

**United Nations Development Programme
Global Project Document**

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)

Expected Output(s): The Global Health Innovative Technology Fund (GHIT) funding of partnerships between the Japanese research organisations and international entities for the development of new global health technologies for TB, Malaria, NTDs and other diseases for patients and citizens of LMICs.

Implementing Partner: The Global Health Innovative Technology Fund (GHIT)

Brief Description

There is a significant gap in the global health sector between 1) the development of new global health technologies for Tuberculosis (TB), Malaria, Neglected Tropical Diseases (NTDs), and other diseases, and 2) the capacity for access and delivery of new global health technologies for TB, Malaria, NTDs, and other diseases in low and middle-income countries (LMICs). This gap is significant as there is a strong reciprocal relationship between health and development: health shapes development and development shapes health. Public-Private Partnerships (PPPs) offer a new means to address this gap in the global health 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. Private sector entities, including pharmaceutical companies and the Bill & Melinda Gates Foundation (BMGF), are now asking multilaterals to participate in PPPs to help bridge this gap between new drug development, and the access and delivery of these new products to LMICs.

In its commitment to achieving the MDGs, and responding to a request from the Government of Japan (GOJ), UNDP will collaborate with the Global Healthcare Innovation Technology Fund (GHIT), a new and unique Japanese PPP, to develop and deliver new global health technologies for TB, Malaria, NTDs, and other diseases. This Project Document addresses UNDP's support of GHIT's funding for the research and development (R&D) of new global health technologies TB, Malaria, NTDs, and other diseases for patients and citizens of LMICs. The separate but interlinked UNDP Project Document on "Building Capacity for Access and Delivery of New Global Health Technologies for TB, Malaria, NTDs and other Diseases in LMICs" complements this project.

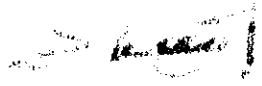
Programme Period:	2013-2017	Total resources required	\$10,920,000
Key Result Area (Strategic Plan)	HIV and Health	Total allocated resources:	\$10,920,000
Atlas Project ID:	00074638	• Regular	0
(UNDP1)		• Other: \$10,920,000	
Start date:	April 2013	o Government of Japan	
End Date	March 2017	Unfunded budget:	0
PAC Meeting Date	23 April 2013	In-kind Contributions	0
Management Arrangements	NGO-IMP		



Agreed by (UNDP): Magdy Martinez-Solímán
Deputy Assistant Administrator and Deputy Director
Bureau for Development Policy

ACRONYMS

BDP	Bureau of Development Policy
LMICs	Low and Middle Income Countries
MDG	Millennium Development Goal
MoFA	Japanese Ministry of Foreign Affairs
NTDs	Neglected Tropical Diseases
GHIT	Global Health Innovative Technology Fund
GOJ	Government of Japan
PATH	Programme for Appropriate Technologies in Health
PDP	Product Development Partnership
PPP	Public Private Partnership
RFP	Request for Proposals
TB	Tuberculosis
UNDP	United Nations Development Programme
WHO	World Health Organization



I. Situation Analysis

A. The Inequities of R&D, and Delivery, of new Products for Global Disease

HIV, malaria, tuberculosis and other epidemics continue to devastate communities throughout the developing world. According to the latest WHO published data in 2012, infectious (including parasitic) diseases were together responsible for the death of more than 8.7 million people worldwide in 2008. These epidemics are massive in numbers with 34 million people living with HIV, 12 million with TB, and half the world's population at risk of malaria.¹ The prevalence of NTDs, endemic in 149 countries, also remains high:

- Schistosomiasis: At least 230 million people require treatment every year. Schistosomiasis transmission has been documented in 77 countries.
- Chagas: An estimated 10 million people are infected with *Trypanosoma cruzi* (the parasite that causes Chagas disease) worldwide, mostly in Latin America.
- Dengue: Incidence grown dramatically in recent decades. Over 2.5 billion people – over 40% of the world's population – are now at risk from dengue. WHO currently estimates there may be 50–100 million dengue infections worldwide every year.
- Leprosy: Affected 182 000 people, mainly in Asia and Africa, at the beginning of 2012, with approximately 219 000 new cases reported during 2011.

**In the context of this Project Document it should be noted that the near eradication of Dracunculiasis (guinea-worm disease) is a result of a private-public partnership between The Carter Center, CDC, WHO, and UNICEF. As of 2011, the annual incidence of the disease has decreased by more than 99% compared to the mid-1980s. (Data from WHO NTDs Report, 2011)*

The majority of deaths caused by infectious disease are of poor people living in low and middle income countries (LMIC), with many occurring in children under five years of age. Africa, with 43 malaria-endemic countries, accounts for the majority of estimated malaria cases (78%) and deaths (91%), but only about 12% of the world's population. South-East Asia, with 10 malaria-endemic countries, accounts for 28 million or 13% of the cases world-wide.²

With these pandemics still prevalent, it is certain that many countries will not meet the MDG targets and much remains to be done beyond 2015, particularly in the lowest income countries, sub-Saharan Africa and South Asia. Part the reason for this lack of progress stems from a failure to reach the most vulnerable populations. A recent assessment of the Post 2015 UN agenda cites the failure of economic development to provide equitable benefits.³ New solutions for the current MDGs, and beyond, must address the inequities in access and delivery of investments for global health.

