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

United Nations Development Programme
Global Project Document

Project Title: 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)

Strategic Plan Outcome 3: Countries have strengthened institutions to progressively deliver universal access to basic services.

Strategic Plan Output 3.3: National institutions, systems, laws and policies strengthened for equitable, accountable and effective delivery of HIV and related services

Intended Global Project Outcome: By 2018, 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 Agency: PATH

Responsible Parties: WHO/TDR and UNDP

Brief Description

As described in the 2013 GHIT Project Document, 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 are required to measure "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 indicates that LMICs have insufficient capacities in the areas of regulatory, legal, and policy frameworks, clinical trial monitoring, pharmacovigilance, local manufacturing, and delivery systems for the introduction of new global health technologies.

In responding to these capacity constraints most of which are of a multi-sectoral nature, 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 of health technologies. UNDP, in the project's first phase, worked with these and other relevant technical partners to 1) provide advisory services to GHIT and, 2) strengthen capacity in select LMICs to in legal and policy frameworks; understanding of specific country needs for new global health technologies; training on safety monitoring; health financing; and pricing, supply and delivery systems. The project therefore provided GHIT with public health oriented advisory services on access and delivery, as well as strengthened the capacity of select LMICs to optimise access and delivery of new health technologies. This project document constitutes a second phase of the project with the implementation of its outputs and activities in other LMICS.

Total resources required	$13,712,047.01
UNDP GMS/ISS	$1,374,405.87
Total allocated resources:	$13,712,047.01
Regular	
Other:	
Government of Japanese	$13,712,047.01
Unfunded budget:	
In-kind Contributions	

Programme Period:	2014-2018
Key Result Area (Strategic Plan)	Output 3.3
Atlas Award ID:	00075333
Start Date	July 2014
End Date	March 2018
PAC Meeting Date	12 June 2014

Agreed by (UNDP):

Magdy Martinez-Soliman, Director, BPPS

ACRONYMS

BPPS	Bureau of Policy and Programme support
BMGF	Bill and Melinda Gates Foundation
DNDI	Drugs for Neglected Diseases Initiative
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHIT	Global Health Innovative Technology fund
GOJ	Government of Japan
LMICs	Low and Middle Income Countries
MDG	Millennium Development Goal
MMV	Medicines for Malaria Venture
MoFA	Japanese Ministry of Foreign Affairs
LMICs	Low and Middle Income Countries
NGO	Non-Governmental Organisation
NTDs	Neglected Tropical Diseases
PDP	Product Development Partnership
PPP	Public Private Partnership
R&D	Research and Development
RFP	Request for Proposals
TB	Tuberculosis
TDR	The Special Programme for Research and Training in Tropical Diseases
UNICEF	United Nations Children's Fund
UNDP	United Nations Development Programme
WHO	World Health Organization

I. Situational Analysis

In 2011, 8.7 million people fell ill with TB, including 1.1 million cases among people with HIV.[1] Ongoing malaria transmission continues to affect 99 countries and territories around the world. In 2010, an estimated 3.3 billion people were at risk of malaria globally.[2] The 17 diseases defined by the WHO as NTDs are endemic in 149 countries, with a high degree of geographical overlap; at least 100 countries are endemic for two or more diseases and 30 countries are endemic for six or more. NTDs disproportionately affect the so-called "bottom billion" – the 1.4 billion people who live below the US$1.25 per day poverty line.[3] In middle income countries ranging from India to Zambia, NTDs produce chronic disability resulting in impaired child growth, and intellectual and cognitive development, impaired pregnancy outcomes, and decreased worker productivity. This is especially notable in sub-Saharan Africa where NTDs geographically overlap with HIV and malaria; infection with a NTD may increase susceptibility to HIV and worsen outcomes in those with HIV, tuberculosis, or malaria. Socio-economic inequality in health and health care access need to be addressed as there is increasing evidence that income inequality exacerbates poor health outcomes for the lowest economic quintile, independent of absolute poverty levels.[4] Effectively addressing the health impact of NTDs, TB and malaria thus represents a major development opportunity to improve health outcomes, and alleviate poverty in LMICs.

