GHIT 3.0 Strategic Plan

FY2023-FY2027
VISION

Our vision is a world free of neglected infectious diseases that affect over a billion people with the aim of achieving health equity.

MISSION

We leverage Japanese innovation and leadership to fight against neglected infectious diseases through investing in research and development and promoting global partnerships.
Celebrating 10 Years Since Our Founding

In 2023, the Global Health Innovative Technology Fund (GHIT Fund) celebrates its 10th anniversary. We are grateful to our funding partners and sponsors for their support and collaboration over the past decade, to our product development partners for their passion and tireless efforts in the fight against neglected infectious diseases, and to the global health community for its solidarity and partnership.

The concept of the GHIT Fund was born from notes written on a paper napkin by the late Dr. Tachi Yamada and GHIT’s founding CEO, Dr. BT Slingsby, in 2013. Since then, we have been fighting neglected diseases in low and middle-income countries by connecting ideas, people, and innovations from around the world. In our experience, passion and vision are more powerful tools than most may realize. Each new drug in development or nearing approval has the potential to save tens of millions of lives.

Cumulative investments over the past 10 years have totaled approximately 30 billion yen, supporting more than 100 R&D projects. More than 50 projects are currently underway, of which 12 are in clinical development. As of April 1, 2023, GHIT’s family of active Japanese and global partners is 170-strong, all supporting our mission to connect Japanese pharmaceutical companies and universities with global partner institutions to accelerate global health innovation.

GHIT 3.0 Strategic Plan

In our third phase of operations (FY2023 – FY2027), we will continue to promote the development of therapeutics, vaccines and diagnostics through global collaboration, aiming for greater efficiency and acceleration of R&D than ever before. Our third five-year plan, “GHIT 3.0”, features three strategic pillars: Galvanize Innovation, Catalyze Partnerships and Maximize Impact. The work under these pillars reinforces our role as an international organization that promotes innovation and product development for neglected diseases prevalent mainly in low and middle-income countries.

Developing new medicines is no easy task, requiring an average of over ten years of painstaking effort and tens of billions of yen to develop a single medicine. But the time and investment are worth it. GHIT’s projects, which have been created and nurtured over the past decade, are about to bear fruit. By delivering the therapeutics, vaccines and diagnostics that result from our development partnerships to sick patients as quickly as possible, we will save countless lives and prevent untold suffering and stigma from the complications of neglected diseases.

At the GHIT Fund, we will continue to promote innovation and R&D from Japan and fight neglected infectious diseases through global partnerships. We remain steadfast in our mission to reduce the suffering caused by neglected infectious diseases that afflict more than a billion people, in support of a healthy world for all. We leap into this work together with you, as partners.

We look forward to your continued support and cooperation.

Osamu Kunii
CEO and Executive Director

Hiroki Nakatani
Board Chair & Representative Director
Value of the GHIT Fund

Japanese Innovation
Improving global health by identifying and investing in Japanese innovation

Global Partnership
Facilitating cross-border & cross-sector partnership to accelerate product development

Support Globalization
Advancing the Globalization of Japan's pharmaceutical industry and reinforcing ESG management

GHIT Product Development Partners

Japanese Organizations 59  Non-Japanese Organizations 111

As of April 1, 2023
Malaria is caused by a parasite called *Plasmodium* and is transmitted to humans through the bite of a female Anopheles mosquito carrying this parasite. There are five types of parasites which cause malaria in humans, and among these, the *Plasmodium falciparum* and the *Plasmodium vivax* have become a threat.

**Tuberculosis**

Tuberculosis (TB) is one of the 10 leading causes of death globally. It is caused by bacteria (*Mycobacterium tuberculosis*), which most often show symptoms in the lungs, and spread through airborne transmission. TB is the leading cause of death among HIV-positive people. Multidrug-resistant TB (MDR-TB) also remains a public health crisis and a threat to health security.

**Neglected Tropical Diseases: NTDs**

Neglected Tropical Diseases (NTDs)—a group of 20 communicable diseases prevalent in tropical and subtropical conditions in approximately 150 countries—affect more than one billion people and cost developing economies billions of dollars every year. Populations living in poverty, without adequate sanitation, and in close contact with infectious vectors, domestic animals, and livestock are those worst affected.

**Investment Scope**

**Malaria**

<table>
<thead>
<tr>
<th>infected in 2021</th>
<th>deaths in 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>247 million</td>
<td>619,000</td>
</tr>
</tbody>
</table>

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**Tuberculosis**

<table>
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<th>infected in 2021</th>
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</tr>
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<tbody>
<tr>
<td>10.6 million</td>
<td>1.6 million</td>
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**Neglected Tropical Diseases: NTDs**

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## Strategic Plan FY2018-FY2022