These inequities prevalent in economic development also persist in the research and development of new products for global disease. Globally, only 10 percent of the world's funds for health research are applied to the study of diseases in developing countries, where 90 percent of the world's preventable deaths occur.⁴ Tropical diseases and tuberculosis account for 12 percent of the global disease burden, yet only 1.3 percent of 1,556 new medicines developed during 1975-2004 were used for treatment of these diseases.⁵ The 2012 MDG Gap Task Force Report also called for increased investment in R&D of new medicines. These costs are significant, however. According to private sector sources, the cost of developing a new medicine from pre-clinical through Phase III is US \$150 million.⁶ To meet these R&D funding needs, and with health tied directly to economic

¹TDR: Global Report for Research on Infectious Diseases and Poverty, 2012.

² Kaiser Family Foundation, Report on Global Health, 2012.

³ UN System Task Team on the Post-2015 UN Development Agenda. 4.2.2013

⁴ MDG Gap Task Force Report: The Global Partnership for Development: Making Rhetoric a Reality (2012).

⁵ PDP Support of Country Decision Making: a discussion paper. W. Wells (TB Alliance), A. Brooks (PATH). October 2012

⁶ Japan's Global Health Policy 2011-2015, Ministry of Foreign Affairs of Japan October 2012.

development, government intervention in the development and delivery of new global health technologies, remains an essential piece of foreign aid.

B. The Global Health Innovative Technology Fund (GHIT)

Japan is a world leader in technology innovation and R&D spending. For example, Japan spends over \$240 billion in R&D overall with \$170 billion within the private sector, and is second to the US in the number of new patents filed internationally. Despite being a leader in R&D globally, however, the Japanese pharmaceutical industry has not as yet participated in developing global health technologies in Japan.

Responding to the need for new global health technologies and the lack of participation by the Japanese pharmaceutical industry, The Government of Japan's Global Health Policy, 2011-2015, calls for a "new approach" or innovation. The Government of Japan (GOJ) directives ask that Japanese government and pharmaceutical industry reach out to "build strategic partnerships with international and domestic stakeholders including UN agencies, other multilateral organizations, NGOs private-sector entities, and academic institutions.⁷ In keeping, the Global Health Policy Division was established in 2011 in the Ministry of Foreign Affairs' (MoFA) International Cooperation Bureau "to strengthen Japan's ability to achieve the MDGs, in the health sector in particular".

In keeping, the GOJ is working with the Japanese research organisations and the BMGF to launch a new initiative: the Global Health Innovation Technology Fund, or GHIT. As a non-profit organization, the GHIT articles of incorporation state that "*The purpose of the association shall be to engage exclusively in activities for the promotion and support of scientific research in the public interest and specifically for the research and development and delivery of medical products and technology for developing countries, and through these activities, to deliver Japanese technologies to the patients and citizens of developing countries making international contributions and as well as rejuvenating innovations in the medical products and technology research and development field*"⁸ As a Public Private Partnership (PPP), GHIT will use funds from the GOJ, the Japanese pharmaceutical industry, and BMGF to leverage the technologies from the Japanese pharmaceutical Industry for global health by supporting partnerships with international entities, Product Development Partnerships (PDPs) and academia for developing new global health technologies for TB, Malaria, NTDs, and other diseases for patients and citizens of LMIC. GHIT, with its mandate reflecting MDG8.E, will support partnerships between Japanese research organisations and global PDPs or academia to provide affordable essential health to LMIC on a sustainable basis.

For the purpose of full clarification, GHIT will fund only partnerships between Japanese research organisations and international entities:

Article 4 (Business for Public Interest Purposes)

The association shall be engaged in the following activities to achieve the purpose in the preceding Article.

- (i) Promotion and support of strategic alliances with institutions, etc. which are engaged in the research and development of medical products and technology for developing countries.
- (ii) Promotion activities, including aid request to promote the business provided in the preceding paragraph.
- (iii) Information exchange, liaison and coordination and cooperation with affiliated organizations, international institutions,
- (iv) Activities incidental or related to any of the foregoing items.

Therefore, GHIT will not fund grant applications that are only from Japanese entities.

C. UNDP's commitment to the MDGs:

⁷ Japan's Global Health Policy 2011-2015, Ministry of Foreign Affairs of Japan 10.2102.

⁸ General Incorporated Association [Global Health Innovative Technology Fund (Global Health Gijyutsu Shnkou Kikin)] Articles of Incorporation. Chapter 1 - General Rules: Article 3 (Purpose).

UNDP is committed to working with partners to achieve the MDGs. Within the MDGs, “MDG 8.E” specifically addresses the sector gap in R&D funding for new global health technologies for global disease and their availability: “In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries”. To indicate success of MDG 8.E, countries must show “a proportion of population with access to affordable essential drugs on a sustainable basis”.⁹ Taken in two parts, MDG 8.E involves 1) cooperating with pharmaceutical companies to develop affordable essential drugs; and 2) supporting the access of these drugs in developing countries. As per the indicator, this access to target populations needs to be sustainable. To fully support MDG 8.E, UNDP must partner with other organizations, as the work involves cooperating with pharmaceutical companies on R&D of global health technologies that is not in UNDP’s mandate. As shown with its strong partnership with the Global Fund to Fight AIDS, TB, and Malaria, UNDP is well positioned and has the capacity to be a leader in partnering with global health organizations to help define and support the delivery of global health products in LMICs.

