

# Project Document Format for non-CPAP Countries or Projects outside a CPAP

## United Nations Development Programme Global Project Project Document

**Project Title/ID:** Building Capacity for Access and Delivery of New Global Health Technologies for Tuberculosis (TB), Malaria, Neglected Tropical Diseases (NTDs), and other Diseases in Low and Middle Income Countries (LMICs)/Project ID 00075333

**Expected Output(s):** By 2017, improve life chances and livelihood opportunities in LMICs through enhanced Government commitment to the MDGs, institutional support for achieving the MDGs and empowered community engagement in the achievement of the MDGs with a special focus on MDG8.E: "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries".

**Executing Entity:** PATH

**Implementing/Responsible Partners:** UNDP, WHO

### Brief Description

As given in the Project Document on GHIT, there are significant gaps in the global health sector regarding 1) new global health technology development for TB, Malaria, NTDs, and other diseases, and 2) capacity to deliver new global health technologies to LMICs. This need for sustainable capacity to deliver new global health technologies is indicated in MDG8.E: "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries". To indicate success of MDG8.E, countries must show "proportion of population with access to affordable essential drugs on a sustainable basis". This indicator of sustainability denotes that countries must have, or develop, the capacity for access and delivery of new global health technologies. Evidence suggests that LMICs currently lack this capacity in the areas of regulatory, legal, and policy frameworks, clinical trial monitoring, manufacturing, and delivery systems for the introduction of new global health technologies.

In responding to this lack of capacity, UNDP recognizes and supports the leadership of the World Health Organization (WHO) on issues of global health, and the role of key technical partners such as PATH, a leading health NGO, working on access and delivery. UNDP will work with these partners and other relevant technical partners to 1) provide advisory services to GHIT and, 2) build capacity in two LMICs to strengthen capacity in legal and policy frameworks; understanding of specific country needs for new global health technologies; training of clinical trial monitors; health financing; and pricing, supply and delivery systems. The outcome will be that GHIT receives the highest calibre of advisory services for access and delivery, and the necessary capacity in two LMICs for access and delivery of GHIT supported new global health technologies.

Programme Period:	2013-2017
Key Result Area (Strategic Plan)	HIV, TB and Malaria
Atlas Project ID:	75333
Start Date	April 2013
End Date	March 2017
PAC Meeting Date	23 April 2013
Management Arrangements	NGO-IMP

Total resources required	17,500,000
Total allocated resources:	_____
Regular	_____
Other:	_____
Third Party Cost Sharing from the Government of Japan	3,500,000
Unfunded budget:	14,000,000

Agreed by (UNDP):

  
Magdy Martinez-Soliman, Deputy Director, BDP

## 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

Evidence suggests that capacity in LMICs, for the access and delivery of new global health technologies for TB, Malaria, NTDs and other diseases, is weak. LMICs require capacity development in areas of legal, and policy frameworks; clinical trial monitoring; and pricing, supply, and delivery systems for the introduction of new global health technologies.<sup>1</sup> This need for sustainable capacity is critical to achieve the MDGs, such as MDG8.E: "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries." To indicate success of MDG8.E, countries must show "a proportion of population with access to affordable essential drugs on a sustainable basis."<sup>2</sup> This indicator of sustainability denotes that countries must have, or develop, the capacity for access and delivery of new global health technologies.

Recent interviews with lead Product Development Partnerships (PDPs) developing new global health technologies for TB, Malaria, NTDs, and other diseases, confirm that there is little capacity for access and delivery in LMICs. As shown below, PDPs are experiencing a lack of access to the markets for which their new products are intended.

"You run into a case of 'What if they build it, and they don't come?' There is a product pile up of regulatory requests collecting dust in national offices".

"We have all the drugs we need for Malaria. The problem is getting them delivered."

G. Jagoe, MMV, 12/12

"We depend on individual countries to manage Phase IV. As a result there is little oversight, and no global standards for product introduction."

A. Brooks, GAVI, 12/12

"I call the Introduction Phase the 'Valley of Death'. There is a critical funding and service gap at this phase of product development."

D. Hozumi, PATH, 12/12

The number of new global health technologies coming to market for TB, Malaria, and NTDs, and other diseases is also increasing. As with their support of the Japanese non-profit GHIT, the Bill and Melinda Gates Foundation (BMGF) also funds 15 Product Development Partnerships (PDPs) that manage a portfolio of projects worldwide for the development of new global health technologies and vaccines for TB, Malaria, NTDs, and other diseases endemic in LMICs. But public health impact will come only after adoption of health technologies into LMIC health systems.<sup>3</sup> This necessitates strengthening capacity for access and delivery in LMICs.

With the BMGF's PDP investment portfolio maturing, there is an increasing number of new global health technologies coming into Phase IV clinical trials, or introduction into a developing country's targeted population. MMV and DNDi, for example, each have six products in Phase IV clinical trials. But, not even the BMGF is taking the lead in bridging this gap between Research and Development (R&D) and Access and Delivery. As recently stated by a BMGF Senior program Officer of Product Development Strategy:

"Given the need, the BMGF will endorse the participation of multi-laterals in the access and delivery of new technologies to developing markets."

R. Lenington, BMGF 20/12

<sup>1</sup> Oxfam. Oxfam Briefing paper: Ending the R&D Crisis in Public Health: Promoting pro-poor medical innovation (2008).

<sup>2</sup> MDG Gap Task Force Report: The global Partnership for Development: Making Rhetoric a Reality (2012).

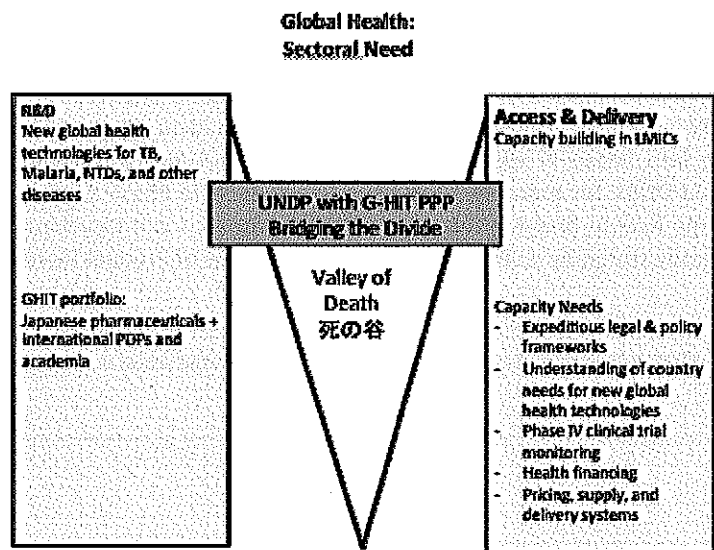
<sup>3</sup> PDP Support of Country Decision Making: A Discussion paper. W.Wells (TB Alliance), A. Brooks (PATH). October 2012.

Bridging this gap between R&D and Access and Delivery, requires innovative new partnerships between key stakeholders including UN agencies, PDPs, NGOs, the private sector and academia.

