

Lessons Learned from Japan and Korea:  
**Innovative Partnerships  
for Global Health  
Research & Development**

By Hannah E. Kettler, PHD | September 2020

## Acknowledgments

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# Table of Contents

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<b>Executive Summary .....</b>	<b>3</b>
<b>Introduction .....</b>	<b>4</b>
<b>Features of the Model.....</b>	<b>8</b>
<i>Partnering concept.....</i>	<i>8</i>
<i>Fund composition.....</i>	<i>9</i>
<i>Organizational governance .....</i>	<i>9</i>
<i>Process for selecting and funding innovation .....</i>	<i>10</i>
<i>Accelerating access .....</i>	<i>11</i>
<i>GHIT fund's support to global health R&amp;D beyond funding .....</i>	<i>12</i>
<i>Operational costs .....</i>	<i>12</i>
<b>Progress.....</b>	<b>13</b>
<b>Key Insights from Interviews:.....</b>	<b>14</b>
<i>Timing matters.....</i>	<i>14</i>
<i>Leadership is everything.....</i>	<i>14</i>
<i>Success requires a strong local and global presence.....</i>	<i>15</i>
<i>Balancing multiple objectives and expectations involves tradeoffs.....</i>	<i>16</i>
<i>Pressure to keep overhead low can trade off with quality and impact.....</i>	<i>16</i>
<i>GHIT Phase 2.0 (or 3.0) may look different .....</i>	<i>17</i>
<b>Conclusions and Recommendations .....</b>	<b>18</b>

# Executive Summary

Billions of dollars and innovative partnership are needed to accelerate the development and deployment of tools with which to fight neglected infectious and emerging disease, globally and specifically in the poorest countries. COVID-19 is a stark reminder of health and economic consequence of not acting, of not investing in innovation.

As many G20 countries explore how to expand and combine government and industry investments to achieve the goals of accelerated tool development and deployment, the Japanese Global Health Innovative Technology Fund (GHIT Fund) and the more recently established Korean initiative, the Research Investment for Global Health Technology Fund (RIGHT Fund), are important models from which to learn.

Japan has world class innovative life science companies, researchers, and a government committed to investing in global health. Yet at the time when the GHIT Fund was officially launched in 2013, Japan was notably underrepresented in the world's research and development (R&D) and partnership efforts to solve global health challenges. The GHIT Fund has provided an organizational construct and the incentives to mobilize and direct Japanese public and private financial and in-kind resources towards globally defined R&D priorities.

The GHIT Fund was established in record speed. The time from project conception to first grants out the door (including fundraising, organization and governance establishment, and solicitation of first proposals) was just 18 months. Over the past eight years, the GHIT Fund has raised over \$300 million from the Japanese government, the Japanese pharmaceutical industry, and the Bill & Melinda Gates Foundation, Wellcome and other global philanthropies. As of May 2020, the GHIT Fund had invested in 91 partnerships and over 130 projects across the value chain from early discovery through to late stage clinical development. Six products are in the clinical phase of development and two products – a pediatric drug for schistosomiasis and a rapid tuberculosis (TB) diagnostic – are expecting regulatory approval in the near future. One of the GHIT Fund's top priorities is to secure the co-funding these late stage projects need to get them through the large-scale clinical development, manufacturing, and registration processes.

From concept to  
first grant:

**18 months**

Amount raised:

**\$300 million**

Partnerships supported:

**91**

Projects funded:

**130**

(as of May 2020)

In 2018, Korea launched its own fund – the RIGHT Fund - with approximately \$45 million (50% from the Korean Ministry of Health and Welfare, 25% from five Korean companies, and 25% from the Bill & Gates Foundation) . In July 2019, it announced its first five grants totaling \$8.5 million. The RIGHT Fund draws extensively on the design, processes, and lessons from the GHIT Fund but targets a modified scope to reflect and leverage the unique competencies and capacities of the Korean biomedical research industry, including biologic manufacturing and formulation.

***Seven key considerations for those looking to build on the learning and experiences in Japan and Korea are:***

**1**

***Be clear and align between key stakeholders about the primary objectives.***

Those objectives might be furthering the best science, delivering new health impact from local technologies, or building local R&D capabilities to advance global health priorities. Build the fund and organization to align with those objectives. The objectives drive key decisions including the minimum necessary size of the fund, the profile and experience of the CEO and board chair, appropriate level of overhead costs, the composition of company partners, performance metrics, timeline to impact, and the sponsoring institution.

**2**

***Engage stakeholders at a level commensurate with the initiative.***

A clear signal of commitment from the top - be that the country's Prime Minister, a company CEO, or a foundation leader - is essential given the risks and uncertainties of product support and funding over many years in the face of often changing Overseas Development Assistance (ODA) priorities and other resource trade-offs.