Given this precipitous juncture in the history of global health, with epidemics continuing to jeopardize the economic development of LMICs; the inadequate amount of spending on R&D to fight these diseases; and the inequitable distribution of new solutions for health, GHIT offers a unique and innovative solution. As a PPP, GHIT will leverage the considerable resources of Japanese research organizations with the global capacity of the public sector, to develop and deliver new products for global disease to developing countries. In keeping, UNDP will assist GHIT in assessing its R&D portfolio in regards to access and delivery. Engaging LMICs in the R&D process of new global health technologies for infectious diseases provides a unique opportunity for the target populations to advise on the viability of access and delivery in the early, middle and late stages of the product development cycle. This advisory role will assist in ensuring that when new products for infectious disease reach Phase IV, or market readiness, they will be viable for delivery to LMICs.

UNDP’s role in providing access and delivery of these new global health technologies, as described in the Project Document on “Building Capacity for Access and Delivery of New Global Health Technologies for TB, Malaria, NTDs, and other Diseases in LMICs” completes the full stages of product development and subsequent delivery, essential for the achievement of the key MDGs such as MDG 8e.¹⁰ The two LMICs identified for capacity building will be chosen by UNDP and the Project Steering Committee. Selection will be based on epidemiological data and specific burden of disease plus further market analysis in regards to access and delivery. This may include political stability, regional considerations, and particular conditions affecting receptive infrastructure for capacity building.

⁹ MDG Gap Task Force Report: The Global Partnership for Development: Making Rhetoric a Reality (2012).

¹⁰ Ibid MDG Gap Taskforce Report.

II. Strategy

A. Strategic Direction

UNDP, as set forth in its Strategic Plan (2008-2013)¹¹, is committed to ending global pandemics such as HIV/AIDS, TB, Malaria and NTDs. Infectious diseases remain key agents of the debilitating poverty that UNDP, with its mandate of empowering lives and building resilient nations, is working to overcome. Stepping up research on global disease and products to fight them will have an enormous impact on efforts to lift people out of poverty.

UNDP's core focus on reducing poverty and achieving the MDGs, including a response to global pandemics, is at the core of its mandate supported by a strong emphasis on capacity development for LMICs. As articulated in the Action Plan for the UNDP Strategic Plan, UNDP's actions for capacity development should include:

- Harnessing and strengthening UNDPs global knowledge network and advisory capabilities to support country level transformations and quality program interventions.
- Cultivating and extending strategic partnerships that facilitate transformative knowledge transfers, both across the South and between the North and the South.
- Leveraging UNDPs global presence to connect partners, knowledge and stakeholders.

Likewise, UNDP's Corporate Strategy on HIV, Health and Development, 2012-2013, states:

*UNDP has an important role in supporting health outcomes by helping countries to address the social, cultural and economic determinants of health, in partnership with the UN system and other organizations. This is done through UNDP's core work in strengthening governance, institutions and management capacity and improving aid coordination and effectiveness. UNDP also contributes through its coordinating and convening role in bringing together multiple partners and resources at national and local levels.*¹²

UNDP must bring together its knowledge networks and advisory capabilities in new strategic partnerships, in order to build the capacity in LMICs to reach the MDGs raising the health levels of populations thereby assisting them out of poverty. But, as in the GOJ's health strategy, UNDP's Strategic Plan, and UNDP's Corporate Strategy on HIV, Health and Development, UNDP must engage in innovative partnerships within the public and private sectors to stop the pandemics of infectious disease.

B. Public Private Partnerships

PPPs offer an innovative means to bridge the sectoral chasm between research and development, and access and delivery of new global health technologies to LMICs. PPPs combine private sector research and development, with public sector health policy and capacity building efforts within developing countries. As stated in a recent WHO report, PPPs for health can range from small, single-product collaborations with industry to large entities hosted in United Nations agencies or private not-for-profit organizations. PPPs can serve to develop and distribute new health products; strengthen health services; educate the public; and improve product quality or regulation.

With PPPs, public agencies clearly benefit from working in collaboration with the private sector in areas where the public sector lacks expertise and experience, e.g. in product development, production process development, manufacturing, marketing and distribution. Likewise, the private sector is realizing that they are not able to access or deliver new health technologies to developing countries and populations for which they were developed, without the assistance of large public partners. Combining the strengths of the private sector in R&D

¹¹ UNDP Strategic Plan 2008 – 2013. Accelerating Global Progress on Human Development.

¹² UNDP (2012) Strategy Note. HIV, Health and Development 2012-2013.

with the public sector in access and delivery can assist developing nations to improve the health of their populations.

UNDP is committed to innovative partnerships with PPPs given the critical needs of the global health sector. A combination of the private sector's capacity in health research and development, with the public sectors work in health policy and capacity building for access and delivery offers an innovative and unique strategy for achieving the MDGs.

PPPs also offer solutions for health financing to ensure the access and delivery of global health products. Within this UNDP partnership strategy, there is a clear intent from both Japanese public and private sector partners to make available new health technologies for LMICs.