Responding to critical needs in the global health sector and in reaching the MDGs, the Government of Japan's Global Health Policy, 2011-2025, calls for a "new approach" or innovation in "building strategic partnerships with international and domestic stakeholders including UN agencies, other multilateral organizations, NGOs, private sector entities, and academic institutions."<sup>4</sup> In keeping, the Global Health Policy Division was established in 2011 in the Ministry of Foreign Affairs's (MoFA) International Cooperation Bureau "to strengthen Japan's ability to achieve the MDGs, in the health sector in particular."<sup>5</sup> The GOJ's engagement is particularly timely, given the maturation of the R&D sector producing new drugs for global diseases and the critical need for building capacity for their access and delivery in LMICs.

UNDP welcomes the Government of Japan's (GOJ) increased participation in the global health sector. As stated in the GHIT Project Document, with funding from the BMGF, The Japanese Pharmaceutical Industry, and the GOJ working with UNDP, GHIT will support partnerships of Japanese research and development entities with international organizations such as the PDPs. Thereby working with GHIT, UNDP can provide access and advisory services at all stages of product development: from pre-clinical to Phase IV, or from design to assisting the new global health technologies' adoption in LMICs. With WHO, PATH and other relevant technical partners, UNDP's work on access and delivery will complement the work of GHIT to support the development of new global health technologies so that they will be viable for use in LMICs. UNDP, working with WHO, PATH and other technical partners will strengthen capacity in two LMICs ensuring appropriate policy and regulatory frameworks; monitoring of Phase IV clinical trials; health financing; pricing, supply and delivery systems for access and delivery of these new global health technologies for TB, Malaria, NTDs, and other diseases.

UNDP's participation with GHIT, thereby offers a unique opportunity for UNDP to participate in an innovative PPP that can bridge the current chasm between R&D and Access and Delivery. In turn, GHIT will have the highest global calibre of resource to ensure adoption of their portfolio in LMICs, which is also part of GHIT's mission. Within this UNDP partnership strategy, there is also a clear intent from both Japanese public and private sector partners to make funding available for the purchase of new global health technologies in LMICs.



<sup>4</sup> Japan's Global Health Policy 2011-2015, Ministry of Foreign Affairs of Japan 10.2012.

<sup>5</sup> Ministry of Foreign Affairs Press Announcement, 2011.

## II. Strategy

UNDP, working with WHO, PATH and other technical partners, can provide the full range of technical skills necessary to build capacity in LMICs to ensure delivery of new global health technologies for TB, Malaria, NTD's, and other diseases. With its commitment to the MDGs, presence in 166 countries, strong track record in health and development issues, and strength in policy, operations, and capacity building, UNDP is well positioned to leverage its mandate and core strengths of providing technical advise to building capacity for the access and delivery of new global health technologies in LMICs. As with its work with the Global Fund to Fight AIDS, TB, and Malaria, where UNDP manages 12% of the Global Fund's portfolio, UNDP can leverage its core expertise in capacity development and its strength as a multilateral by providing regional and global oversight on multi-country initiatives.

UNDP supports WHO's leadership in global health. As United Nations based programmes, UNDP and WHO serve to compliment each other in setting policy and direction, and building the capacity necessary to deliver global health solutions. WHO's expertise in research, mapping, and understanding of diseases in LMICs is imperative for the access and delivery work of new global health technologies.

Likewise, PATH's mission is to foster new technologies for global diseases. With strong ties to the private sector, PATH adapts technologies from the wealthiest countries for use in LMICs. For this, PATH works on affordability and product design for ease of access and use by LMIC populations. PATH's work in LMICs includes capacity building for understanding of market size and demand, pricing, supply chain, and delivery. Other technical partners such as OECD, WIPO amongst others will also contribute to this initiative.

UNDP supports WHO's leadership in setting overall policy and direction; pre-qualification programme for new health products; support in the training of monitors for clinical trials; as well as ensuring that LMICs have the capacity to understand their role in accelerating access to a new health technology. PATH's understanding of product supply and demand, product valuation, and costing also provides critical skills in local supply and commercialization. UNDP, WHO and PATH's combined capabilities provide the full range of technical skills necessary to strengthen capacity in LMICs necessary for the adoption of new global health technologies and to achieve the MDGs.

For this project with the GOJ, UNDP will provide the following: 1) advisory services on access and delivery for the GHIT portfolio, and 2) technical and policy advise to strengthen capacity in two LMICs for the access and delivery of new global health technologies for TB, Malaria, NTD's, and other diseases. Working with WHO, PATH and other technical partners, UNDP as overall project manager is uniquely qualified to provide the following:

- 1) **Capacity building in LMICs:** To ensure that country capacity will be adequate for the access and delivery of GHIT portfolio products, UNDP will begin immediately to work with government, private sector and civil society in LMICs to strengthen capacity for the introduction of new global health technologies. UNDP and its partners will:
  1. Support strengthening of legal and policy frameworks, to expedite access and delivery of new global health technologies for TB, Malaria, NTDs, and other diseases.
  2. Build capacity on evaluation of epidemiological studies to understand country specific needs for new global health technologies, potential market size, and user perspectives.
  3. Strengthen health sector capacity in monitoring of Phase IV trials.
    - 4a. Strengthen capacity within LMICs to ensure the financing of new global health technologies.
    - 4b. Build capacity on consumerization to ensure that new global health technologies are priced appropriately, and supply meets population demand.
  5. Strengthen capacity of delivery systems including supply chain of new global health technologies for TB, Malaria, NTDs, and other diseases.

2. **Advisory Services to GHIT:** UNDP and its partners will provide robust reviews of all grant applications to determine if the proposed product is viable in terms of access and delivery. This advice will be completely neutral without any preference whatsoever to a particular product or geography.

The two recipient LMICs for capacity building will be chosen by UNDP and the Project Steering Group. 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.

### III. RESULTS AND RESOURCES FRAMEWORK

**Intended Outcome:** By 2017, Improve life chances and livelihood opportunities for all through enhanced Government commitment to the MDGs, institutional support for achieving the MDGs and empowered community engagement in the achievement of the MDGs with a special focus on MDG8.E: "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries".

**Outcome Indicators:**  
Greater capacity in two LMICs to ensure the access and delivery of new global health technologies for Neglected Tropical Diseases (NTDs), Tuberculosis (TB), Malaria and other diseases.

**Applicable Key Result Area (from 2008-11 Strategic Plan):** UNDP Operations B 61: As legislated by General Assembly resolutions 59/250 and 62/208, a more rigorous systematic approach to supporting capacity building and development to enhance UNDP assistance to the efforts of programme countries to achieve MDGs and support human development.

**Partnership Strategy:** UNDP will work with the World Health Organization (WHO), PATH, a leading NGO in health and other technical partners as appropriate. UNDP will serve as Project Manager, with WHO and PATH contributing complementary technical skills for a full range of capacity building activities.

Total budget amount: \$17.5 million for 5 years. The current annual workplan and budget is set up for the funds received from the donor in 2013.