**3**

***Local ownership and leadership are critical for sustainability.***

While it is a multi-stakeholder partnership and decisions will be based on a consensus among partners, sustainable impact of this construct critically depends on strong ownership and leadership by local partners. This is important to secure stable financing in the long-term and to ensure that the fund evolves to reflect the strengths of the local context.

#### 4 *There is no one size that fits all countries.*

As the Korea and Japan cases illustrate, every country has a unique technical context (e.g. industry and research comparative advantages, capabilities, and capacities) and sociopolitical one, including national ODA spending and priorities. The right size and scope, composition of partners, board and CEO profile for a sustainable, impactful fund should be led with understanding of this local context.

#### 5 *Don't underestimate the importance of CEO and board chair recruitment.*

Funders should and will make their commitments contingent on the CEO and board chair appointments. These are tough positions to fill, often requiring a combination of experience in product development, a strong knowledge base of global health, and a track record of garnering respect from and influencing key stakeholders in government, industry, and not-for-profits. Helpful fund leadership qualities include diplomacy and advocacy, communications, strategic planning, and strong initiative to take action and make decisions.

#### 6 *A "GHIT Fund" is not a silver bullet.*

The GHIT Fund cannot afford to fully finance products from discovery through development on its own. To be successful, the GHIT Fund depends on its validation by, and integration into, the broader global health ecosystem. Informed by Japan's experience, funders looking to establish a new GHIT Fund-like initiative should proactively invest in complementary efforts. Examples include formal partnerships with co-funders for late stage development like European and Developing Country Trials Partnership (EDCTP), the lining up of domestic incentive programs like regulatory fast track, and a Priority Review Voucher program with their scope to increase corporate commitments.

#### 7 *Leave room for flexibility.*

Over time, the priorities of the government and stakeholders of global health R&D will evolve. The ability of the GHIT and RIGHT Funds to adapt and evolve is necessary and desirable for sustainable impact. In the case of Korea, for example, it became clear within its first two years that its comparative strengths may be in the broad application of mHealth/eHealth platforms, rather than the initial predictions of biologics and second-generation vaccine formulations. Upfront investment in defining articles of incorporation and governance rules is time and money well spent, including to define the roles and responsibilities of the council and board in decisions related to significant pivots in strategy.

# Introduction

New biomedical innovation is an essential component of the broader global effort to accelerate progress towards the ambitious global health goals captured in the Sustainable Development Goals (SDGs).<sup>1</sup> Recent studies put the gap at \$1.5-2 billion a year between current and needed resources to advance the portfolio.<sup>2</sup>

It is not just a matter of money. To solve for global health research and development (R&D) challenges, we need an enabling environment that motivates the best companies, researchers, and institutions with the most transformational technologies to work together on those solutions. As diseases that disproportionately impact the poor have relatively limited market incentives, over the past 20 years, the global health community has worked together to create multiple innovative financing and product development mechanisms to attract partners and build this sophisticated and specialized global health R&D ecosystem. Japan's Global Health Innovation Technology Fund (GHIT Fund) is one of those innovative financing mechanisms.



**To solve for global health research and development (R&D) challenges, we need an enabling environment that motivates the best companies, researchers, and institutions with the most transformational technologies to work together on those solutions**

Despite being one of the Organization for Economic Co-operation and Development (OECD) leaders in health Overseas Development Assistance (ODA), with a pharmaceutical industry second only to the United States in size and level of innovation,<sup>3</sup> as recently as 2012 Japan did

<sup>1</sup> <https://unstats.un.org/sdgs/report/2019/The-Sustainable-Development-Goals-Report-2019.pdf>

<sup>2</sup> <https://gatesopenresearch.org/articles/2-23/v3>

<sup>3</sup> <https://www.ghitfund.org/overview/history>

not factor on the global health R&D radar. Four of the largest Japanese companies were clustered at the bottom of the Access to Medicines Index<sup>4</sup> with very few partnerships or projects with the network of global product developers (i.e. the Product Development Partnerships (PDPs) ) and the Japanese government did not register on the annual R&D funding tracker, G-FINDER.<sup>5</sup>

Dr. Tachi Yamada, then Senior Vice President and Chief Medical Officer at Takeda and formerly the President of Global Health at the Bill & Melinda Gates Foundation (the Gates Foundation) , and Dr. BT Slingsby, then Director for Global Health Access at Eisai, took the initiative to approach the Japanese government with a new R&D model that would be good for Japan, for Japanese industry, and for global health R&D. They proposed pooling resources from Japanese pharmaceutical companies, global health philanthropists (leading with the Gates Foundation) , and Japanese government ODA into a new fund to attract, support, and integrate Japanese research, innovation capabilities, and leadership into the global efforts to advance new products for global health R&D priorities.