C. GHIT: A Unique Solution

GHIT

The Global Health Innovative Technology Fund, GHIT, offers a unique solution to the critical needs of global health by its strategy of combining equitable R&D of new global health technologies for HIV/AIDS, TB, Malaria, NTDs and other diseases, combined with its commitment to deliver these products to LIMCs. As stated in the articles of incorporation:

"The purpose of the association shall be to engage exclusively in activities for the promotion and support of scientific research in the public interest and specifically for the research and development and delivery of medical products and technology for developing countries, and through these activities, to deliver Japanese technologies to the patients and citizens of developing countries making international contributions and as well as rejuvenating innovations in the medical products and technology research and development field."

This innovative business strategy addresses the sectoral need of increasing R&D spending for global diseases, while simultaneously addressing the viability of their delivery to developing countries, or the populations for which they were intended. Likewise, GHIT serves to initiate engagement of Japanese research organizations to develop products for global health, in Japan. Private companies and other Japanese research entities, will only qualify for GHIT funding if they partner with an international organization already engaged in developing products for global disease. This ensures that products will be developed efficiently, leveraging the knowledge of Japanese research organizations with international PDPs, or other development entities.

In responding to the inequities of delivery of global health solutions, as given in recent analysis of the state of the MDGs, GHIT's partnership with UNDP will ensure the participation of LIMCs in the development and delivery of new products for their constituencies. This will indeed differentiate GHIT's work in the global health arena distinguishing the investment by the GOJ and the work of UNDP.

III. Results and Resources Framework

<p>Intended Outcome: Research and development of new global health technologies for TB, Malaria, NTDs and other diseases for patients and citizens of LMICs.</p> <p>Outcome indicators: Funded partnerships between Japanese research organizations and international research organization for the research and/or development of global health technologies for TB, Malaria, NTDs and other diseases for patients and citizens of LMICs.</p> <p>Applicable Key Result Area (from 2008-11 Strategic Plan): Achieving MDG8.E: "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries."</p> <p>Partnership Strategy: GHIT is a grant making PPP funding partnerships Japanese research organizations and international research organization for the research and/or development of global health technologies for TB, Malaria, NTDs and other diseases for patients and citizens of LMICs.</p> <p>Project title: GHIT: Research and Development of new global health technologies for TB, Malaria, NTDs and other diseases for patients and citizens of LMICs.</p>				
INTENDED OUTPUTS	OUTPUT TARGETS FOR (YEARS)	INDICATIVE ACTIVITIES	RESPONSIBLE PARTIES	INPUTS
<p>Output 1: Support of the discovery and development of new global health technologies for TB, Malaria and NTDs, and other diseases endemic to LMICs.</p>	<p>Year One Funding of partnership(s) between Japanese research organizations and international research organization for the research and/or development of global health technologies for TB, Malaria, NTDs and other diseases.</p>	<p>Activity Result Year One Solicit, review and funding of partnerships between Japanese research organizations and international research organization for the research and/or development of global health technologies for TB, Malaria, NTDs and other diseases.</p> <p>Actions Year One:</p> <ul style="list-style-type: none"> • Issue Request for Proposal and receive grant applications. • Review and selection of grantees. • Disbursement of funds to grantees. 	<p>GHIT and its grantees</p>	<p>\$10,920,000 (equivalent of JPY 1.05 billion, based on UN Rate 15 March)</p>