**Project title and ID (ATLAS Award ID):** Building Capacity for Access and Delivery of New Global health technologies for NTDs, TB, Malaria, and other Diseases

INTENDED OUTPUTS	OUTPUT TARGETS FOR (YEARS)	INDICATIVE ACTIVITIES	RESPONSIBLE PARTIES	INPUTS
<p><b>Project Oversight</b></p> <p>Well articulated global project with operational business plan, partnership agreements, and resource mobilization for building access and delivery capacity in two LMICs.</p>	<p><b>Target Year 1:</b></p> <ul style="list-style-type: none"> <li>Strengthen strategic direction of project operations</li> <li>Build strong partner relationships</li> <li>Manage interface with donors</li> <li>Strengthen resource mobilization from multiple funders</li> <li>Manage efficient financial resources management</li> </ul>	<p><b>Activity Result Year 1:</b></p> <ul style="list-style-type: none"> <li>Robust Business Plan</li> <li>Partnership Agreements</li> <li>Well informed lead donor (GOJ)</li> <li>Grant applications to 2 additional donors</li> <li>Strong financial management, conforming to UNDP standards</li> </ul> <p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>Work with Steering Group – partners and LMICs- plus sector thought leaders and civil society, to develop a business and operational plan for global Access &amp; Delivery Project</li> <li>Work with partners, WHO, PATH and other technical partners, to establish partnership agreements</li> <li>Identify two potential new funders</li> <li>Develop and submit grant applications to these two funders</li> </ul>	UNDP	<p>Headquarters, New York:</p> <ul style="list-style-type: none"> <li>Director D1*</li> <li>Project Advisor, P5</li> <li>Project Specialist, P3</li> <li>Project Support, G6*</li> </ul> <p>*Staff not funded by GOJ</p>

		<ul style="list-style-type: none"> <li>• Establish systems for financial management and administration</li> <li>• Regular audits of Project funding</li> </ul>		
<p><b>Access and Delivery</b></p> <p><b>Output 1</b></p> <p>Support strengthening of legal and policy frameworks to expedite access and delivery of new global health technologies for NTDS, TB, Malaria, and other diseases.</p>	<p><b>Targets Year 1:</b></p> <ul style="list-style-type: none"> <li>• Establishing R&amp;D learning networks between countries and development partners</li> <li>• Developing stakeholder capacity on innovation models</li> <li>• Capacity development on IP, licensing, and enabling legal environment.</li> </ul> <p><b>Targets Year 2:</b></p> <ul style="list-style-type: none"> <li>• Technical assistance to public sector R&amp;D organizations in country and region to develop R&amp;D capacity</li> <li>• Capacity development on negotiating technology transfer agreements</li> </ul>	<p><b>Year 1:</b></p> <p><b>Activity Result</b></p> <ul style="list-style-type: none"> <li>• Networks between eligible R&amp;D learning centres and partners established</li> <li>• Capacity developed on innovation models, intellectual property and enabling legal environment</li> </ul> <p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>• Conducting desk and field research to identify eligible research centres in LMICs</li> <li>• Arranging meeting between eligible research centres in select African countries and partners</li> <li>• Trainings on various forms of innovation (from publications, data sharing, material transfer and patent licensing)</li> <li>• Establishing mechanisms and networks to ensure knowledge sharing, skills transfer, and promotion of communities of practice.</li> </ul> <p><b>Year 2:</b></p> <p><b>Activity Result</b></p> <ul style="list-style-type: none"> <li>• Capacity developed for government officials and research institutes to negotiate licensing and technology transfer agreements</li> </ul> <p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>• Trainings on IP management, development oriented licensing agreements and enabling legal environment to promote R&amp;D</li> <li>• Trainings between LMICs and developing partners on enabling legal and regulatory environment conducive to developing R&amp;D capacity</li> </ul>	<p>UNDP and relevant technical partners</p>	<p>P5 and P3, plus consultants, New York</p>



<p><b>Output 2</b></p> <p>Strengthened capacity on evaluation of epidemiological studies to understand country specific needs for new global health technologies, potential market size, and patient perspective.</p>	<p><b>Targets Year 1:</b></p> <ul style="list-style-type: none"> <li>Assisting countries to identify and review existing data to estimate the burden of disease.</li> <li>Identifying needs for additional evidence and/or country specific information needs.</li> <li>Assisting countries to develop a plan to address information needs. (This may include demonstration projects of the product in the country.)</li> <li>Identify product decision making process (in collaboration with Output 1).</li> </ul> <p><b>Year 2 and 3:</b></p> <ul style="list-style-type: none"> <li>Implementation of study plans</li> </ul> <p><b>Year 3 or 4:</b></p> <ul style="list-style-type: none"> <li>Assist countries for interpretation of the results of the study and facilitate the decision making and implementation planning.</li> <li>Strengthen the country's ability to develop an introduction and implementation plan of a new product.</li> </ul>	<p><b>Year 1:</b></p> <p><b>Activity Result</b></p> <ul style="list-style-type: none"> <li>Country data review and interpretation</li> <li>Country health systems assessment related to potential implementation of target products</li> <li>Demonstration projects of target products within country.</li> <li>Product specific national policy support.</li> </ul> <p><b>Actions</b></p> <ul style="list-style-type: none"> <li>Build capacity in data review and interpretation.</li> <li>Promote participation of women in decision making and activities</li> <li>Technical training in health systems assessment related to potential implementation of scenarios of target products.</li> <li>Strengthen capacity in identification of country specific data needs and ways to develop a study plan.</li> <li>Build capacity in design and implementation of market, epidemiological and/or cost studies.</li> <li>Technical assistance in design and implementation of demonstration projects for target products.</li> <li>Assist country's in developing product specific policy support.</li> </ul>	<p>WHO and PATH</p>	<p>tbd</p>
<p><b>Output 3</b></p> <p>Strengthened health sector capacity in monitoring of Phase IV trials for new global health technologies for TB, Malaria, NTDS, and other diseases.</p>	<p><b>Targets Year 1:</b></p> <ul style="list-style-type: none"> <li>Strengthening stakeholder capacity in the monitoring of Phase IV Clinical Trials</li> <li>Provision of regional or global coordination of trained monitors of Phase IV clinical trials</li> </ul>	<p><b>Activity Result:</b></p> <ul style="list-style-type: none"> <li>Capacity strengthened for monitoring of Phase IV clinical trials in two low or middle income countries</li> </ul> <p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>Development of Distance learning tools, modules specifically for the training of monitors for Phase IV clinical trials</li> <li>On the job training and mentoring</li> </ul>	<p>WHO and relevant technical partners</p>	<p>tbd</p>