It took the founding GHIT Fund Management team just 18 months to move from concept to getting its first grants out the door. In the nearly eight years since the GHIT Fund was launched in 2013, it has raised over \$300 million (75% from Japanese public and private sources and 25% from international ones) , issued 48 requests for proposals (RFPs) , and invested over \$209 million in 91 partnerships involved in 134 R&D projects as of 27<sup>th</sup> May 2020.<sup>6</sup> Each partnership is comprised of at least one Japanese and one non-Japanese partner. As of 2020, two of the GHIT Fund's sponsored products had progressed to the registration phase with approval expected in the near future. Japanese pharmaceutical companies have contributed almost \$100 million into the fund and invested tens of millions more in-kind as partners in projects.<sup>7</sup>

In 2018, Korea established its own fund – the Research Investment Global Health Technology Fund (RIGHT Fund) – modeled after the GHIT Fund. Korea's life science industry is less mature than Japan's, with current strengths in formulation and manufacturing technologies, second generation vaccines, and biologics. The Korean government saw an opportunity through the GHIT Fund model to expand its ODA presence through investments in global health R&D, leveraging for-profit and not-for-profit private resources while at the same time supporting its local research capacity and industry. Launched with approximately \$45 million (50% from the Korean Government, 25% from the Gates Foundations and 25% from five Korean life science companies) , they have already issued two RFPs and approved five investments valued at \$8.5 million.<sup>8</sup>

<sup>4</sup> [https://accesstomedicinefoundation.org/media/uploads/downloads/5bc5ede888c3d\\_2012-Access-to-Medicine-Index.pdf](https://accesstomedicinefoundation.org/media/uploads/downloads/5bc5ede888c3d_2012-Access-to-Medicine-Index.pdf)

<sup>5</sup> [http://policycures.org/downloads/GF2012\\_Report.pdf](http://policycures.org/downloads/GF2012_Report.pdf)

<sup>6</sup> <https://www.ghitfund.org/investment/overview>

<sup>7</sup> Interview

<sup>8</sup> <http://www.rightfund.org/overview/introduction/>



At a time when the demand for global health R&D, innovation activity, and the need for new funders is growing,<sup>9</sup> it is important to learn from Japan's experience with the GHIT Fund and explore whether similar models might work in other countries beyond Korea.

**The purpose of this report is twofold:**

- ◆ **to describe the GHIT Fund model including what it does, how it works, who is involved, and what kind of impact it is having on global health R&D**
- ◆ **to explore what the lessons from the GHIT and RIGHT Funds suggest about the potential replicability of the model in other settings**

The report is informed by publicly available data, 12 interviews with stakeholders who are or were involved in GHIT Fund's and RIGHT Fund's establishment, management, and/or oversight, and GHIT and RIGHT Funds' grant proposals to the Gates Foundation.

This report is organized into five sections. In the next section, the model's key features are summarized, followed by a section on progress, one of lessons from stakeholders, and finally recommendations and conclusions for future initiatives.

## Features of the Model

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This section documents key features of the GHIT Fund model drawing primarily on the Japan example given its longer track record. In design, Korea's RIGHT Fund is modeled closely on, though is not identical to, the GHIT Fund.

### Partnering concept

The GHIT Fund was set up with the explicit goal to mobilize and integrate Japanese funding, research, and innovation capacity into the global effort to build tools to fight infectious diseases prevalent in low- and middle-income countries (LMICs). The crux of the model sits with the requirement that applicants propose a partnership comprised of at least one Japanese and one non-Japanese partner. This simple idea sets the GHIT Fund up as a "two-way-street" with benefit for the Japanese industry and researchers through access to dedicated research funding and global networks – a critical criteria to secure the Japanese government contribution to the GHIT Fund – and benefits for the global health community through access to untapped Japanese resources and capabilities – a critical criteria to securing the Gates Foundation's contribution.