IV. ANNUAL WORK PLAN 2013-2017

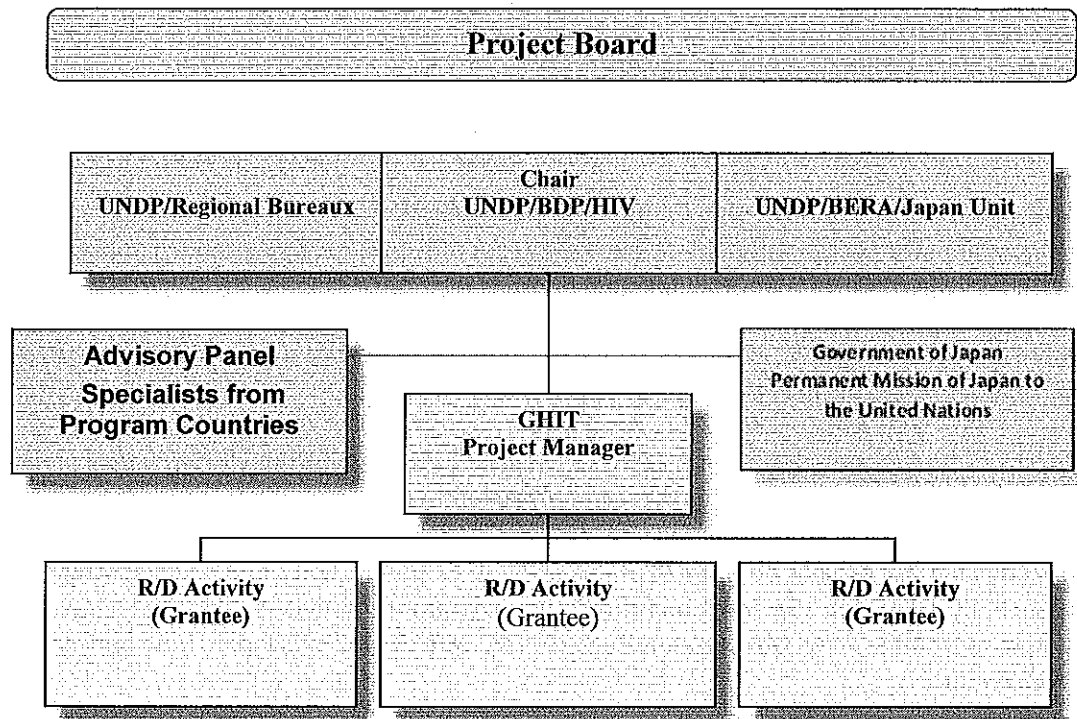
Year: 2013

EXPECTED OUTPUTS	PLANNED ACTIVITIES <i>List activity results and associated actions</i>	TIMEFRAME				RESPONSIBLE PARTY	PLANNED BUDGET		Amount
		Q1	Q2	Q3	Q4		Funding Source	Budget Description	
Output 1 Support of the discovery, development of new global health technologies for TB, Malaria and NTDs, and other diseases endemic to LMICs.	Activity Result Year One Solicit, review and funding of partnerships between Japanese research organizations and international research organization for the research and/or development of global health technologies for TB, Malaria, NTDs and other diseases. Actions Year One: <ul style="list-style-type: none"> • Issue Request for Proposal and receive grant applications. • Review and selection of grantees. • Disbursement of funds to grantees. 		X		X	GHIT and its grantees	Government of Japan	Grants	\$5,460,000

Year: 2014

EXPECTED OUTPUTS	PLANNED ACTIVITIES <i>List activity results and associated actions</i>	TIMEFRAME				RESPONSIBLE PARTY	PLANNED BUDGET	
		Q1	Q2	Q3	Q4		Funding Source	Budget Description Amount
Output 1 Support of the discovery, development of new global health technologies for TB, Malaria and NTDs, and other diseases endemic to LMICs.	Activity Result Year One Solicit, review and funding of partnerships between Japanese research organizations and international research organization for the research and/or development of global health technologies for TB, Malaria, NTDs and other diseases. Actions Year One: <ul style="list-style-type: none"> • Issue Request for Proposal and receive grant applications. • Review and selection of grantees. • Disbursement of funds to grantees. 		X		X	GHIT and its grantees	Government of Japan	\$5,460,000
PROJECT TOTAL								\$10,920,000

V. MANAGEMENT ARRANGEMENTS



Note: Number of R/D activities is not defined. These R/D activities in the chart show only relationships with GHIT and there are outside of the Project Board.

▪ Project Implementation Modality

This project will be implemented under NGO implementation modality. The project activities will be done by GHIT based on the Project Cooperation Agreement (PCA) between UNDP and GHIT. Results-based management and operational, practical and targeted coordination are the main management arrangements followed under this project. In line with UNDP prevailing rules and regulations and on the basis of indicators and required capacities, GHIT will be the responsible NGO for the overall accountability, management and administration of the project. GHIT will designate a Project Manager and mobilize other support personnel as appropriate to implement the project under the framework of PCA. PCA will be prepared and signed by UNDP and GHIT year by year for the period 5 years from April 2013 to March 2017.

▪ Roles and responsibilities of Project Board

Project Board will provide policy guidance and monitor the performance (timely implementation of all components) of the project, review progress on a periodic basis in terms of the delivery of project results and benefits, approve progress reports and final completion report, managing risks and ensure that project milestones are managed and completed. It provides guidance on matters concerning overall project issues as raised by the Project Manager (GHIT) and UNDP's assigned staff. It will be composed of:

Members will include:

- The BDP HIV, Health and Development Group representative (Chair);
- The BERA/RPC representative;

- The representatives from Regional Bureaux which will be responsible for the programme countries of the access and delivery project;
- Representatives from Ministry of Foreign Affairs of Japan/Permanent Mission of Japan to the United Nations (as the donor of the Fund for the project)
- Representatives from GHIT
- Advisory Panel (specialists from program countries)