<p><b>Output 4a</b></p> <p>Work with LMICs to ensure the financing for new global health technologies for TB, Malaria, NTDs, and other diseases.</p>	<p><b>Targets Year 1:</b></p> <ul style="list-style-type: none"> <li>• Landscaping of country capacity and options for funding of new global health technologies for TB, Malaria, NTDs and other diseases.</li> </ul>	<p><b>Activity Result</b></p> <ul style="list-style-type: none"> <li>• Situation analysis and capacity building needs assessment</li> <li>• Understanding of options for financing of new global health technologies for TB, Malaria, NTDs and other diseases.</li> </ul> <p><b>Actions</b></p> <ul style="list-style-type: none"> <li>• Technical assistance in developing situation analysis and capacity building needs assessment.</li> <li>• Technical assistance in review of financing options.</li> </ul>	<p>WHO and relevant technical partners</p>	<p>tbd</p>
<p><b>Output 4b</b></p> <p>Build capacity on consumerization ensuring that new global health technologies are priced appropriately, and supply meets population demand.</p>	<p><b>Targets Year 1:</b></p> <ul style="list-style-type: none"> <li>• Landscaping of population need and demand for new global health technologies.</li> </ul>	<p><b>Activity Result:</b></p> <ul style="list-style-type: none"> <li>• Capacity building in understanding of market size and demand</li> <li>• Understanding of pricing of new global health technologies given particular country conditions.</li> </ul> <p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>• Building capacity to develop demand forecasting for health products.</li> </ul> <p>Landscaping of population and purchasing ability for new global health technologies.</p>	<p>PATH</p>	<p>tbd</p>
<p><b>Output 5</b></p> <p>Strengthened capacity of delivery systems including supply chain of new global health technologies for TB, Malaria, NTDs and other diseases.</p>	<p><b>Targets Year 1:</b></p> <ul style="list-style-type: none"> <li>• Strengthening stakeholder capacity in strategic supply forecasting</li> <li>• Strengthening stakeholder capacity in local manufacturing Assessment</li> </ul> <p><b>Targets Year 2:</b></p> <ul style="list-style-type: none"> <li>• Strengthening capacity in distribution system readiness</li> </ul>	<p><b>Activity Result:</b></p> <ul style="list-style-type: none"> <li>• Strengthened capacity in evaluation of distribution system readiness.</li> <li>• Country readiness in manufacturing support and license.</li> </ul> <p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>• Provide technical assistance to determine distribution system readiness.</li> </ul>	<p>PATH</p>	<p>tbd</p>

<p><b>R&amp;D Advisory Services</b></p> <p><b>Output 6:</b> Regular and robust reviews of all grant applications to determine if the proposed product is viable in terms of access and delivery.</p>	<p><b>Target Year 1:</b></p> <ul style="list-style-type: none"> <li>• Review of grant applications as a response to GHIT's first Request for Proposals (RFP).</li> </ul> <p><b>Target Year 2:</b></p> <ul style="list-style-type: none"> <li>• Review of grant applications as a response to GHIT's second RFP.</li> <li>• Review of partnership products that have reached Phase IV in regards to access and delivery.</li> </ul>	<p><b>Activity Results Year 1:</b></p> <ul style="list-style-type: none"> <li>• All grant application to GHIT have been reviewed by UNDP and partners in regards to viability of access and delivery.</li> </ul> <p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>• Review first group of proposals within a 3-4 month period upon receipt from GHIT. All advice will be completely neutral without any preference whatsoever to a particular product or geography.</li> </ul> <p><b>Activity Results Year 2:</b></p> <ul style="list-style-type: none"> <li>• All grant application to GHIT's second round of funding have been reviewed by UNDP and partners in regards to viability of access and delivery.</li> <li>• If available, products in Phase III, IV have been reviewed in regards to country access and delivery.</li> </ul> <p><b>Actions</b></p> <ul style="list-style-type: none"> <li>• Review second group of proposals within a 3-4 month period upon receipt from GHIT. All advice will be completely neutral without any preference whatsoever to a particular product or geography.</li> <li>• Review of products in Phase III, IV by UNDP and partners in regards to country access and delivery.</li> </ul>	<p>UNDP and technical partners</p>	
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\*Results and Resources Framework will be reviewed and revised annually before the commencement of each year's activity.

**\*\* Project Staffing:**

**1. UNDP**

**Headquarters, New York:**  
Director, D1\* (30%)  
Project Advisor, P5 (100%)  
Project Specialist P3 (100%)  
Project Support G6\* (30%)  
Interim Consultant (100%)  
(\* Not funded by GOJ)

**2. WHO**

**Headquarters, Geneva:**  
Consultants (P4 @ \$330 per day for 284.5 days) = \$93,870  
Manager (20% P5 for 6 months) = \$34,200

**3. PATH**

**Headquarters, Seattle:**  
Consultants for Activity 4A: 40,000  
Consultants for Activity 4B: 21,000

**IV. AWP Budget Sheet (US\$):**

**For Year 2013 [1 April 2013 – 31 December 2013]**

EXPECTED OUTPUTS	PLANNED ACTIVITIES List activity results and associated actions	RESPONSIBLE PARTY		PLANNED BUDGET		
		Year		Funding Source	Budget Description	Amount
<p><b>Project Oversight</b> Well-articulated global project with operational business plan, partnership agreements, and resource mobilization for building access and delivery capacity in two LMICs</p>	<p><b>Activity Result</b></p> <ul style="list-style-type: none"> <li>▪ Strengthened strategic directions for project implementation</li> <li>▪ Strong partner relationships developed and built</li> </ul> <p><b>Action</b></p> <ul style="list-style-type: none"> <li>▪ Organize 3 Project Partners meetings for development, coordination and implementation of work plan</li> <li>▪ Organize 1 Advisory Group meeting</li> <li>▪ Develop and implement communications strategy</li> <li>▪ Develop monitoring and evaluation plan</li> <li>▪ Project management and coordination (incl. implement resource mobilization strategy)</li> </ul>	2013	UNDP	GOI	<ul style="list-style-type: none"> <li>▪ 1 Project Partners meeting [\$30,000]</li> <li>▪ Advisory Group meeting [\$50,000]</li> <li>▪ Communications consultant [\$20,000]</li> <li>▪ Project management and coordination [\$46,105]</li> </ul>	<b>\$146,105</b>