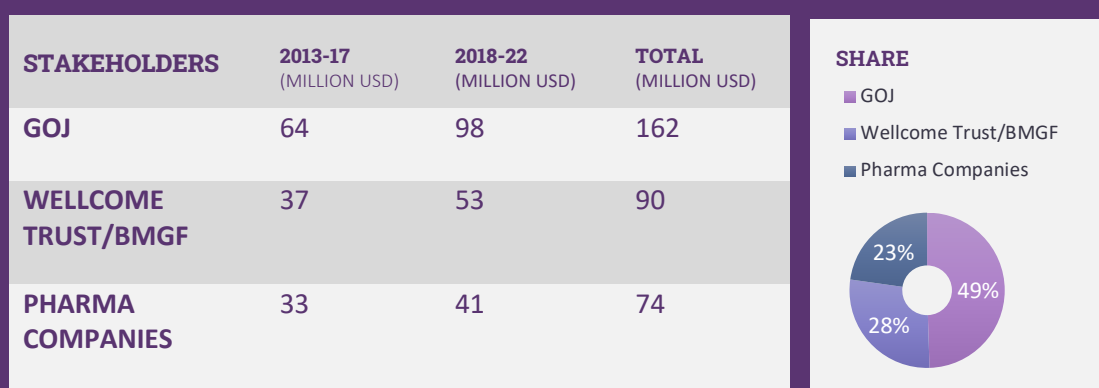
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<sup>9</sup> <https://s3-ap-southeast-2.amazonaws.com/policy-cures-website/assets/app/uploads/2020/02/11150341/G-Finder2019.pdf>

## Fund composition

In both the Japan and Korea cases, the government has provided 50% of the funds, matching the sum of the industry and Gates Foundation and other philanthropic contributions.<sup>10</sup> The resulting 50-25-25 split provides leverage for all stakeholders. In the case of GHIT, at the time of launch, the Gates Foundation's money was matched 3-1. With the addition of more company funders and the Wellcome Trust as a second philanthropic funder, the match is closer to 5-1.

### GHIT Financial Commitments by Stakeholder



In Japan, beyond their contributions to specific projects they might be involved in, six pharmaceutical companies committed \$1 million per year for the first five years to support GHIT and renewed for a second five years in 2018. Symbolic in size, this investment is an important gesture from companies that had, up until 2013, contributed comparatively little to global health. GHIT also represents one of the first times where a group of companies have joined as investors in the establishment and operations of a non-profit global health R&D organization.

## Organizational governance

The GHIT Fund's governance is comprised of a council with the companies' CEOs and senior representatives from the government ministries and foundations, an independent international board of directors, a selection committee, and a management team. The board oversees the operations of the GHIT Fund's leadership, business and strategic planning processes, and funding decisions based on recommendations from the selection committee.

<sup>10</sup> In the case of GHIT it, in 2015, Chugai joined as a 6th pharmaceutical company funder and the Wellcome Trust joined as a 2nd philanthropic funder.

## Process for selecting and funding innovation

The GHIT Fund makes funding decisions via open RFPs. The GHIT Fund facilitates the partnership building but does not take part in the R&D. The GHIT Fund Management Team has done extensive industry and research landscapes of potential Japanese and international applicants, some targeted outreach to partners, and offered grant writing workshops and other support to academic researchers who do not have experience applying for international grants.

The GHIT Fund's management team issues RFPs for each of their R&D platforms on a biannual schedule. The different platforms - a Targeted Research, a Screening, a Hit-to-Lead, a Product Development platform – target different types of local assets, capabilities, and partners.<sup>11</sup>

**Proposals must meet eligibility criteria to be considered for funding:**

- ◆ **Involve an eligible Japanese and non-Japanese partner.**
- ◆ **Meet duration and total funding limits, including evidence of required co-funding. In Japan, for example, a proposal for Phase II and beyond work must demonstrate 50% co-funding. In the case of Korea, the RIGHT Fund, as a rule, only funds 50% of any project.**
- ◆ **Align with one of the targeted diseases and product needs as specified in the RFP, which are informed by global target product profiles.**
- ◆ **Confirmation that all partners will agree to the data and product access policies.**

The GHIT Fund's management team reviews the *Intent to Apply* and requests full proposals from a subset of those applicants. These proposals are reviewed by a select number of external reviewers that make recommendations to the selection committee. The selection committee interviews a short list of applicants and makes their funding recommendations to the board for their approval. The proposals are evaluated based on merit according to their scientific and technical feasibility, global health impact, and partnership and project management capabilities. Once approved, the GHIT Fund's management team negotiates the terms and milestones with the awardees. The process from RFP issue to signed agreement is set up to take approximately eight months.

Partners who successfully complete a project can return to request additional funds to continue their work. Moving projects along the value chain from discovery to registration, and ultimately to the patients, is a strategic priority for the GHIT Fund so ideally good programs would continue to receive support but there is no guarantee. Each RFP is open to both new and program continuations and so, in theory, there could be more attractive new projects that get prioritized

<sup>11</sup> The RIGHT Fund issues RFPs 3 times a year – 2x for a Technical Accelerator Awards and 1x for a Product Development Award.

over a follow-on grant. Given expected attrition rates, the GHIT Fund aspires to balance between feeding the pipeline and supporting existing projects. The GHIT fund also seeks to balance between the diseases and between the different tools. Beyond proactive outreach to encourage more applications from different types of partners, from a governance perspective, the GHIT Fund Management Team does not influence the selection process to explicitly address imbalances.

