Innovation Changes Health. Change Innovation.







In Sub-Saharan Africa, about one in every 20 adults is infected with HIV. Around 71% of all HIV patients worldwide are concentrated in this region. There are 2.9 million HIV-infected African children, almost all infected at birth by their mothers.

While there is no cure for HIV/AIDS today, antiretroviral drugs (ARV) allow patients to live longer with a higher quality of life. As of 2013, a total of 11.7 million people in developing nations were receiving HIV antiretroviral therapy (ART). Use of these drugs has reduced HIV infections and deaths compared to the peak of the disease a decade ago. However, close to 16 million people who need treatment are unable to obtain it. In addition, better HIV diagnostics are needed, as well as drugs formulated for HIV-infected children.



About 198 million people are infected with malaria, which kills some 584,000 people every year, according to 2013 WHO estimates. Close to 90% of these deaths are in sub-Saharan Africa. Every second, the disease kills a child under five years old.

Drug-resistant malaria has emerged as a growing problem in recent years. Resistance to artemisinin – currently the most effective anti-malarial drug – was reported in 2009 on the Thai-Cambodian border, and has spread to other parts of Southeast Asia, underscoring the need for new drugs and a vaccine to effectively fight the disease.



Tuberculosis infected 9.0 million in 2013, causing 1.5 million deaths, according to WHO. An overwhelming 95% of the fatalities occurred in low- and middle-income countries, where many HIV-infected patients also have tuberculosis. The South-East Asia and Western Pacific Regions collectively accounted for 56% of the world's TB cases in 2013.

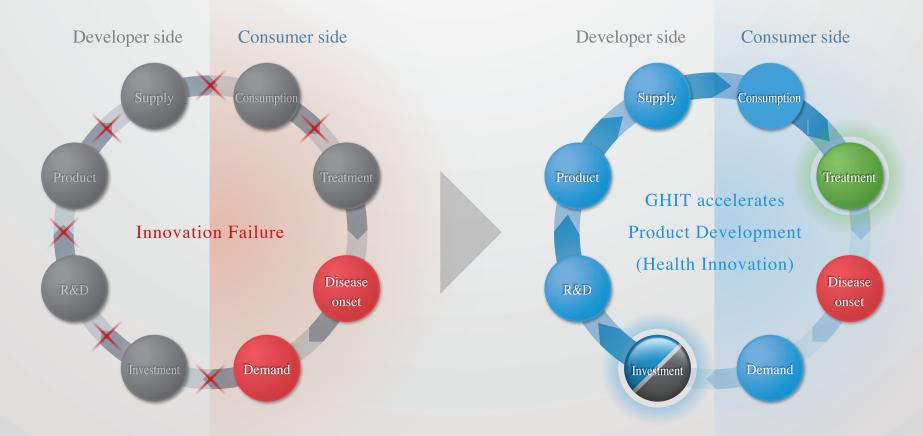
WHO recommends that TB patients take multiple medications for six months or more under the supervision of a medical professional to treat the diseases. Outbreaks of "multiple-drug-resistant tuberculosis" (MDR-TB) and "extensively-drug-resistant tuberculosis" (XDR-TB)—the latter incurable by first- and second-line drugs—has made effective treatment increasingly difficult. In addition, TB drug costs are too high for many patients in developing countries to afford.



Neglected Tropical Diseases (NTDs), also known as "the burden of the bottom billion," are prevalent among the poorest groups in developing regions of Africa, Asia and South America. These diseases often cause chronic mental or physical disorders.

Unlike HIV/AIDS, malaria and tuberculosis, NTDs are not typically fatal. They do, however, create suffering and disabilities that sometimes last a lifetime. Over the medium to long term, these chronic impairments seriously undermine patients' quality of life. Their signs and symptoms cause patients to become targets of stigma and discrimination, with devastating social and medical consequences. Data have increasingly shown that NTDs wreak social and economic havoc on individuals, their countries and entire regions in much the same way as HIV/AIDS, malaria, and tuberculosis.