<p><b>Output 1</b> Support strengthening of legal and policy frameworks to expedite access and delivery of new global health technologies for NTDs, TB, Malaria, and other diseases.</p>	<p><b>Activity Result</b></p> <ul style="list-style-type: none"> <li>▪ R&amp;D learning networks established between target countries and development partners</li> <li>▪ Stakeholder capacity developed on innovation policy and models</li> <li>▪ Stakeholder capacity strengthened on IP, licensing negotiations and enabling legal environment</li> </ul> <p><b>Activity Action in Asia:</b></p> <ul style="list-style-type: none"> <li>▪ Conduct regional review of policy coherence (using the common research template as Africa)</li> <li>▪ Conduct review of domestic legal and policy environment in target countries</li> <li>▪ Establishment of national task force on integrating R&amp;D and access to affordable health technologies</li> <li>▪ Organize capacity building and training workshop(s) for patent examiners</li> </ul> <p><b>Activity Action in Africa:</b></p> <ul style="list-style-type: none"> <li>▪ Awareness-raising/advocacy at international public health events</li> <li>▪ Conduct a regional study on innovation and local pharmaceutical production in Africa</li> <li>▪ Organize a regional meeting to establish R&amp;D networks between select African countries</li> <li>▪ Organize 2 national capacity development trainings on innovation models, licensing and enabling legal/regulatory environments</li> </ul>	2013	UNDP	GOU	<ul style="list-style-type: none"> <li>▪ In-country consultant support in 2 target countries [\$60,000]</li> </ul> <p><b>Asia</b></p> <ul style="list-style-type: none"> <li>▪ Regional review on policy coherence [\$50,000]</li> <li>▪ National review of legal and policy environment in 2 target countries [\$50,000]</li> </ul> <p><b>Africa</b></p> <ul style="list-style-type: none"> <li>▪ Consultant support on Africa activities [\$20,000]</li> <li>▪ Regional study on innovation and pharmaceutical production [\$50,000]</li> </ul>	\$230,000
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<p><b>Output 2</b> Strengthened capacity on evaluation of epidemiological studies to understand country specific needs for new global health technologies, potential market size, and patient perspective.</p>	<p><b>Activity Result</b> In 2 target countries:</p> <ul style="list-style-type: none"> <li>▪ Strengthened capacity to identify and review existing data to estimate burden of disease</li> <li>▪ Needs for additional data and evidence identified</li> <li>▪ Strengthened capacity to promote women's participation in activities relating to Output 2</li> </ul> <p><b>Activity action</b></p> <ul style="list-style-type: none"> <li>▪ Organize 2 training courses to facilitate development of relevant skills within health systems to estimate burden of disease, plan, study, analyze and implement appropriate activities for addressing identified bottle necks and mitigating bottle necks</li> <li>▪ Organize 2 stakeholder consultations to review existing information, assess needs and identify barriers/bottles necks in scale up and effective use of health technologies</li> <li>▪ Adopt a plan for mentoring of country resource persons with a view to identify and train women health professionals; and sustain capacity built beyond the lifetime of the project.</li> </ul>	2013	WHO/TDR	GOI	<ul style="list-style-type: none"> <li>▪ Stakeholder consultations for scale up and effective use of health technologies (2 meetings @ \$64,000 each) [\$148,000]</li> </ul>	\$148,000
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<p><b>Output 3</b> Strengthened health sector capacity in monitoring of Phase IV trials for new global health technologies for NTDS, TB, Malaria and other Diseases</p>	<p><b>Activity Result</b> In 2 target countries:</p> <ul style="list-style-type: none"> <li>▪ Strengthened health sector capacity for monitoring Phase IV Clinical Trials, collating &amp; analyzing safety &amp; efficacy of newly introduced health technologies (medicines and diagnostics)</li> <li>▪ Engagement in regional or global pharmacovigilance networks</li> </ul> <p><b>Actions</b></p> <ul style="list-style-type: none"> <li>▪ Organize 2 stakeholder consultations for needs and capacity assessment and sensitization of resource persons in target countries</li> <li>▪ Develop learning modules to train undergraduate and qualified health care professionals in pharmacovigilance and the importance of reporting ADRs</li> <li>▪ Facilitate linkages with WHO programme for international drug monitoring and other similar bodies for continuous learning and improvement</li> </ul>	2013	WHO/TDR	GOI	<ul style="list-style-type: none"> <li>▪ Stakeholder consultations for needs and capacity assessment (2 meetings @ \$80,000 each) [\$190,000]</li> </ul>	\$190,000
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<p><b>Output 4a</b> Work with LMICs to ensure the financing for new global health technologies for TB, Malaria, NTDs, and other diseases</p>	<p><b>Activity Result</b> In 2 target countries:</p> <ul style="list-style-type: none"> <li>▪ Capacity developed for assessment of country capacity and options for funding of new global health technologies for TB, Malaria, NTDs and other diseases</li> </ul> <p><b>Actions</b></p> <ul style="list-style-type: none"> <li>▪ Review existing and new mechanisms for financing R&amp;D, and access and delivery, of new global health technologies to produce a menu of financing mechanisms relevant to LMICs</li> <li>▪ Produce situation analysis on financing policy, processes and opportunities for new technologies to identify opportunities and needs for financing capacity building</li> <li>▪ Develop a plan of action for capacity building in collaboration with in-country partners</li> <li>▪ Initiate capacity building initiatives with in-country and regional partners to support the implementation of appropriate financing mechanisms for new health technologies</li> </ul>	2013	PATH	GOI	<ul style="list-style-type: none"> <li>▪ Study on existing R&amp;D financing mechanisms, including financing policy situation analysis and financial bottlenecks analysis [5165,000]</li> </ul>	\$215,000
			UNDP	GOI	<ul style="list-style-type: none"> <li>▪ Study on new R&amp;D mechanisms [550,000]</li> </ul>	

<p><b>Output 4b</b> Build capacity on consumerization ensuring that new global health technologies are priced appropriately, and supply meets population demand</p>	<p><b>Activity Result:</b> In 2 countries:  <ul style="list-style-type: none"> <li>▪ Tools developed and pilot tested to assess demand/market for potential new global health technologies for use by target countries and partners</li> <li>▪ Generic tools developed to assess country's existing conditions to support local manufacturing of new health technologies and to assess manufacturing capacities</li> </ul> <b>Actions</b> <ul style="list-style-type: none"> <li>▪ Gather and review existing tools, including through literature review and survey of PATH and other relevant PPPs</li> <li>▪ Develop appropriate assessment tools for adoption and uptake of potential new technologies (as identified by Output 6)</li> <li>▪ Organize consultation meeting with key stakeholders to obtain feedback on feasibility of the tools</li> <li>▪ Adopt plan for piloting application of the tools in one or two target countries</li> </ul> </p>	2013	PATH	GOI	<ul style="list-style-type: none"> <li>▪ Review and survey of existing tools [\$100,000]</li> <li>▪ Assessment tool for adoption and uptake of new technologies [\$107,000]</li> </ul>	\$207,000
<p><b>Output 5</b> Strengthened capacity of delivery systems including supply chain and local manufacturing of new global health technologies for TB, Malaria, NTDs, and other Diseases</p>	<p><b>Activity Result</b> In 2 target countries:  <ul style="list-style-type: none"> <li>▪ Stakeholder capacity in strategic supply forecasting strengthened</li> <li>▪ Stakeholder capacity in procurement of new technologies strengthened</li> <li>▪ Capacity in distribution system readiness strengthened</li> </ul> <b>Actions</b> <ul style="list-style-type: none"> <li>▪ Produce framework and technical paper on Pathways to Procurement for New Technologies</li> <li>▪ Create supply systems assessment tool for adoption of new technologies</li> <li>▪ Conduct supply capacity assessment in target countries</li> <li>▪ Preparations for workshops on supply systems barriers in target countries</li> </ul> </p>	2013	PATH	GOI	<ul style="list-style-type: none"> <li>▪ Framework and technical paper on procurement pathways [\$72,000]</li> <li>▪ Systems assessment tool for adoption of new technologies [\$73,000]</li> </ul>	\$145,000

<p><b>Output 6</b> Regular and robust reviews of all grant applications to determine if the proposed product is viable in terms of access and delivery</p>	<p><b>Activity Result</b></p> <ul style="list-style-type: none"> <li>▪ Policy framework developed for enhanced access and delivery of emerging health technologies for global health, focusing on products from public-private partnerships</li> <li>▪ Strategic interventions identified to improve access and delivery within a range of technology landscapes</li> </ul> <p><b>Actions</b></p> <ul style="list-style-type: none"> <li>▪ Produce advisory report(s) on impact of upstream decisions in R&amp;D pipeline on downstream access and delivery</li> <li>▪ Mapping of catalytic interventions including piloting of approaches to pharmaceutical innovation that enable delivery of affordable health technologies in LMICs</li> <li>▪ Analyse, in conjunction with relevant partners, bottle necks and opportunities for changing the enabling policy environment for pharmaceutical innovation</li> </ul>	2013	UNDP	GOJ	<ul style="list-style-type: none"> <li>▪ Advisory report(s) on impact of upstream decisions [\$10,000]</li> <li>▪ Interventions map and pilot approaches [\$30,000]</li> </ul>	\$40,000
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**For Year 2014 [1 January 2014 – 31 March 2014]**