### Advancement of Investments in R&D and Product Development

<table>
<thead>
<tr>
<th>Objective</th>
<th>R&amp;D milestone</th>
<th>Targeted by</th>
<th>Achieved by</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostics</td>
<td>Innovative diagnostics technologies identified and funded</td>
<td>5</td>
<td>11</td>
<td>Achieved</td>
</tr>
<tr>
<td>Lead Identification</td>
<td>Hit-to-lead programs funded</td>
<td>5</td>
<td>17</td>
<td>Achieved</td>
</tr>
<tr>
<td>Preclinical</td>
<td>Preclinical candidates identified</td>
<td>8</td>
<td>14</td>
<td>Achieved</td>
</tr>
<tr>
<td>Phase I</td>
<td>First-in-human clinical trials conducted</td>
<td>5</td>
<td>6</td>
<td>Achieved</td>
</tr>
<tr>
<td>Phase II - Phase III</td>
<td>Proof of concept achieved</td>
<td>3</td>
<td>4</td>
<td>Achieved</td>
</tr>
<tr>
<td>Registration</td>
<td>Approval from a stringent regulatory authority</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

As of March 31, 2023

**GHIT Fund** has played the pivotal role in promoting research and development to fight neglected diseases by making most of Japanese technology and innovation and promoting global partnership between academia, public and private sector.

**Peter Piot, MD, PhD**
Professor of Global Health, London School of Hygiene & Tropical Medicine Special Advisor on COVID-19 to the President of the European Commission

**Dr. Jutta Reinhard-Rupp**
Chair of the Pediatric Praziquantel Consortium Board Head of the Global Health Institute at Merck

**Prof. Kiyoshi Kita**
Dean, Graduate School of Tropical Medicine and Global Health, Nagasaki University

At the end of 2022, the European Medicines Agency validated our application and started the scientific review process for the potential new pediatric treatment option for schistosomiasis. Having reached this milestone after more than 10 years of intense and collaborative work makes me very proud.

GHIT's achievements are not limited to promoting research and development, but also include contributing to the globalization and human resource development of researchers in the field of infectious diseases in Japan. I believe that GHIT’s unique investment in joint research between Japanese and foreign organizations further strengthens the research capabilities and partnerships of Japanese research institutions.

**2023.8**
GHIT 3.0 Strategic Plan
Galvanize Innovation

Accelerate Late-Stage Product Development

Strategic Plan FY2023-FY2027

<table>
<thead>
<tr>
<th>Objective</th>
<th>R&amp;D milestone</th>
<th>Targeted by March 2027</th>
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<tbody>
<tr>
<td>Lead Identification</td>
<td>5</td>
<td>Hit-to-lead-programs funded</td>
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<tr>
<td>Preclinical</td>
<td>12</td>
<td>Preclinical candidates identified</td>
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<td>3</td>
<td>Proof of concept achieved</td>
</tr>
<tr>
<td>Registration</td>
<td>3</td>
<td>Products approved by stringent regulatory authority</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Local program implementation of a product</td>
</tr>
</tbody>
</table>

Promote Open, Collaborative R&D

* Co-creation of products through international joint research and transparency in sharing findings between various industries of academia, research institutes, pharmaceutical companies, SMEs and Japanese and international startups.

2023.8
Leverage Resources

- Continue to leverage limited resources by exploring various funding mechanisms and prioritizing sustainability.

Enhance Governance and Institutional Management

- Further enhance corporate governance and institutional development.
- Ensure organizational sustainability through deployment of appropriate HR management and financial strategies.

GHIT 3.0 Strategic Plan
Maximize Impact

Optimize Portfolio

Phase I: Creation
- Establish an innovative funding mechanism to create international public goods from Japan through public-private partnership (Japanese government × private companies × foundations).
- Launch R&D projects utilizing Japanese drug discovery technologies and innovations.

Phase II: Growth
- Advance product development pipelines through active management of existing portfolio alongside proactive new investments in innovative technologies applicable to global health.
- Support access and delivery through close collaboration with international organizations.

Phase III: Harvest
- Accelerate product development for malaria, tuberculosis and NTDs.
- Optimize portfolio and resources to maximize the investment impact and further strengthen institutional development.
- Foster and promote domestic and international partnerships aimed at sparking innovation.

GHIT 1.0
FY2013-FY2017

GHIT 2.0
FY2018-FY2022

GHIT 3.0
FY2023-FY2027
GHIT 3.0 Strategic Plan

Catalyze Partnerships

Create an Enabling Environment for Access & Delivery

GHIT works proactively with product development partners to help them develop robust launch strategies and establish strategic, product-focused partnerships for appropriate, timely access and delivery of their innovations. Key considerations are illustrated below.

Access & Delivery

- Regulatory
- Financing
- Procurement & Supply Chain
- Manufacturing
- Demand Forecast

Policy & Advocacy

Regulatory Harmonization, Capacity Building (UNDP-led Access and Delivery Partnership (ADP))

Patient

GHIT facilitates strategic partnerships for Access and Delivery

Top-down approach:
Create a platform for aligned action across the innovation–access–delivery continuum.

Bottom-up approach:
Ensure launch strategies for GHIT-invested clinical candidates

Strengthen Strategic Partnerships, Focusing on LICs & LMICs

* Continue to extend institutional presence in LICs and LMICs and explore innovations from the ground up.

