolved in 2015.

VII. Next steps

During its initial phase, the GHIT Fund has successfully completed a number of milestones towards the project goal of advancing the discovery and development of new health technologies for developing countries by leveraging the intellectual, technological and financial resources present in Japan. These milestones include the establishment and implementation of a governance and management structure that represents key stakeholders and ensures efficiency and quality in the product development grant-making process. GHIT has also developed a grant-making process that reflects the strategic goals of the programmes and ensures a transparent system of review and selection of grants with health impact as the foremost criterion. Finally, GHIT has solicited, reviewed and selected grantees and through eight grants is supporting R&D efforts to advance the discovery and development of new health technologies for developing countries.

These achievements have provided the infrastructure that will support GHIT's continued operations and grant-making over the project's years 2 to 5. GHIT will continue to post RFPs twice a year through years 2 to 5. For year 2, the third call for proposals (GHIT Fund RFP 2014-001) was issued with a final deadline on 15 April 2014. The fourth call for proposals (GHIT Fund RFP 2014-002) was released on 13 June 2014, with an application deadline of 18 September 2014.[9] UNDP continues to monitor the GHIT Fund's grant-making activities through periodic reports on the progress, achievements and results of the project.

9. https://www.ghitfund.org/afag/grant

Annexes

Annex 1: GHIT governance overview

COUNCIL

Name	Designation	Affiliation
Takehiro Kagawa	Member	Director-General for Global Issues, Ministry of Foreign Affairs
Mitsuhiro Ushio	Member	Deputy Director-General for Global Health, Minister's Secretariat, Ministry of Health, Labour and Welfare
Trevor Mundel, PhD	Member	President of Global Health Program, Bill & Melinda Gates Foundation
Astellas Pharma Inc.	Member	Yoshihiko Hatanaka, Representative Director, President and CEO
Daiichi Sankyo Co. Ltd.	Member	Joji Nakayama, Representative Corporate Officer, President and CEO
Eisai Co., Ltd.	Member	Haruo Naito, President and CEO
Shionogi & Co., Ltd.	Member	Isao Teshirogi, PhD, President and CEO
Takeda Pharmaceutical Co. Ltd.	Member	Yasuchika Hasegawa, President and CEO

BOARD OF DIRECTORS

Name	Designation	Affiliation
Kiyoshi Kurokawa, MD	Representative Director and Chair	Academic Fellow, National Graduate Institute for Policy Studies Chairman, Health and Global Policy Institute
B.T. Slingsby, MD, PhD, MPH	Executive Director	CEO, Global Health Innovative Technology Fund
Peter Piot, MD, PhD	Member	Director, London School of Hygiene & Tropical Medicine
Ann M. Veneman	Member	Former Executive Director of UNICEF
Eiji Hinoshita, MD, PhD	Member	Director, Office of International Cooperation, International Affairs Division, Minister's Secretariat, Ministry of Health, Labour and Welfare
Hiroyuki Yamaya	Member	Director, Global Health Policy Division, International Cooperation Bureau, Ministry of Foreign Affairs
Hikaru Ishiguro, LLM	Board Advisor	Board Member and President, Health and Global Policy Institute
Ko-Yung Tung, JD	Board Advisor	Senior Counselor, Morrison & Foerster
Kim C. Bush	Ex-Officio	Director of Life Sciences Partnerships, Bill & Melinda Gates Foundation

SELECTION COMMITTEE

Name	Designation	Affiliation
Mahima Datla	Selection Committee Member	Sr. Vice President at Biological E. Ltd.
Ken Duncan, PhD	Selection Committee Member	Deputy Director, Discovery & Translational Sciences, Bill & Melinda Gates Foundation
Penny M. Heaton, MD, MPH	Selection Committee Member	Director, Vaccine Development and Surveillance, Bill & Melinda Gates Foundation
Kiyoshi Kita, PhD	Selection Committee Member	Professor, Department of Biomedical Chemistry, Graduate School of Medicine, University of Tokyo
Alex Matter, MD	Selection Committee Member	CEO, Experimental Therapeutics Centre and D3, A*STAR, Singapore
Yasuko Mori, MD, PhD	Selection Committee Member	Professor, Division of Clinical Virology, Center for Infectious Diseases, Kobe University Graduate School of Medicine
Dennis Schmatz, PhD	Selection Committee Member	Former Head of Infectious Diseases Research, Merck Research Labs, USA; Former Head of Research, MSD-Japan