Investing in Global Health R&D

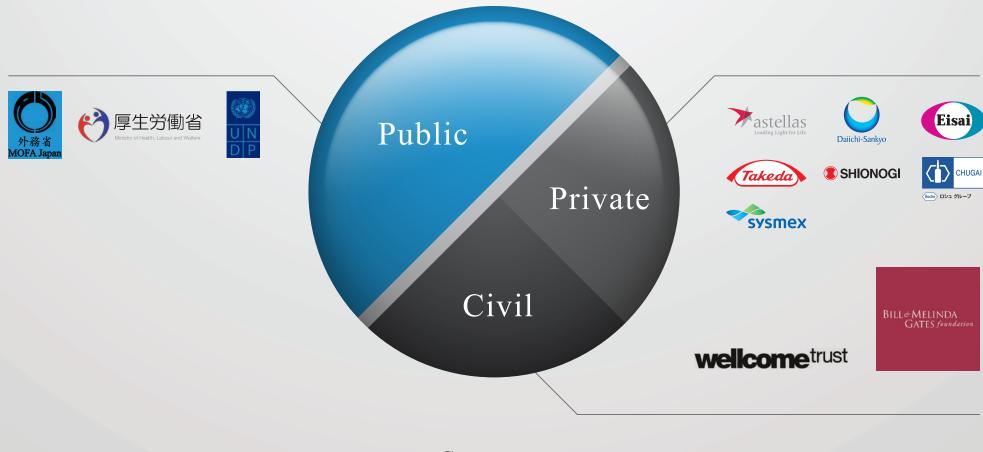


The reason that product development for infectious diseases is not advancing for poor countries is that companies cannot expect profits in line with their investments. Product development is an extremely high-risk investment, and most patients in developing nations, which form a large proportion of the world's poor, live on less than one US dollar per day. This gives them little purchasing power, so that market principles cannot function. In fact, only 1% of new chemical entities developed between 2000 and 2011 were for neglected diseases.

*Pedrique, Belen et al. The drug and vaccine landscape for neglected diseases (2000–11): a systematic assessment. The Lancet Global Health, Volume 1, Issue 6, e371 - e379

The lack of expected profits proportional to R&D costs reduces the likelihood that private-sector companies will undertake vigorous product development programs for infectious diseases of the poor on their own. As a result, patients fail to gain access to the pharmaceuticals needed to treat their conditions. Free-market-based business models carry structural limitations with regard to the development of new products targeted for infectious diseases. In this context, patients and their diseases in developing nations have been relegated to so-called "neglected" status. Here, the GHIT Fund makes an investment in product development for infectious disease of the poor. This investment bandages the market-based model and thus accelerates health innonvation.

Partners



Sponsors









GHIT leverages more investment from the private sector

International organizations receive the majority of their funding from the public sector (i.e., governments). Today GHIT Fund is the best leverage mechanism of public funding in global health among international organizations.





GHIT Fund
Global Health Innovative Technology Fund

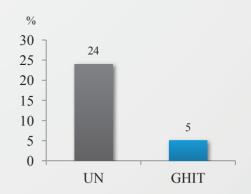
Public : Private = 94% : 6%

Public : Private = 76% : 24%

Public : Private = 50% : 50%

Efficient and Streamlined Organizational Management

GHIT has an efficient and streamlined management structure that keeps administrative and indirect costs at 5% of its budget, so that 95% of its funding goes to investments in product development.



"I've never seen an organization manage operating costs more carefully than GHIT."

Trevor Mundel

Leadership

Council

[Roles and Function] Appointment and dismissal of members of the Council and Board of Directors/Amendments to the Articles of Incorporation/Determination of the terms for the Board/Advocacy for the GHIT Fund/Approval of Financial Statements



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



Naoko Yamamoto, MD, MPH, PhD 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 Christophe Weber Representative Director, President & CEO

Leadership

Board of Directors

[Roles and Function] Approval of midterm strategies / Approval of annual plans and budget - Appointment and dismissal of Selection Committee members / Approval of selection criteria and priorities for the Selection Committee



Representative Director and Chair

Kiyoshi Kurokawa, MD

Adjunct Professor, National Graduate Institute for Policy Studies & Chairman, Health and Global Policy Institute



Vice Chair

Peter Piot, MD, PhD

Director and Professor of Global Health, London School of Hygiene and Tropical Medicine, Former Executive Director, UNAIDS



Executive Director

BT Slingsby, MD, PhD, MPH

CEO,

Member

Global Health Innovative Technology Fund



Member

Member

Mahima Datla

Managing Director, Biological E. Limited



Member

Eiji Hinoshita, MD, PhD

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



Supervisory Board Member

Hikaru Ishiguro, LLM

Board Member, Health and Global Policy Institute



Supervisory Board Member

Former Secretary,

Ann M. Veneman, JD

Former Executive Director, UNICEF

United States Department of Agriculture

Ko-Yung Tung, JD

Senior Counselor, Morrison & Foerster Former Senior Vice President and General Counsel of the World Bank