EXPECTED OUTPUTS	PLANNED ACTIVITIES List activity results and associated actions	RESPONSIBLE PARTY		PLANNED BUDGET		
		Year		Funding Source	Amount	
<p><b>Project Oversight</b> Well-articulated global project with operational business plan, partnership agreements, and resource mobilization for building access and delivery capacity in two LMICs</p>	<p><b>Activity Result</b></p> <ul style="list-style-type: none"> <li>▪ Strengthened strategic directions for project implementation</li> <li>▪ Strong partner relationships developed and built</li> </ul> <p><b>Action</b></p> <ul style="list-style-type: none"> <li>▪ Organize 3 Project Partners meetings for development, coordination and implementation of work plan</li> <li>▪ Organize 1 Advisory Group meeting</li> <li>▪ Develop and implement communications strategy</li> <li>▪ Develop monitoring and evaluation plan</li> <li>▪ Project management and coordination (incl. implement resource mobilization strategy)</li> </ul>	2014	UNDP	GOJ	<p><b>Budget Description</b></p> <ul style="list-style-type: none"> <li>▪ 1 Project Partners meeting + technical briefing [\$60,000]</li> <li>▪ Communications consultant [\$30,000]</li> <li>▪ M&amp;E consultant [\$20,000]</li> <li>▪ Project management and coordination [\$20,000]</li> </ul>	\$130,000

<p><b>Output 1</b> Support strengthening of legal and policy frameworks to expedite access and delivery of new global health technologies for NTDs, TB, Malaria, and other diseases.</p>	<p><b>Activity Result</b></p> <ul style="list-style-type: none"> <li>▪ R&amp;D learning networks established between target countries and development partners</li> <li>▪ Stakeholder capacity developed on innovation policy and models</li> <li>▪ Stakeholder capacity strengthened on IP, licensing negotiations and enabling legal environment</li> </ul> <p><b>Activity Action in Asia:</b></p> <ul style="list-style-type: none"> <li>▪ Conduct regional review of policy coherence (using the common research template as Africa)</li> <li>▪ Conduct review of domestic legal and policy environment in target countries</li> <li>▪ Establishment of national task force on integrating R&amp;D and access to affordable health technologies</li> <li>▪ Organize capacity building and training workshop(s) for patent examiners</li> </ul> <p><b>Activity Action in Africa:</b></p> <ul style="list-style-type: none"> <li>▪ Awareness raising/advocacy at international public health events</li> <li>▪ Conduct a regional study on innovation and local pharmaceutical production in Africa</li> <li>▪ Organize a regional meeting to establish R&amp;D networks between select African countries</li> <li>▪ Organize 2 national capacity development trainings on innovation models, licensing and enabling legal /regulatory environments</li> </ul>	2014	UNDP	GOI	<ul style="list-style-type: none"> <li>▪ In-country consultant support in 2 target countries [\$40,000]</li> </ul> <p><b>Asia</b></p> <ul style="list-style-type: none"> <li>▪ National task force workshop [\$45,000]</li> <li>▪ Patent examiner workshop(s) [\$60,000]</li> </ul> <p><b>Africa</b></p> <ul style="list-style-type: none"> <li>▪ National capacity development trainings [\$140,000]</li> <li>▪ Regional meeting for R&amp;D networks [\$150,000]</li> </ul>	\$435,000
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<p><b>Output 2</b> Strengthened capacity on evaluation of epidemiological studies to understand country specific needs for new global health technologies, potential market size, and patient perspective.</p>	<p><b>Activity Result</b> In 2 target countries:</p> <ul style="list-style-type: none"> <li>▪ Strengthened capacity to identify and review existing data to estimate burden of disease</li> <li>▪ Needs for additional data and evidence identified</li> <li>▪ Strengthened capacity to promote women's participation in activities relating to Output 2</li> </ul> <p><b>Activity action</b></p> <ul style="list-style-type: none"> <li>▪ Organize 2 training courses to facilitate development of relevant skills within health systems to estimate burden of disease, plan, study, analyze and implement appropriate activities for addressing identified bottle necks and mitigating bottle necks</li> <li>▪ Organize 2 stakeholder consultations to review existing information, assess needs and identify barriers/bottles necks in scale up and effective use of health technologies</li> <li>▪ Adopt a plan for mentoring of country resource persons with a view to identify and train women health professionals; and sustain capacity built beyond the lifetime of the project</li> </ul>	2014	WHO/TDR	GOI	<ul style="list-style-type: none"> <li>▪ Training courses for skills development (2 trainings @ \$84,000 each) [5202,000]</li> </ul>	\$202,000
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<p><b>Output 3</b> Strengthened health sector capacity in monitoring of Phase IV trials for new global health technologies for NTDs, TB, Malaria and other Diseases</p>	<p><b>Activity Result</b> In 2 target countries:</p> <ul style="list-style-type: none"> <li>▪ Strengthened health sector capacity for monitoring Phase IV Clinical Trials, collating &amp; analyzing safety &amp; efficacy of newly introduced health technologies (medicines and diagnostics)</li> <li>▪ Engagement in regional or global pharmacovigilance networks</li> </ul> <p><b>Actions</b></p> <ul style="list-style-type: none"> <li>▪ Organize 2 stakeholder consultations for needs and capacity assessment and sensitization of resource persons in target countries</li> <li>▪ Develop learning modules to train undergraduate and qualified health care professionals in pharmacovigilance and the importance of reporting ADRs</li> <li>▪ Facilitate linkages with WHO programme for international drug monitoring and other similar bodies for continuous learning and improvement</li> </ul>	2014	WHO/TDR	GOJ	<ul style="list-style-type: none"> <li>▪ Development of learning modules on pharmacovigilance [\$110,000]</li> </ul>	\$110,000
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<b>Output 4a</b> Work with LMICs to ensure the financing for new global health technologies for TB, Malaria, NTDs, and other diseases	<b>Activity Result</b> In 2 target countries: ▪ Capacity developed for assessment of country capacity and options for funding of new global health technologies for TB, Malaria, NTDs and other diseases  <b>Actions</b> ▪ Review existing and new mechanisms for financing R&D, and access and delivery, of new global health technologies to produce a menu of financing mechanisms relevant to LMICs ▪ Produce situation analysis on financing policy, processes and opportunities for new technologies to identify opportunities and needs for financing capacity building ▪ Develop a plan of action for capacity building in collaboration with in-country partners ▪ Initiate capacity building initiatives with in-country and regional partners to support the implementation of appropriate financing mechanisms for new health technologies	2014	PATH	GOU	▪ Plan of action for capacity development [55,000] ▪ Capacity building workshops (\$100,000)	\$155,000
			UNDP	GOU		