## Accelerating access

The GHIT Fund's day-to-day efforts are dedicated to advancing product development, while the funders, especially the government, are ultimately holding them accountable for saving lives. It is incumbent on the GHIT Fund to set their projects up for access if/when regulators approve them. The GHIT Fund does not have the resources or the experience to directly engage in delivery but has levers to influence access.

**First**, before they are selected for funding, projects are evaluated from the standpoint of their potential for global health impact, whether they are needed, and whether the product is “usable.” Here the GHIT Fund draws on established target product profiles and needs assessments of established global organizations like the World Health Organization (WHO) to design their RFPs and to the expertise of independent global health experts as reviewers and on the Selection Committee.

**Second**, funding is contingent on all partners' willingness to agree to access policies that includes setting no-profit no-loss prices for any sales in Low and low middle income countries (LMICs).

**Third**, in the current five-year strategy (FY2018-FY2022), the GHIT Fund's management team has started to ask the partners with late-stage projects to develop access and delivery strategies for the board to review. These strategies are not yet required as a prerequisite for funding. The GHIT Fund is also proactively exploring collaborations with delivery partners such as Unitaid<sup>12</sup> to help support the GHIT Fund's products.

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<sup>12</sup> <https://unitaid.org/news-blog/the-global-health-innovative-technology-fund-and-unitaid-collaboration-to-accelerate-access-to-innovative-solutions/#en>

## GHIT Fund's support to global health R&D beyond funding

**The GHIT Fund punches well above its weight through its non-funding roles as connector, advocate, and educator.**

- ◆ In support of the projects and applicants, they educate and support researchers in grant writing and collaboration development, help identify and facilitate partnerships within Japan between researchers and companies, and between Japan and the global network of product developers and funders – the latter important both for co-funding the GHIT Fund projects and non-GHIT Fund projects.
- ◆ In support of global funders like the Gates Foundation, they can provide introductions and access to companies and researchers for potential conversations above and beyond GHIT Fund projects.
- ◆ In support of the local operating environment, they can serve as a neutral facilitator of dialogue among companies, and between companies and government.
- ◆ In support of global health R&D more broadly, they are an important advocate and awareness builder both at home – key for sustaining funding and support long term – and internationally, which can help build deal flow and also integrate their pipeline into the global ecosystem.

## Operational costs

Up until now, the GHIT Fund has operated with less than 5% overhead. To meet their funder's low overhead expectations, the GHIT Fund has made strategic decisions to use RFPs rather than building direct partnerships and to rely heavily on volunteer time rather than full-time employees or retained consultants, for the Selection Committee, the expert reviews, and on-going project management.

## Progress

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The GHIT Fund has consistently met or exceeded its funders' milestones. This includes issuing RFPs, processing and evaluating proposals, approving and negotiating grants, building and managing a portfolio of partnerships, advancing projects along the value chain – including six into clinical trials - expanding the scope of their international footprint in terms of partners, and raising additional funds. Over the course of its first five years, the GHIT Fund brought in additional philanthropic and company investors and raised sponsorships to support its events and communications and advocacy objectives. In 2016, the GHIT Fund turned that strong performance record into a successful replenishment, doubling the fund to support a second five-year strategy, GHIT 2.0 (FY2018-FY2022).

So far, progress can be measured in terms of volumes – 48 RFPs, 128 partners, and 91 projects awarded, of which 32 are screening projects involving thousands, if not millions, of compounds. Harder to measure and evaluate is the quality and the potential impact of these activities. Are the best companies and scientists applying for funds? Is the best science and technologies being tested? To what degree has the global health community “accessed” Japan’s “assets” via the GHIT Fund? Are the projects that are getting funded working on products and solutions that global health really needs? Are the right sets of global partners involved? Are the projects performing well against milestones?

Anecdotal evidence from interviews paint an incomplete qualitative picture. The process of evaluating proposals is deemed to be robust with global experts serving on the selection committee and as expert reviewers, and the projects are being assessed and selected according to absolute science and impact potential thresholds. If none of the projects submitted in any one RFP meet the thresholds, none get funded. Whether these GHIT Fund projects would be prioritized if they were compared with a global pool of opportunities is harder to judge, especially given the broad scope of projects across multiple diseases, multiple tools, and multiple development phases.

Several people interviewed suggest that the GHIT Fund could benefit from more technical in-house or retained consulting staff to support and evaluate the progress of the projects against milestones once they are funded systematically and adequately. It is hard to assess the impact of any insufficient oversight on the project and portfolio performance. One could imagine some sub-optimal use of resources if projects miss milestones or continue when they might better have been stopped or redirected.