Ex-Officio Observer

Labour and Welfare

Hiroyuki Yamaya

Director, Office of International

Cooperation Ministry of Health,

Kim C. Bush

Director, Life Sciences Partnerships, Bill & Melinda Gates Foundation



Ex-Officio Observer

Richard Seabrook, PhD, MBA

Head, Business Development, Innovations, Wellcome Trust

Leadership

Selection Committee

[Roles and Function] Review and evaluate grant proposals and progress reports from grantees/Recommend provision of grants to Board of Directors based on results of review and 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

Penny M. Heaton, MD, MPH

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



Member

Yasuko Mori, MD, PhD

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



Member

Ken Duncan, PhD

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



Member

Kiyoshi Kita, PhD

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



Dennis Schmatz, PhD

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



Member

Kouji Hattori, PhD

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



Member

Alex Matter, MD

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





Member

Awa Marie Coll Seck, MD, PhD

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



Member

Michael R. Reich, PhD

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



Peter Singer, MD, MPH, FRCPC

Grand Challenges Canada



Member

Harvey V. Fineberg, MD, PhD

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



Member

Kumi Sato

President and CEO, Cosmo Public Relations Corporation



Member

Dai Hozumi, MD, MSM, MPH

Senior Advisor, Health Systems and Policy, PATH



Member

Lorenzo Savioli, MD, DTM&H, MSc

Former Director, Department of Neglected Tropical Diseases, WHO

Our Platforms

 $\longleftarrow \mathsf{DISCOVERY} \longrightarrow \longleftarrow \mathsf{PRECLINICAL} \longrightarrow \longleftarrow \mathsf{CLINICAL} \longrightarrow \longleftarrow \mathsf{REG} \longrightarrow$

DRUG DEVELOPMENT

| Drug | Target Research Platform in partnership with Grand Challenges | | Screening Platform | Hit-to-Lead Platform | Product Development Platform | | | | | |
|------|---|----------------------|-----------------------|-------------------------|------------------------------|-------------------------|------------------------------------|------------------------------------|------------------------------|--------------|
| | Target Identification | Target Validation | Hit Identification | Lead Identification | Lead Optimization | Preclinical Development | Phase 1 Clinical Development | Phase 2 Clinical Development | Phase 3 Clinical Development | Registration |

VACCINE DEVELOPMENT

| Vaccine | i i | Target Research Platform in partnership with Grand Challen, | Product Development Platform | | | | | |
|---------|---------------------------|---|---------------------------------------|----------------------------|------------------------------------|------------------------------------|------------------------------------|--------------|
| | Antigen Identification | Vaccine Concept Development | Technology Platform Identification | Preclinical Development | Phase 1 Clinical Development | Phase 2 Clinical Development | Phase 3 Clinical Development | Registration |

DIAGNOSTIC DEVELOPMENT

| | i | Target Research Platform n partnership with Grand Challen; | | Product Development Platform | | | | |
|------------|------------------------|--|----------------------------|------------------------------|------------------------|-----------------------|--------------|--|
| Diagnostic | Concept Development | Technical Feasibility | Development Feasibility | Product Design | Product Development | Product Validation | Registration | |

GHIT Funding Mechanism



Survey

We conduct periodic surveys to delineate unmet medical needs in the global pipeline.



Define

We define specific target product profiles for each technology of interest in each Request for Proposals.



Approve

GHIT Board discusses and approves scope and details of Request for Proposals.











Press release

We announce press releases for each Request of Proposals.



Communication

We inform the public on our investment opportunities through multiple communication channels.



Seminars

We provide proposal writing seminars to improve the quality of proposals among academicians, researchers and biotech.

High quality proposals





GHIT Funding Mechanism











Investments

External Review

External Reviewers – experts with years of experience in anti-infectives R&D – independently review each proposal.