<p><b>Output 4b</b> Build capacity on consumerization ensuring that new global health technologies are priced appropriately, and supply meets population demand</p>	<p><b>Activity Result:</b> In 2 countries:  <ul style="list-style-type: none"> <li>▪ Tools developed and pilot tested to assess demand/market for potential new global health technologies for use by target countries and partners</li> <li>▪ Generic tools developed to assess country's existing conditions to support local manufacturing of new health technologies and to assess manufacturing capacities</li> </ul> <b>Actions</b> <ul style="list-style-type: none"> <li>▪ Gather and review existing tools, including through literature review and survey of PATH and other relevant PDPs</li> <li>▪ Develop appropriate assessment tools for adoption and uptake of potential new technologies (as identified by Output 6)</li> <li>▪ Organize consultation meeting with key stakeholders to obtain feedback on feasibility of the tools</li> <li>▪ Adopt plan for piloting application of the tools in one or two target countries</li> </ul> </p>	2014	PATH	GOJ	<ul style="list-style-type: none"> <li>▪ Stakeholder consultation meeting [\$152,000]</li> <li>▪ Action plan for pilot implementation [\$81,000]</li> </ul>	<b>\$233,000</b>
<p><b>Output 5</b> Strengthened capacity of delivery systems including supply chain and local manufacturing of new global health technologies for TB, Malaria, NTDs, and other Diseases</p>	<p><b>Activity Result</b> In 2 target countries:  <ul style="list-style-type: none"> <li>▪ Stakeholder capacity in strategic supply forecasting strengthened</li> <li>▪ Stakeholder capacity in procurement of new technologies strengthened</li> <li>▪ Capacity in distribution system readiness strengthened</li> </ul> <b>Actions</b> <ul style="list-style-type: none"> <li>▪ Produce framework and technical paper on Pathways to Procurement for New Technologies</li> <li>▪ Create supply systems assessment tool for adoption of new technologies</li> <li>▪ Conduct supply capacity assessment in target countries</li> <li>▪ Preparations for workshops on supply systems barriers in target countries</li> </ul> </p>	2014	PATH	GOJ	<ul style="list-style-type: none"> <li>▪ National supply capacity assessments in 2 target countries [\$134,000]</li> <li>▪ Preparation for workshops on supply systems barriers [\$171,000]</li> </ul>	<b>\$305,000</b>

<p><b>Output 6</b> Regular and robust reviews of all grant applications to determine if the proposed product is viable in terms of access and delivery</p>	<p><b>Activity Result</b></p> <ul style="list-style-type: none"> <li>▪ Policy framework developed for enhanced access and delivery of emerging health technologies for global health, focusing on products from public-private partnerships</li> <li>▪ Strategic interventions identified to improve access and delivery within a range of technology landscapes</li> </ul> <p><b>Actions</b></p> <ul style="list-style-type: none"> <li>▪ Produce advisory report(s) on impact of upstream decisions in R&amp;D pipeline on downstream access and delivery</li> <li>▪ Mapping of catalytic interventions including piloting of approaches to pharmaceutical innovation that enable delivery of affordable health technologies in LMICs</li> <li>▪ Analyse, in conjunction with relevant partners, bottle necks and opportunities for changing the enabling policy environment for pharmaceutical innovation</li> </ul>	2014	UNDP	GOJ	<ul style="list-style-type: none"> <li>▪ Analysis of bottlenecks and opportunities for pharmaceutical innovation [(\$55,000)]</li> </ul>	\$55,000
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Note: AWP will be reviewed and revised annually before the commencement of each year's activity

## Access and Delivery Summary Budget:

	Government of Japan	UNDP Contribution (in kind)																									
<b>Requested Total for Year 1 Capacity Building</b>	<b>\$3,639,389</b>																										
<p><b>Capacity Building in 2 Countries: (see budget notes)</b>            Project Oversight with operational business plan, partnership agreements, and resource mobilization for building access and delivery capacity in two LMICs.</p> <p>1. Strengthen legal and policy frameworks to expedite access and delivery of new global health technologies for TB, Malaria, NTDs and other diseases \$276,105</p> <p>2. Strengthen capacity for epidemiological study review and market needs assessment \$665,000</p> <p>3. Strengthen health research capacity in monitoring of Phase IV trials \$350,000</p> <p>4a. Strengthen capacity within LMIC Government to ensure the financing for new global health technologies \$300,000</p> <p>4b. Build capacity on consumerization to ensure that new global health technologies are priced appropriately, and supply meets population demand \$370,000</p> <p>5. Strengthen capacity of delivery systems including supply chain of new global health technologies for TB, Malaria, NTDs and other diseases \$440,000</p> <p>6. Robust reviews of grant applications to determine if the proposed product is viable for access and delivery in LMICs \$450,000</p> <p>\$95,000</p>																											
<b>Sub Total for Advisory and Capacity Building Activities (A)</b>	<b>\$2,946,105</b>																										
<b>Staff Costs (Breakdown)</b>																											
<table border="1"> <thead> <tr> <th>Level</th> <th>Salary/yr</th> <th>Time</th> <th></th> <th></th> </tr> </thead> <tbody> <tr> <td>Director Level 1 in New York</td> <td>\$326,168</td> <td>30%</td> <td></td> <td>\$97,850</td> </tr> <tr> <td>Programme Advisor, P5 Level in New York</td> <td>\$279,491</td> <td>50%<sup>1</sup></td> <td>\$139,746</td> <td></td> </tr> <tr> <td>Project Specialist, P3 in New York</td> <td>\$197,228</td> <td>50%<sup>1</sup></td> <td>\$98,614</td> <td></td> </tr> <tr> <td>Project Admin/Fin. Associate, General Staff G6 in New York</td> <td>\$96,501</td> <td>30%</td> <td></td> <td>\$28,950</td> </tr> </tbody> </table>	Level	Salary/yr	Time			Director Level 1 in New York	\$326,168	30%		\$97,850	Programme Advisor, P5 Level in New York	\$279,491	50% <sup>1</sup>	\$139,746		Project Specialist, P3 in New York	\$197,228	50% <sup>1</sup>	\$98,614		Project Admin/Fin. Associate, General Staff G6 in New York	\$96,501	30%		\$28,950		
Level	Salary/yr	Time																									
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Project Admin/Fin. Associate, General Staff G6 in New York	\$96,501	30%		\$28,950																							
<b>Sub Total for Staff (B)</b>	<b>\$238,360</b>	<b>\$126,800</b>																									
<p><b>UNDP Cost recovery:</b>            General Management Services (7.5%)<sup>2</sup> \$272,955            Implementation Support Services (5%) \$181,969</p>																											
<b>Sub Total (C)</b>	<b>\$454,924</b>																										
<b>GRANT TOTAL BUDGET (A) + (B) + (C)</b>	<b>\$3,639,389</b>	<b>\$126,800<sup>3</sup></b>																									

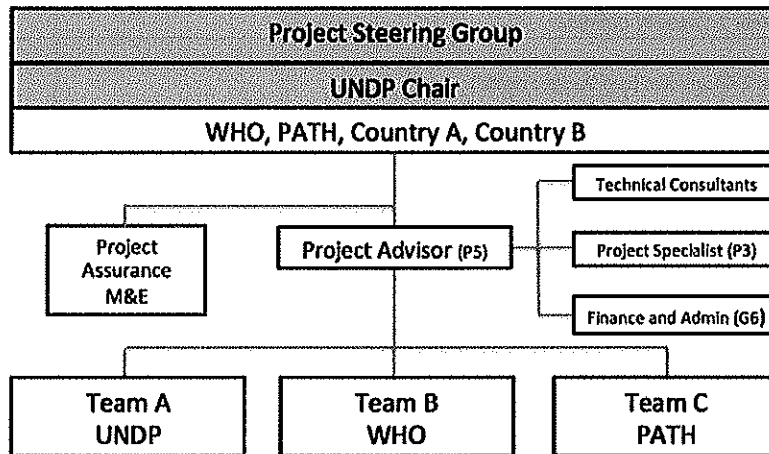
<sup>1</sup> The budget reflects 50% of the proforma for staff costs as the recruitment of staff was completed in the middle of the Year 1.