It may be too early to judge whether the GHIT Fund is motivating more than just the “usual suspects” to apply for funds, especially as it relates to companies. Up until now, a few companies are involved in multiple projects. This might not be a bad thing – these companies might have all the best ideas and assets – but it does suggest that other companies, including the others on the

council, have not substantively stepped up their engagement in global health since they joined the GHIT Fund.

The GHIT Fund has not systematically measured and documented their impact on Japan's competitiveness in terms of improving and supporting researchers or helping Japanese companies. Again, anecdotal evidence suggests that the involved researchers and companies have benefited directly through the funding and global partnerships, and also indirectly such as tips in grant writing, project-gained experience in new markets, exposure to new funders, and positive initiative associated visibility. What difference these make at the aggregate in terms of the competitiveness of Japan's biopharmaceutical research sectors is not yet clear.

## Key Insights from Interviews:

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Interviews with the current and former CEOs of the GHIT and RIGHT Funds, current and former board members, members of the selection committee, grant managers at the Gates Foundation, and a scientist from one of the lead Japanese pharmaceutical companies congregate around a number of key insights.

### Timing matters

In both countries, the initiative champions were able to take advantage of a specific political opportunity. In Japan, at the time when the GHIT Fund was established, the Prime Minister was looking to expand his role as a global leader and accelerate economic growth through greater globalization of Japan's core industries. He was also dealing with the aftermath of the devastating 2011 earthquake and tsunami. Thus, a partnership concept that combined an increase in ODA - some of which could flow back into the local economy - and increased access to global markets and networks for Japan's leading pharmaceutical companies resonated with him and his decisionmakers. In the case of Korea, the government was looking for opportunities to increase their visibility as a donor and to support their life science industries and were attracted to the GHIT Fund concept. A challenge for the RIGHT Fund is that government championing for the initiative was voted out of power after the funds were appropriated but before the organization was formally established. Luckily, the current government continues to support the RIGHT Fund, though it has its own vision and priorities.

### Leadership is everything

The GHIT Fund model's success depends on its ability to raise and sustain financial commitments, facilitate and manage a portfolio of product partnerships, and connect across continents, stakeholders, partners, and stages in development. This all comes down to the commitment, drive, and alignment of its leaders.

The CEO requires a unique set of experiences, skills, and personality. S/he must understand the business – ideally both global health and life science product development - must be able to

intuit the culture and needs of the different stakeholders, be pioneering, flexible, and prepared to get out there and actively advocate for the organization's success both internationally and at home. Educating non-technical constituents about biomedical R&D and retaining alignment between funders around the agreed set of objectives and target outcomes has proven to be almost a full-time job, especially in instances of government changes, as is the case in Korea.

Stakeholder management is a critical role for the board chair as well. S/he needs to invest time in board oversight, be prepared to advocate and champion for the organization, remain neutral while at the same time leverage their respect and influence with partners to help secure funding. Respect in and knowledge of the global health community is also desirable.

Finally, all funders are making hard tradeoffs in their decision to support the GHIT Fund. For the government, to commit ODA to the GHIT Fund is likely a decision not to fund something else and may necessarily involve more than one ministry. At the company, to work on global health projects comes with direct and opportunity costs from not working on something more lucrative. At the Gates Foundation, to fund a Japanese-specific initiative is to not fund a global R&D initiative. To secure and sustain funding and organizational engagement requires buy in and support from the top – from company CEOs, foundation(s) president(s), and ideally from the country Prime Minister or President. These leaders influence and hold each other accountable and provide the entity the legitimacy and visibility it needs to secure the funding and partner interest to operate at scale.

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**These leaders influence and hold each other accountable and provide the entity the legitimacy and visibility it needs to secure the funding and partner interest to operate at scale.**

## Success requires a strong local and global presence

To build a strong pipeline of products and secure the co-funding needed to get products to market, the GHIT Fund management team needs to invest time in building awareness, partnerships, and networks at home and abroad. Integration into the global ecosystem is important to avoid a scenario where GHIT Fund ends up investing domestic candidates that may not be a priority for other funders or, ultimately, the patients. With scarce total global health R&D resources and increased calls for greater coordination across a common set of priorities,<sup>13</sup> it is critical that domestic funds do not end up funding irrelevant projects.