ADVISORY PANEL

Name	Designation	Affiliation
Peter Agre, MD	Advisor	Director, Johns Hopkins Malaria Research Institute
Harvey V. Fineberg, MD, PhD	Advisor	Former President, Institute of Medicine of the National Academies
Dai Hozumi, MD, MSM, MPH	Advisor	Senior Advisor for Health Systems and Policy, PATH
Calestous Juma	Advisor	Professor of the Practice of International Development and Director of the Science, Technology, and Globalization Project, Harvard Kennedy School
Michael R. Reich, PhD	Advisor	Taro Takemi Professor of International Health Policy, Harvard School of Public Health
Kumi Sato	Advisor	President and CEO, Cosmo Public Relations Corp.
Lorenzo Savioli, MD, DTM&H, MSc	Advisor	
Peter Singer, MD, MPH, FRCPC	Advisor	CEO of Grand Challenges Canada and Director, Sandra Rotman Centre

Annex 2: List of 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
Dr. Nancy Le Cam Bouveret
Dr. Tom Brewer
Dr. David Brown
Dr. Simon Campbell, CBE FRS
Dr. Shing Chang
Dr. Robert Chen
Dr. Simon Croft
Dr. Peter Dailey
Dr. Thomas Dick
Dr. Carter Diggs
Dr. Boro Dropulic
Dr. Filip Dubovsky
Dr. Hiroyoshi Endo
Dr. Alan Fairlamb
Dr. Hermann Feldmeier
Dr. Michael J. Free, OBE
Dr. Birgitte Giersing
Dr. Ann Ginsberg
Dr. Federico Gomez de las Heras
Dr. Glenda Gray
Dr. Brian Greenwood
Dr. Sanjay Gurunathan
Dr. R. Kiplin Guy
Dr. Lee Hall
Dr. Yoshihisa Hashiguchi
Dr. Chris Hentschel
Dr. Gray Heppner
Dr. Toshihiro Horii
Dr. Sanjay Jain
Dr. Nisha Jain Garg
Dr. Takushi Kaneko
Dr. Niranjan Kanesa-Thasan
Dr. Shigeyuki Kano
Dr. Gilla Kaplan
Dr. Subhash Kapre
Dr. Naoto Keicho
Dr. David Kelso
Dr. Kent Kester
Dr. Akinori Kimura
Dr. Sue Kinn
Dr. Somei Kojima
Dr. Rebecca Richards Kortum
Dr. Hidehito Kotani
Dr. Michael Kurilla
Dr. Dennis Kyle
Dr. James LeDuc
Dr. John Mansfield
Dr. Carol Marzetta
Dr. Greg Matlashewski
Dr. James McCarthy
Dr. Carl Mendel
Dr. Charles Mgone
Dr. Melinda Moree
Dr. Kouichi Morita
Dr. Charles Mowbray
Dr. Peter Myler
Dr. Daniel Neafsey
Dr. Christian Ockenhouse
Dr. Giuseppe Pantaleo
Dr. David Persing
Dr. Meg Phillips
Dr. Punnee Pitisuttithum
Dr. David Pompliano
Dr. Regina Rabinovich
Dr. Rino Rappuoli
Dr. Zarifah Reed
Dr. Yves Ribeill
Dr. Paul Roepe
Dr. Polly Roy
Dr. Peter Ruminski
Dr. Philip Russell
Dr. Judy Sakanari
Dr. Hing Sham
Dr. George Siber
Dr. KJ Singh
Dr. Peter Smith
Dr. Lynn Soong
Dr. Dan Stinchcomb
Dr. Nathalie Strub-Wourgaft
Dr. Marcel Tanner
Dr. Kaoru Terashima
Dr. Katsushi Tokunaga
Dr. Nadia G. Tornieporth
Dr. Bruno Travi
Dr. Takafumi 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