Demonstrate End-to-End R&D/A&D Ecosystems

* Leverage UNDP and other global networks to ensure seamless connectivity between innovation (R&D) and access and delivery (A&D).
Leadership

Council

Composed of representatives of the Japanese government, global foundations and private companies which contribute funding, GHIT’s Council votes on important affairs, such as the election and dismissal of governors, amendments to the articles of incorporation, and the approval of financial statements.

Takeshi Akahori
Ambassador, Director-General for Global Issues
Ministry of Foreign Affairs

Eiji Hinoshita, MD, Ph.D, MSc.
Assistant Minister for Global Health and Welfare
Ministry of Health, Labour and Welfare

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

Cheryl Moore
Chief Research Programmes Officer
Wellcome

Astellas Pharma Inc.
Kenji Yasukawa
Representative Director, Chairman of the Board

Osamu Okuda, PhD
Representative Director, President & CEO
Shionogi & Co., Ltd.

Daichi Sankyo Company, Limited
Sunao Manabe, Ph.D
Representative Director, Executive Chairperson & CEO

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

Isao Teshirogi, PhD
Representative Director, President and CEO
Takeda Pharmaceutical Company Limited

Board of Directors

Composed of global health and management experts, GHIT’s Board of Directors oversees the work of the leadership team and votes on important affairs related to business management, such as the approval of important regulations, mid-term strategies, annual plans, budgets, and investment opportunities.

Hinoki Nakatani, MD, PhD, MHPEd
Visiting Professor
Keio University School of Medicine

Peter Piot, MD, PhD
Professor of Global Health, London School of Hygiene & Tropical Medicine
Special Advisor on COVID-19 to the President of the European Commission

Osamu Kunii, MD, PhD, MPH
CEO, GHIT Fund

Osamu Okuda, PhD
Representative Director, President & CEO
Shionogi & Co., Ltd.

Mahima Datla
Managing Director
Biological E. Limited

Satoshi Ezoe, MD, MPH, MPA, PhD
Director, Global Health Policy Division
International Cooperation Bureau
Ministry of Foreign Affairs

Hikaru Ishiguro, LLM
Statutory Auditor
INSPiRE Corporation

Peter Piot, MD, PhD
Professor of Global Health, London School of Hygiene & Tropical Medicine
Special Advisor on COVID-19 to the President of the European Commission

Tetsuya Itani
Director
Office of Global Health Cooperation
Ministry of Health, Labour and Welfare

Daikichi Momma
Vice Chairman
Institute for International Economic Studies

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

Ex-Officio
Katey Einterz Owen, PhD
Director, Neglected Tropical Diseases Pharmaceutical Industry Leadership Engagement
Bill & Melinda Gates Foundation

Saori Nakamura
Attorney at Law
Hirayama Nagareya Shirai Law Office

Supervisory Board Member
Ko-Yung Tung, JD
Lecturer on Law, Harvard Law School,
Former Senior Vice President and General Counsel, World Bank

Richard Seabrook, PhD, MBA
Independent Senior Advisor, Innovations,
Wellcome CEO 360Biomedical Ltd
Royal Society Entrepreneur in Residence University of Bristol

Ex-Officio
2023.8
Leadership

Selection Committee

Composed of domestic and foreign experts with a wealth of knowledge and experience in R&D of therapeutic agents, vaccines, and diagnostic agents, the Selection Committee (SC) examines and evaluates applications and progress reports from program applicants and recommends investment opportunities to the Board of Directors. To avoid any conflict of interest between our backers and development partners, the SC does not include private sector representatives.

Leadership Team

The leadership team facilitates the development of business, investment, and organizational growth strategies, executes strategies based on the approval of the Board of Directors, and implements administrative tasks.

As of October 31, 2023
GHIT Fund is a Japan-based global public-private partnership fund for global health R&D. We invest in nonprofit product development for malaria, tuberculosis, and Neglected Tropical Diseases (NTDs). GHIT’s sponsor companies provide in-kind services in support of GHIT’s mission.

**Funding Partners and Sponsors**

As of August 31, 2023

**Government**

- **Full Partners**
  - Ministry of Foreign Affairs (Japan)
  - Ministry of Health, Labour and Welfare (Japan)
  - United Nations Development Programme

- **Foundation**
  - Bill & Melinda Gates Foundation
  - Wellcome

**Private Companies**

- **Full Partners**
  - Astellas Pharma Inc.
  - Chugai Pharmaceutical Co., Ltd.
  - Daiichi Sankyo Co., Ltd.
  - Eisai Co., Ltd.
  - Shionogi & Co., Ltd.
  - Takeda Pharmaceutical Company Limited

- **Associate Partners**
  - FUJIFILM Corporation
  - Fujirebio Holdings, Inc.
  - Otsuka Pharmaceutical Co., Ltd.

- **Affiliate Partners**
  - Kyowa Kirin Co., Ltd.
  - Merck KGaA
  - Mitsubishi Tanabe Pharma Corporation
  - Sumitomo Pharma Co., Ltd.

- **Sponsors**
  - Burson Cohn & Wolfe Japan Inc.
  - Diligent Japan Ltd.
  - Linkties Co., Ltd.
  - Mori Building Co., Ltd.
  - Morrison & Foerster LLP
  - Salesforce Japan Co., Ltd.

As of August 31, 2023