<sup>13</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6407558/>



## Balancing multiple objectives and expectations involves tradeoffs

The GHIT Fund's primary mission is to use its funding and connections to mobilize, integrate, and support the research and innovative resources of Japan to accelerate global health R&D. There is also a government expectation that the GHIT Fund deliver domestic benefits such as funding to Japanese researchers, access to international networks, funders, and markets for Japanese industry and academics, and positive visibility for the Japanese government and the industry. In the case of Korea, the government sees an opportunity to learn and build biomedical innovative capabilities via the global health projects funded by the RIGHT Fund. The pursuit of both global health and domestic outcomes will invariably involve tradeoffs.

In Japan, the GHIT Fund management team has had to adapt their strategy to meet the government's expectation that their investments in the GHIT Fund generate health impact in the relatively short term. First, they have sought to manage expectations by educating the public and politicians about the realities of the high risks and long timelines for biopharmaceutical R&D. Second, they have accommodated the expectation for shorter term health benefits by prioritizing some incremental projects that have a better shot at getting to market sooner while at the same time protecting funds needed for riskier but potentially more impactful innovative projects that are further from approval.

## Pressure to keep overhead low can trade off with quality and impact

The GHIT Fund's funders' push to keep overhead below 5% comes with tradeoffs. Most importantly, low overheads may limit the resources the GHIT Fund spends on shaping and improving the quality of the proposals before the funding decision and managing the performance of projects after the funding decision. According to the current process, there is little time or resources available to work with grant proposal applicants to shape their proposals in advance of final committee review. This extra effort might result in fewer but potentially better designed proposals to ensure a pathway to impact.

Going one step further, with more operational funds, the GHIT Fund could invest more in project "hunting" - actively seeking out partners and building funding opportunities in an effort analogous to how a venture capitalist builds investment opportunities. RFPs are good when you are not sure what you are looking for, you don't know who all the key players are, or what opportunities there are out there and you want to cast as wide a net as possible. This strategy made sense at the beginning. Going forward, important questions are whether the GHIT Fund should do more "hunting" as a supplement to RFPs, and if yes, whether it is currently set up to do so given the design of the organization, composition of the team, expectations of the funders.

Regarding grant management, the GHIT Fund has built more sophisticated tools for process tracking against milestone and program check ins. However, the GHIT Fund could still use more technical expert people power – be that on staff or on retainer - to manage and monitor the projects against milestones. More active project management would allow for more timely decisions about whether to terminate a project early, or, alternatively, give additional support to get it back on track.



**With more operational funds, the GHIT Fund could invest more in project “hunting” – actively seeking out partners and building funding opportunities in an effort analogous to how a venture capitalist builds investment opportunities.**

## **GHIT Phase 2.0 (or 3.0) may look different**

Several stakeholders spoke to the questions of whether and how the GHIT Fund will optimize its impact on global health in the longer term. Up until now, the GHIT Fund has had a relatively good response rate to the RFPs and the selection committee continues to make funding recommendations. Just as there are not infinite resources, there are also not an infinite number of partnering opportunities in the traditional pharmaceutical space. The GHIT Fund needs a plan to get ahead of eventual declines in RFP responses.

One option is to stay the course, doubling down on what is in the pipeline, concentrating funds and attention towards the successful development and introduction of products, and looking to optimize the impact of bets made to date.

Investing more in deal and applicant “hunting” and nurturing, per above, is another option. Funders would likely have to accept an increase in overhead costs (or commit to provide more total funds to allow for a larger staff) , but it is possible that a more active effort as a complement to the passive RFP approach could unlock new partnerships and opportunities.

Both GHIT and RIGHT Funds’ boards have also explored the idea of expanding and/or redirecting the scope to new sectors, such as information and communications technology (ICT) , new indications, such as non-communicable diseases and/or new tools, such as devices and/or

vectors. Assuming a similar constellation of strong local and global partners, there is good reason to expect that the GHIT Fund model can be applied to new sectors. The key question is whether in the case of Japan, for example, the current GHIT Fund has the right people, experience, and sector specific know-how to redirect or expand its scope. Much of the people infrastructure including the CEO, the member companies, and selection committee are biopharmaceutical sector specialists. To expand, would the GHIT Fund need a new dedicated team? Dedicated and separate resources?

In the case of Korea, the RIGHT Fund has already started to shift away from the initial vaccine and biologics focus to consider a broader set of mHealth/eHealth platforms including diagnostics, big data, and AI. These sectors may better reflect Korea's comparative strengths and the RIGHT Fund's ability to make timely impact with its current resources. Critical to making this shift is leadership agility including changes to the composition of the council to incorporate new companies.

Ultimately, the direction of the next strategy will come down to the core funders, especially the Japanese and Korean governments and the Gates Foundation to align on their impact expectations and how they want to their money invested over time.