Annex 3: GHIT grants overview table

Project title	Grantee	Summary	Contractual Amount	Disbursed Amount
RFP 2013-001				
1. **Accelerating Development of Vaccines for Malaria Elimination Using a Novel Clinical Target Validation Approach**	Japan's Ehime University, CellFree Sciences in partnership with PATH	To identify novel targets of immunity and accelerate the development of malaria vaccines to support elimination and eradication. The project addresses one of the main challenges by aiming to increase the percentage of potential targets on the parasite surface that have been screened for their vaccine potential.	$591,397	$459,592.43
2. **Development of DSM265 as a Long-acting Antimalarial Compound**	Medicines for Malaria Venture (MMV) in partnership with Takeda Pharmaceutical Company Limited	To study a promising new anti-malaria compound, DSM265, to clinical proof-of-concept stage. The new drug candidate, which kills the malaria parasite through inhabitation of an essential enzyme, is a compound with a long duration of action that could potentially be part of a new malaria treatment, with the potential to be part of a single-dose cure.	$2,538,796	$1,932,607.90
3. **Optimization of Diversity-Oriented Synthesis (DOS)-derived Trypanocidal Small Molecule ML342 towards Investigational New Drug Status for Chagas Disease**	Eisai Co., Ltd. and the Board Institute of MIT and Harvard for Chagas disease	To promote the discovery of drugs against chronic Chagas infection, which affects an estimated 8 million people worldwide	$500,000	$253,807.10
4. **Development of ELQ3000 as a Long-lasting Antimalarial**	MMV in partnership with Takeda	For the development and its formulation of ELQ300, an antimalarial compound that is in an earlier stage of development. ELQ300 has the potential to be given once a month to treat and prevent malarial infections. However, some additional work related to its formulation is needed before it can be tested in patients. This partnership provides access to novel Japanese compounds, expertise and support for the development of a solid oral dose form development.	$560,000	$558,244.68

Project title	Grantee	Summary	Contractual Amount	Disbursed Amount
5. **Development of Recombinant hPIV2 Virus Vector as a New TB Vaccine**	National Institute of Biomedical Innovation, Japan's Create Vaccine Co., Ltd. and Aeras	To support early work on a novel vaccine candidate against TB. The vaccine is the first to target the patient's mucous membranes to keep TB from entering the lungs. The award will help advance vaccine candidates based on the rhPIV2 technology created by the Tsukuba Primate Research Center at NIBIO through pre-clinical stages.	$700,000	$710,659.90
6. **Clinical Development of BK-SE36/CpG Malaria Vaccine**	Research Institute for Microbial Diseases at Osaka University in partnership with the Medical Center for Translational Research, Osaka University Hospital, and Gulu University in Uganda	To test their newly formulated BK-SE36 malaria vaccine. A recent published study showed that the vaccine demonstrated efficacy against severe malaria infections, making it a promising malaria vaccine candidate.	$714,500	$454,822.34
Subtotal for RFP 2013-01			$5,604,693	$4,369,734.35
RFP 2013-002				
7. New Drug Compounds against Wolbachia Bacteria	Liverpool School of Tropical Medicine and the University of Liverpool's collaboration with Eisai	To study new drug compounds against Wolbachia bacteria. The partnership aims to identify a single candidate for potential drug development against Wolbachia within one to two years.	$109,316,675	$499,246.87
8. Paediatric Formulation of Gold Standard Drug for Schistosomiasis	Top Institute Pharma of the Netherlands, Merck KGaA of Germany, Astellas Pharma Inc. of Japan and Swiss Tropical and Public Health Institute	To develop and register a paediatric formulation of praziquantel, the gold-standard treatment for schistosomiasis	$1,864,899	$1,102,628.13
9. Development of rhPIV2 as a Potential New TB Vaccine Candidate	National Institute of Biomedical Innovation, Japan's Create Vaccine Co., Ltd. and Aeras	For the work on a novel vaccine candidate to combat TB in November 2013. The additional award will enable further pre-clinical development to advance to a phase 1 clinical trial to test its safety and immunogenicity.	$5,649,620	$0

Project title	Grantee	Summary	Contractual Amount	Disbursed Amount
10. A New Treatment for Chagas Disease	Drugs for Neglected Diseases initiative (DNDi) and Eisai	For development of a new combination therapy for Chagas disease that consists of benznidazole and an experimental trazole compound known as E1224. The partnership will conduct a phase 2 proof-of-concept study of the efficacy and safety to the combination. Over the next two years, this partnership aims to conduct a phase 2, phase 3 and work toward the registration of E1224, including several required chemistry, manufacturing and controls activities and non-clinical tests.	$3,840,893	$0
Subtotal for RFP 2013-02			$12,448,579	$1,601,875.00
Grand total				**$5,971,609.35**
Interest				**$173.52**
Balance				**$4,946,729.92**

Annex 4: Interim financial report

As of 27 October 2014

Project Title: GHIT: Research and Development (R&D) of New Global Health Technologies for TB, Malaria, NTDs and Other Diseases for Patients and Citizens of Low- and Middle-Income Countries (LMICs)

Project ID: 00086939

Project Period: 1 April 2013 to 31 March 2014

Planned Budget (A)	Expenditures (B)	Interest (C)	Utilization % (B) / (A)	Balance (A) – (B) + (C)
$10,918,165.75	$5,971,609.35	$173.52	55%	$4,946,729.92

Phase 1
Final Report