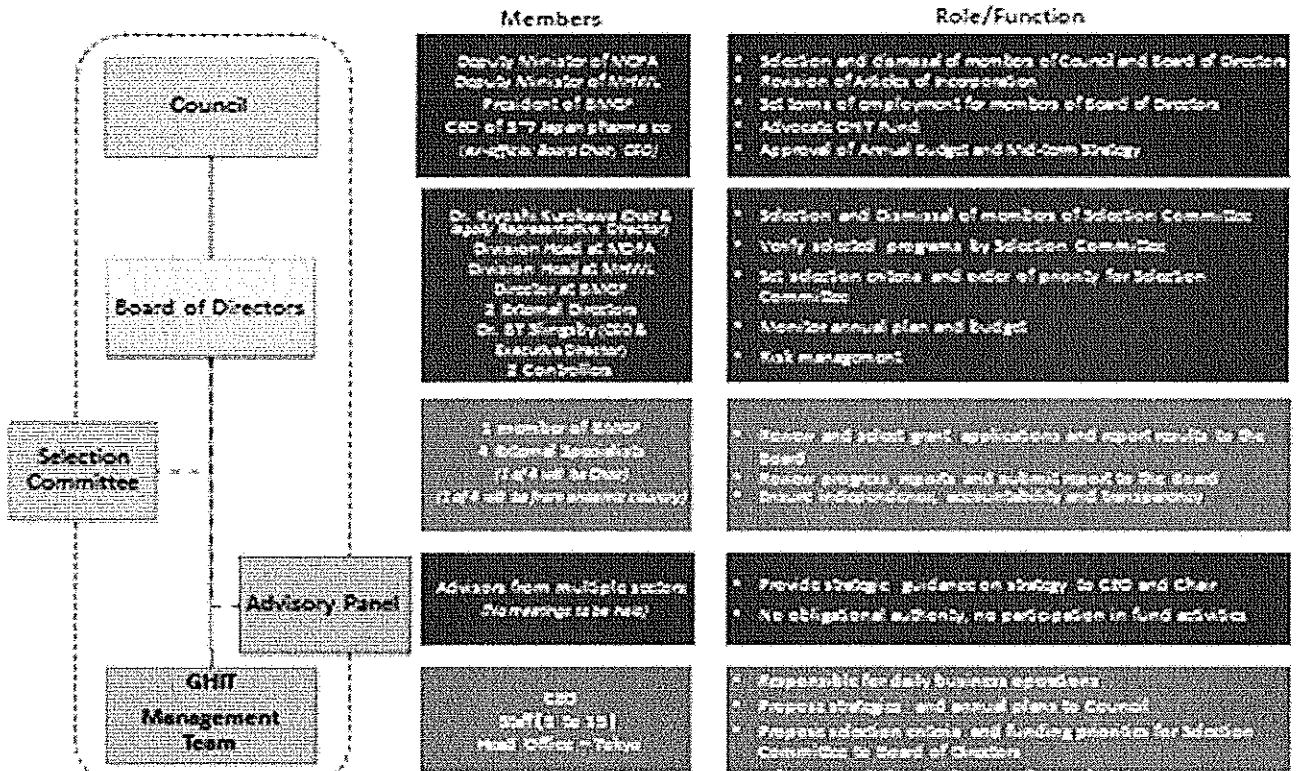
Additional members may be invited at the discretion of the Board.

The Project Board will review and appraise the Component's Annual Work Plans and reports, commission evaluations, and make revisions to the component as necessary. For the purposes of proper cooperation with GHIT, the BDP representative will serve as chair, the Regional Bureaux which are responsible of program countries of 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 which is responsible of the Japan-UNDP Partnership Fund will participate in the Project Board as project stakeholders from UNDP.

Programme Advisor (P-5) and Programme Specialist (P-3) based in BDP will be responsible for providing support to the two interlinked projects "GHIT: Research and Development of New Medicines for NTDs, TB, Malaria and other Diseases" and "Building Capacity for Access and Delivery of New Medicines for NTDs, TB, Malaria and other Diseases". They are responsible for project delivery by managing the PCA with GHIT and coordinating with the Project Manager assigned by GHIT for the implementation of programme activities, financial management, knowledge exchange and reporting. They will communicate closely with BERA/RPC/Japan Unit and concerned Regional Bureaux as appropriate.

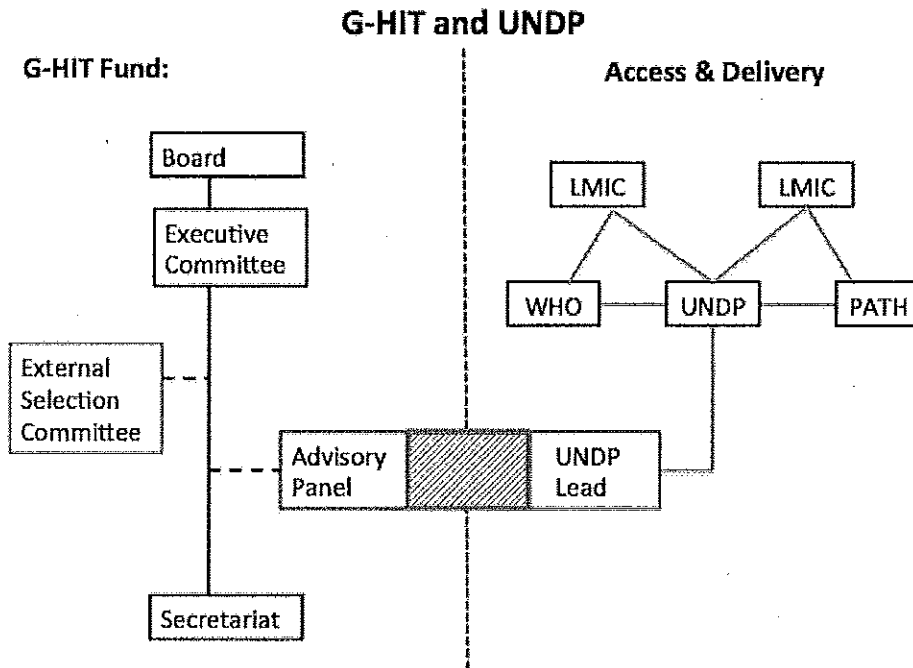
The project "GHIT: Research and Development of New Global Health Technologies for TB, Malaria, NTDs, and other Diseases for Patients and Citizens of LMICs" is going to be implemented by UNDP under the Programme Cooperation Framework (PCA). GHIT is a non-profitable organization established in Japan with the purpose of the association shall be to engage exclusively in activities for the promotion and support of scientific research in the public interest and specifically for the research and development and delivery of medical products and technology for developing countries, and through these activities, to deliver Japanese technologies to the patients and citizens of developing countries making international contributions and as well as rejuvenating innovations in the medical products and technology research and development field. GHIT has its governance structure as in the below chart.