## Conclusions and Recommendations

Amid the COVID-19 pandemic crisis, there are unique pressures on governments to seek and take bold action to coordinate partners across countries and between public and private. As countries explore new models, here are some important takeaways from the GHIT Fund model to consider.

1

*Be clear and align between key stakeholders about the primary objectives.*

Those objectives might be furthering the best science, delivering new health impact from local technologies, or building local R&D capabilities to advance global health priorities. Build the fund and organization to align with those objectives. The objectives drive key decisions including the minimum necessary size of the fund, the profile and experience of the CEO and board chair, appropriate level of overhead costs, the composition of company partners, performance metrics, timeline to impact, and the sponsoring institution.

2

*Engage stakeholders at a level commensurate with the initiative.*

A clear signal of commitment from the top - be that the country's Prime Minister, a company CEO, or a foundation leader - is essential given the risks and uncertainties of product support and funding over many years in the face of often changing Overseas Development Assistance (ODA) priorities and other resource trade-offs.

### 3 *Local ownership and leadership are critical for sustainability.*

While it is a multi-stakeholder partnership and decisions will be based on a consensus among partners, sustainable impact of this construct critically depends on strong ownership and leadership by local partners. This is important to secure stable financing in the long-term and to ensure that the fund evolves to reflect the strengths of the local context.



**Sustainable impact of this construct critically depends on strong ownership and leadership by local partners.**

### 4 *There is no one size that fits all countries*

As the Korea and Japan cases illustrate, every country has a unique technical context (e.g. industry and research comparative advantages, capabilities, and capacities) and sociopolitical one, including national ODA spending and priorities. The right size and scope, composition of partners, board and CEO profile for a sustainable, impactful fund should be led with understanding of this local context.

### 5 *Don't underestimate the importance of CEO and board chair recruitment.*

Funders should and will make their commitments contingent on the CEO and board chair appointments. These are tough positions to fill, often requiring a combination of experience in product development, a strong knowledge base of global health, and a track record of garnering respect from and influencing key stakeholders in government, industry, and not-for-profits. Helpful fund leadership qualities include diplomacy and advocacy, communications, strategic planning, and strong initiative to take action and make decisions.

## 6 *A “GHIT Fund” is not a silver bullet.*

The GHIT Fund cannot afford to fully finance products from discovery through development on its own. To be successful, the GHIT Fund depends on its validation by, and integration into, the broader global health ecosystem. Informed by Japan’s experience, funders looking to establish a new GHIT Fund-like initiative should proactively invest in complementary efforts. Examples include formal partnerships with co-funders for late stage development like European and Developing Country Trials Partnership (EDCTP), the lining up of domestic incentive programs like regulatory fast track, and a Priority Review Voucher program with their scope to increase corporate commitments.

## 7 *Leave room for flexibility.*

Over time, the priorities of the government and stakeholders of global health R&D will evolve. The ability of the GHIT and RIGHT Funds to adapt and evolve is necessary and desirable for sustainable impact. In the case of Korea, for example, it became clear within its first two years that its comparative strengths may be in the broad application of mHealth/eHealth platforms, rather than the initial predictions of biologics and second-generation vaccine formulations. Upfront investment in defining articles of incorporation and governance rules is time and money well spent, including to define the roles and responsibilities of the council and board in decisions related to significant pivots in strategy.

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As countries beyond Japan and Korea consider the pros and cons of replicating the GHIT Fund-like model, there is an opportunity for the governments and other donors, like the Gates Foundation, to explore how they might work together to spread the operating costs and core functions of their respective country-specific initiatives across a larger pool of resources and projects by building and sharing common infrastructure.

Local context and leadership, as well as economic, industry, and reputational benefits will remain important and must be retained; the idea is not to establish a “global R&D fund.” One idea worth considering – and suggested by a GHIT board member – is that of an alliance, analogous to the one airlines use.

### **Proposal: A “Star Alliance” for Global Health Innovative Technology Funds:**

Countries build their own initiative with their own CEO, sector and strategic focus, brand, and communication strategy; Japan and Korea have the option to join with their existing initiatives.

These initiatives share the back office and funding infrastructure, including the RFP and grant award processes and execution, project management, evaluation tools, and a retained pool of expert reviewers and project monitors.

Governments contribute a fixed share or fee towards the operations and shared infrastructure similar to the way Japanese government is currently partnering with the United Nations Development Program (UNDP) to support the GHIT Fund and Korean government is partnering with International Vaccine Initiative (IVI) to process its contributions to the RIGHT Fund.

The Alliance develops relevant shared agreements with anchor partner collaborations with organizations such as EDCTP and Unitaid.

As appropriate, the individual initiatives explore how to leverage each other’s global networks and the value and opportunity for formal joint ventures where they are investing in similar or complementary industries and technologies.