<sup>2</sup> The current for GMS is 7% but the rate is subject to change in 2014 based on UNDP EB recommendations and decisions to increase it to 8%, hence, the rate of 7.5% is used to account for the potential increase in 2014.

<sup>3</sup> The cost is funded from other UNDP projects.

## V. MANAGEMENT ARRANGEMENTS

### Access and Delivery Project Organization Structure



#### ▪ Project Implementation Modality

Using UNDP's NGO implementation (execution) modality, PATH will be implementing the project, together with WHO and UNDP as the responsible parties. Under this modality, PATH, WHO and UNDP will be responsible for the implementation of their assigned components of the project. The overall programme budget for year 1 is \$2,946,105 for which PATH will be responsible for the implementation of activities and budget utilization amounting to \$1,110,000, while WHO and UNDP will be responsible for \$650,000 and \$1,186,105, respectively, as outlined in the Annual Work Plan above.

A Project Steering Group will be established, comprising of UNDP, WHO, PATH and regional economic organizations in Africa and Asia. BDP's Director of HIV, Health and Development will be the Chair of the Project Steering Group. The Project Steering Group will be responsible for guiding overall management, decision-making and monitoring of the project. Regular monitoring will be conducted to ensure that the project fits with strategy, is on schedule (programmatic and financial).

On behalf of PATH, UNDP will identify and appoint the Programme Advisor (P-5) who will be the Project Manager of the Access and Delivery Project. The Programme Advisor (P-5) will oversee the implementation of the project, as well as partnership relationships and the management of financial resources. The Programme Advisor will report to the Chair of the Steering Group. A Project Specialist (P-3), supervised by the Programme Advisor, will be responsible for supporting financial and project management.

#### ▪ Roles and responsibilities of Project Steering Group

The Project Steering Group 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. Additional members may be invited at the discretion of the Group.

The Project Steering Group will, where appropriate, coordinate with the activities of GHIT project.

## Visibility

The following actions will be undertaken to ensure visibility of project partners:

- Banners including the collaborating partners' logos in all seminars/ workshops
- Material depicting the collaborating partners' logos will be prominently displayed in all workshops
- Engage local Embassy of Japan in program countries in any local activity
- Visibility concerns will be discussed with the project partners upon initiation of the project.
- Any planned communication with public visibility, which relates to the project will be shared in draft form and agreed between partners prior to release.

## **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:

### **Within the Annual Cycle**

- On a quarterly basis, a quality assessment shall record progress towards the completion of key results, based on quality criteria and methods captured in the Quality Management table below.
- An Issue Log shall be activated in Atlas and updated by the Project Manager to facilitate tracking and resolution of potential problems or requests for change.
- Based on the initial risk analysis submitted (see annex A), a risk log shall be activated in Atlas and regularly updated by reviewing the external environment that may affect the project implementation.
- Based on the above information recorded in Atlas, a Project Progress Reports (PPR) shall be submitted by the Project Manager to the Project Steering Group through Project Assurance, using the standard report format available in the Executive Snapshot.
- A project Lesson-learned log shall be activated and updated regularly to ensure on-going learning and adaptation within the organization, and to facilitate the dissemination of lessons learned amongst partners throughout and at the final reporting stage of the project. A Monitoring Schedule Plan shall be activated in Atlas and updated to track key management actions/events

### **Annually**

- **Annual Review Report**
  - An Annual Review Report shall be prepared by the Project Manager and shared with the Project Board and the Outcome Board. As minimum requirement, the Annual Review Report shall consist of the Atlas standard format for the QPR covering the whole year with updated information for each above element of the QPR as well as 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 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.

### **Audit**

- UNDP may conduct audit on this project. 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.

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## 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 SBAA's 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 SBAA with UNDP, attached hereto and forming an integral part hereof.

This project will be implemented by PATH, with UNDP and WHO as responsible parties, in accordance with UNDP financial regulations, rules, practices and procedures. 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](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 for Access & Delivery Project:

#	Risk Description	Category	Impact & Probability Level	Countermeasures / Management Response
1	GHIT may not have products ready for Phase IV, or country access in Year Two, 2014.	Operational	Unknown	UNDP will build start to build capacity for access and delivery of new technologies for global health immediately in two LMICs to prepare for GHIT products.
2	GHIT may not produce products for Phase IV access and delivery in the next five years.	Operational	High.	By building capacity in two LMICs, the GOJ will mitigate risk of GHIT not producing any products for delivery in LMICs. These capacities can be used in the meantime to expedite other products for global health.
3	Limited ability of UNDP to influence GHIT's operational and management decision-making	Legal	High	UNDP cannot participate on any of GHIT's executive or management structures, either in a voting or non-voting role. Advisory Services will be through the Advisory Committee only.
4	UNDP being incorrectly understood as a donor	Political	High. UNDP is not a donor, but rather a technical partner to build capacity in low and middle income countries. Supporting R&D in high income countries is not in UNDP mandate.	<ul style="list-style-type: none"> <li>• UNDP role is seen as a bridge between R&amp;D and Access. This needs to be fully documented and agreed upon by all parties.</li> <li>• 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.</li> </ul>
5	Insufficient funding to purchase new global health technologies once introduced	Operational	High. Need for health financing resources.	Within this UNDP partnership strategy, there is a clear intent from both Japanese public and private sector partners to make funding available for the purchase of new health technologies in LMICs.
6	Reputational risk being associated with GHIT, which is a new organization	Operational	High. Not a proven entity. Organisational capacity is not established.	To be justified through capacity assessment process. GOJ providing an undertaking on the capacity of GHIT.
7	Unsatisfactory or un-operational Agreement on Intellectual Property between UNDP and GHIT sub-grantees.	Legal	High. Agreement on Intellectual Property between UNDP and GHIT sub-grantees has not yet been settled. UNDP needs to work within the framework of the legal context as described in Section VII.	UNDP is exploring options for alternatives with its legal team.
8	New global health technologies are not affordable for LMICs.	Operational	High. New global health technologies must be affordable for developing countries.	GHIT's Access Policy must reflect commitment to ensuring that new global health technologies are affordable for patients with the target diseases in LMICs.