Global Health Innovative Technology Fund (GHIT Fund)



* Number of meetings per year: Council = 1, Board of Directors = 4, Selection Committee = 2, Advisory Panel = none

UNDP, working with WHO, PATH and other relevant technical partners, will also collaborate with GHIT, through a complementary project “Building Capacity for Access and Delivery of New Global Health Technologies for TB, Malaria, NTDs, and other Diseases in LMICs”. The main elements of this project are 1) capacity building on access and delivery in 2 LMICs, and 2) access and delivery advisory services via GHIT’s Advisory Panel and GHIT management. Therefore, UNDP will have a role in the R&D of new global health technologies by assessing their viability for access and delivery, as well as in supporting their access and delivery in LMICs. The chart below indicates the relationship between UNDP and GHIT.



Visibility

GHIT will make every effort to identify UNDP and the Government of Japan as the partners and disseminate information about this project program whenever possible. Material depicting the collaborating partners’ logo will be prominently displayed on all possible occasions.

VI. MONITORING FRAMEWORK AND EVALUATION

In accordance with the programming policies and procedures outlined in the UNDP User Guide, the project will be monitored through the following:

1. Annual Report:

- GHIT shall provide UNDP with an annual report on the progress, activities, achievements and results of the Project. This annual report shall be prepared by the Project Manager and shared with the Project Board. As minimum requirement, the Annual Review Report shall consist of a summary of results achieved against pre-defined annual targets at the output level.
- Annual Project Review. Based on the above report, an annual project review by UNDP shall be conducted during the fourth quarter of the year or soon after, to assess the performance of the project and appraise the Annual Work Plan (AWP) for the following year. In the last year, this review will be a final assessment. This review is driven by the Project Board and may involve other stakeholders as required. It shall focus on the extent to which progress is being made towards outputs, and that these remain aligned to appropriate outcomes.

2. Financial reporting will be quarterly:

(a) GHIT prepares a financial report and submits it to the UNDP responsible official no later than 30 days after the end of each quarter in English.

(b) The purpose of the financial report to list the disbursements incurred by budgetary component on a quarterly basis, and to reconcile outstanding advances and foreign exchange loss or gain during the quarter.

(c) The financial report has been designed to reflect the transactions of a project on a cash basis. For this reason, un-liquidated obligations or commitments should not be reported to UNDP, i.e., the reports should be prepared on a "cash basis", not on an accrual basis, and thus will include only disbursements made by GHIT and not commitments. However, GHIT shall provide an indication when submitting reports as to the level of un-liquidated obligations or commitments, for budgetary purposes;

(d) The financial report contains information that forms the basis of a periodic financial review and its timely submission is a prerequisite to the continuing funding of the Project. Unless the Financial Report is received, the UNDP responsible official will not act upon requests for advances of funds from UNDP;

(e) Any refund received by GHIT from a supplier should be reflected on the financial report as a reduction of disbursements on the component to which it relates.

3. Final Report:

Within two months of the completion of the Project or of the termination of the present Agreement, GHIT shall submit a final report on the Project activities and include a final financial report on the use of UNDP funds, as well as an inventory of supplies and equipment.

Audit

- UNDP may conduct audit on this project. GHIT shall be requested to submit to the UNDP responsible official a certified annual financial statement on the status of funds advanced by UNDP. The Project will be audited at least once during its lifetime but may be audited annually, as will be reflected in the annual audit plan prepared by

UNDP Headquarters (Office of Audit and Performance Review) in consultation with the Parties to the Project. The audit shall be carried out by the auditors of the GHIT or by a qualified audit firm, which will produce an audit report and certify the financial statement (refer to the Article XII. Audit Requirements, PCA).

Quality Management for Project Activity Results

Replicate the table for each activity result of the AWP to provide information on monitoring actions based on quality criteria. To be completed during the process "Defining a Project" if the information is available. This table shall be further refined during the process "Initiating a Project"

OUTPUT 1:		
Activity Result 1 (Atlas Activity ID)	Short title to be used for Atlas Activity ID GHIT	Start Date: 1 April 2013 End Date: 31 March 2017
Purpose	What is the purpose of the activity? Support of the discovery and development of new global health technologies for TB, Malaria and NTDs, and other diseases endemic to LMICs.	
Description	Planned actions to produce the activity result. <ul style="list-style-type: none"> • Issue Request for Proposal and receive grant applications. • Review and selection of grantees • Disbursement of funds to grantees. 	
Quality Criteria How/with what indicators the quality of the activity result will be measured?	Quality Method Means of verification. What method will be used to determine if quality criteria has been met?	Date of Assessment When will the assessment of quality be performed?
Grant Proposals are received.	# of grant proposals received	March 2014
Grant Proposals are reviewed and selected.	# of grant proposals reviewed and selected against objective selection criteria.	March 2014
Funds are disbursed to grantees.	# of agreements signed between GHIT and grantees. Amount of funds disbursed to grantees.	March 2014

VII. LEGAL CONTEXT

REGIONAL AND GLOBAL PROJECTS

This project forms part of an overall programmatic framework under which several separate associated country level activities will be implemented. When assistance and support services are provided from this Project to the associated country level activities, this document shall be the "Project Document" instrument referred to in: (i) the respective signed SBAs for the specific countries; or (ii) in the Supplemental Provisions attached to the Project Document in cases where the recipient country has not signed an SBA with UNDP, attached hereto and forming an integral part hereof.