Interactive Interviews

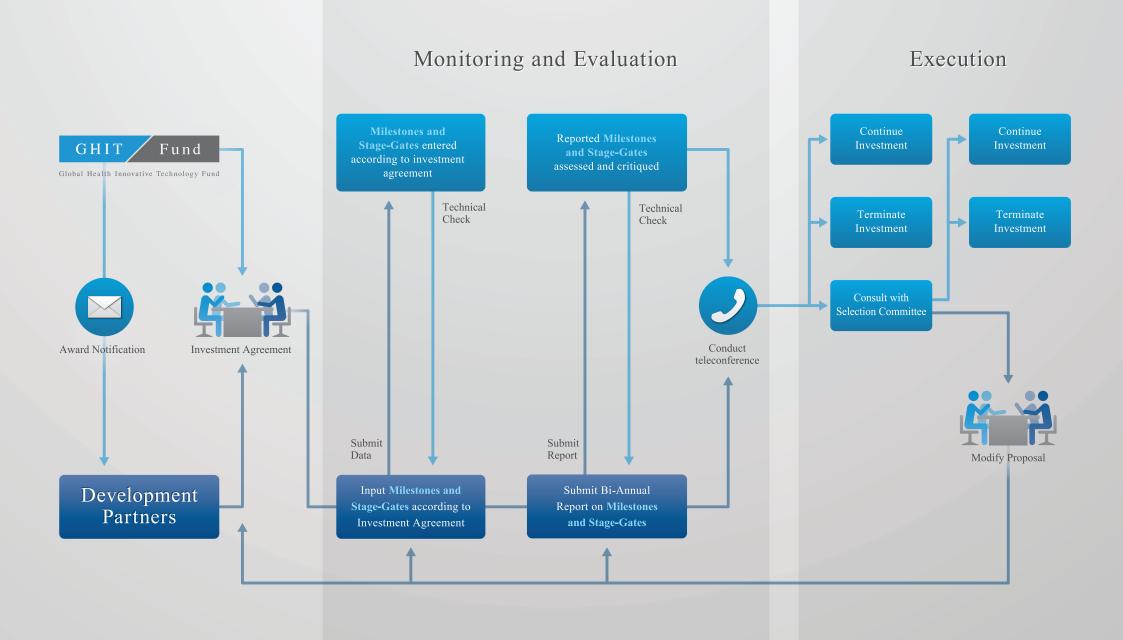
GHIT Selection Committee conducts interactive interviews with the top-tier of applicants.

Selection Committee

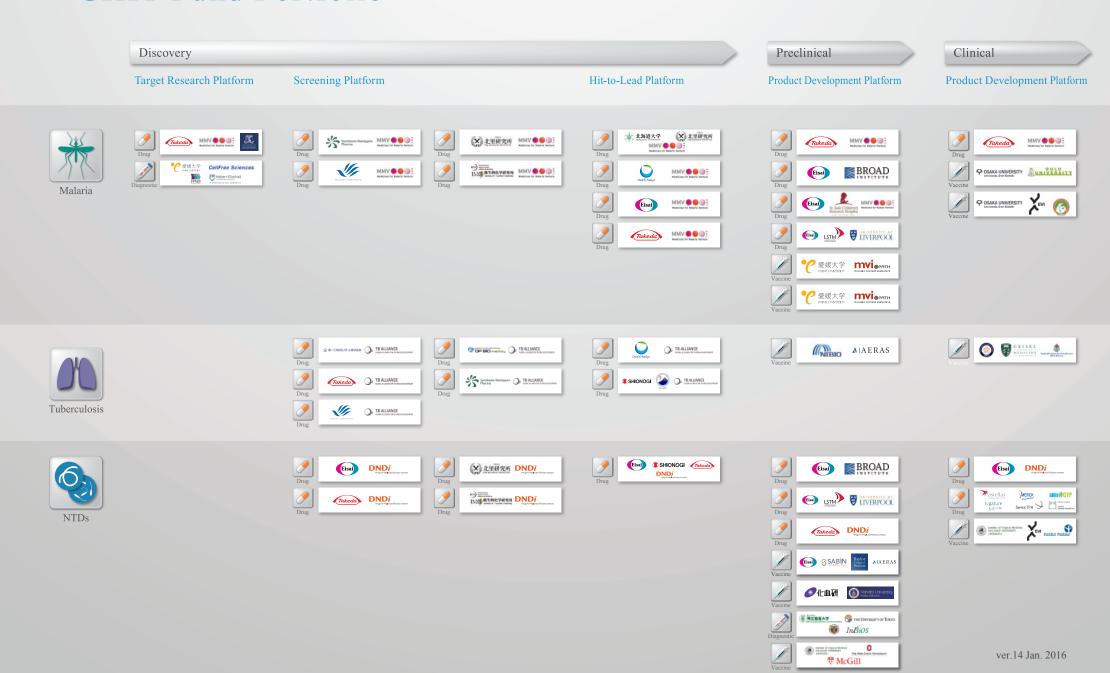
GHIT Selection Committee evaluates each proposal, assesses each quality product development plan and recommends funding to the Board.

Approve

GHIT Board directs portfolio strategy and awards funding using a milestone-based approach to ensure return with minimal risk.



GHIT Fund Portfolio



Tangible Impact





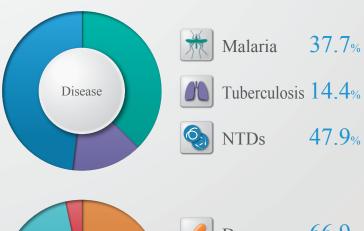








Investments to date USD 53.8 Million







GHIT Invested Clinical Trials



^{*} Clinical trials are scheduled to begin by 2017.