This project will be executed by the Global Health Innovation Technology Fund (GHIT) in accordance with its financial regulations, rules, practices and procedures only to the extent that they do not contravene the principles of the Financial Regulations and Rules of UNDP. Where the financial governance of an Implementing Partner does not provide the required guidance to ensure best value for money, fairness, integrity, transparency, and effective international competition, the financial governance of UNDP shall apply.

The responsibility for the safety and security of the Implementing Partner and its personnel and property, and of UNDP's property in the Implementing Partner's custody, rests with the Implementing Partner. The Implementing Partner shall: (a) put in place an appropriate security plan and maintain the security plan, taking into account the security situation in the country where the project is being carried; (b) assume all risks and liabilities related to the Implementing Partner's security, and the full implementation of the security plan. UNDP reserves the right to verify whether such a plan is in place, and to suggest modifications to the plan when necessary. Failure to maintain and implement an appropriate security plan as required hereunder shall be deemed a breach of this agreement.

The Implementing Partner agrees to undertake all reasonable efforts to ensure that none of the UNDP funds received pursuant to the Project Document are used to provide support to individuals or entities associated with terrorism and that the recipients of any amounts provided by UNDP hereunder do not appear on the list maintained by the Security Council Committee established pursuant to resolution 1267 (1999). The list can be accessed via http://www.un.org/sc/committees/1267/aq_sanctions_list.shtml. This provision must be included in all sub-contracts or sub-agreements entered into under this Project Document.

VIII. ANNEXES

Annex A: UNDP and GHIT Partnership Risk Analysis:

#	Risk Description	Category	Impact & Probability Level	Countermeasures / Management Response
1	Funding R&D is not in UNDP's mandate	Legal	High	Through an NGO partnership agreement (Programme Cooperation Agreement or CPA), UNDP will ask MoFA for indemnification against lawsuits.
2	It is not in UNDP's mandate to support R&D	Political	High	Reputational risk cannot be mitigated, even with legal protection.
3	UNDP serving on GHIT's Management Teams, such as the Board or Steering Committee	Legal	High	UNDP can not participate on any of GHIT's executive or management structures, either in a voting or non-voting role. UNDP advisory services will be provided through the Advisory Panel and GHIT management team only.
4	UNDP as a donor	Political	High. UNDP is not a donor, but rather a technical partner to build capacity in LMICs. Supporting R&D in high-income countries is not in UNDP's mandate.	UNDP role is seen as a bridge between R&D and Access. This needs to be fully documented and agreed upon by all parties. UNDP's primary role in GHIT is to be the voice of developing countries by providing advisory services to GHIT and capacity development to LMICs.
5	Unknown number of GHIT funded products will get through Phase III.	Operational	High. UNDP sources say that out of a portfolio of 25 products, 1-2 may actually get through Phase III.	Build capacity in 2 LMICs that can be used for potential GHIT supported products as well as existing products from global PDPs needing access and delivery. This also mitigates risk for MoFA.
6	High cost of bringing new global health technologies from pre-clinical to Phase IV	Financial	High. Estimated US \$150m per global health technology, from pre-clinical through Phase III. US \$500-\$1Billion to develop entire portfolio of 25 grantees, with 1-2 global health technologies reaching Phase IV. Source: Skyline Venture Capital and Synergenics, LLC. There is uncertainty about the level of funds GHIT has and if these funds are sufficient.	UNDP can build capacity in LMICs for access and delivery that will be utilized for product delivery by other PDPs. This funding for capacity building would mitigate risk in achieving targeted outcomes.
7	Agreement on Intellectual Property between UNDP and GHIT sub-grantees has not been settled.	Legal	High. UNDP needs to work within the framework of the legal context as described in Section VII.	UNDP is exploring viable options with its legal team.
8	GHIT is a new organization.	Operational	High. Not a proven entity. Organisational capacity is not established.	To be justified through capacity assessment process and with an undertaking/reference from the GOJ
9	LMICs do not have sufficient funding to purchase new medicines once introduced.	Operational	High. AMC has not worked. Need for other funding resources.	Access and delivery capacity building will include strengthening LMIC capacity in health financing and procurement. There is a clear intent from both public and private

#	Risk Description	Category	Impact & Probability Level	Countermeasures / Management Response
				sector partners (GOJ as well as GHIT and its private sector stakeholders) to make available new global health technologies for LMICs, (as documented on page 7).
10	New global health technologies developed are not affordable for LMICs.	Operational	High.	GHIT's Access Policy must reflect commitment to ensuring that new global health technologies are affordable for patients with the target diseases in LMICs.
11	GHIT External Selection Committee and Advisory Panel do not have sufficient representation of expertise in R & D as well access and delivery from endemic countries.	Political	Medium to high.	UNDP has suggested the names of individuals with the relevant expertise for the External Selection Committee and the Advisory Panel.