While NTDs account for 11.4% of the global disease burden, the investment in developing diagnostics, medicines and vaccines to treat them is disproportionately low. Of the 1,556 new medicines approved between 1975 and 2004, only 1.3% were specifically developed for tropical diseases and TB. Standard anti-TB drugs have been used for decades, and resistance to the medicines is growing. Disease strains that are resistant to a single anti-TB drug have been documented in every country around the world. Multidrug-resistant tuberculosis (MDR-TB) is a form of TB caused by bacteria that do not respond to isoniazid and rifampicin, two standard anti-TB drugs. Disease caused by resistant bacteria fails to respond to conventional, first-line treatment. Extensively drug-resistant TB, XDR-TB, is a form of multi-drug resistant tuberculosis that responds to even fewer available medicines, including the most effective second-line anti-TB drugs.

Even as the number of new health technologies coming to market increases slowly, the capacity in several LMICs to deliver these products to patients in need remains very weak. Health systems need to be strengthened so that these medicines can be delivered and accessed in a timely manner. To address the issues of NTDs, a synergistic approach is needed; one which brings together and increasing levels of research and development for new vaccines, diagnostics and medicines to address NTDs, TB and malaria; and increasing capacities of countries to deliver new health technologies to patients in need.

The factors impacting on the ability of LMICS to access and delivery health technologies required to address Malaria, TB and NTDs in LMICs, can be clustered into three sets of issues: The first relates to economies of scale and market dynamics and includes determining factors such as the availability funding, local pharmaceutical manufacturing capacity, the availability of market intelligence regarding the pricing and supply of medicines and capacity to forecast demand for health technologies. The second set of issues are related to the legislative, policy and regulatory environment which cuts across industrial policy, patent, competition and medicines legislation and the capacity of drug regulatory authorities to approve new pharmaceutical technologies in a way that promotes access to treatment. The final set of factors addresses the ability of the national supply chain system to delivery health technologies to those in need in every given country.

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[1] WHO (2012) Global Tuberculosis Report Factsheet, Available at: http://www.who.int/tb/publications/factsheet_global.pdf

[2] Report by the Director General of the World Health Organization, 5 April 2013, Implementation of General Assembly resolution 66/289 on consolidating gains and accelerating efforts to control and eliminate malaria in developing countries, particularly in Africa, by 2015. Available at: http://www.who.int/malaria/publications/atoz/UNGA_malaria_report_ 2013_English.pdf

[3] Ibid WHO (2010)

[4] Strategy Note – HIV, Health and Development 2012-2013

Improving the ability of several LMICs to review and efficiently introduce new global health technologies for TB, Malaria, NTDs and other diseases into their national health systems is a key impediment to accessing health technologies. LMICs often lack the requisite capacity in areas of legal, and policy frameworks; safety monitoring; and pricing, supply, and delivery systems for the introduction of new global health technologies.[5] 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."[6] 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 of new global health technologies in LMICs. As shown below, PDPs are experiencing a lack of access to the markets for which their new products are intended.

The number of new global health technologies coming to market for TB, Malaria, and NTDs, and other diseases is increasing. As with their support of the Japanese non-profit GHIT, the Bill and Melinda Gates Foundation (BMGF) also funds 15 different Product Development Partnerships (PDPs) which together, manage a large portfolio of projects worldwide for the development of new global health technologies for TB, Malaria, NTDs, and other diseases endemic in LMICs. However while these important initiatives are starting to address the dearth in innovation in health technologies, the public health impact of all these developments will largely hinge on the ability of LMICs to optimally absorb health technologies through their domestic health systems and to make them available to their citizens at an affordable price.[7] Capacity strengthening of LMIC government officials in order to improve the ability of domestic health systems to absorb and deliver health technologies is a key determinant in eventually increasing access to technologies.

With the BMGF's PDP investment portfolio maturing, there are an increasing number of new global health technologies coming into Phase IV clinical trials, or being introduced into a developing country's targeted population. MMV and DNDi, for example, each have six products in Phase IV clinical trials. However, BMGF is not working on 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

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. The Japanese government's investment in the GHIT Fund is a direct realization of the country's 2013 strategy on Global Health Diplomacy, which encourages strategic collaborations with international partners and the use of domestic R&D capabilities in continued support of achieving the UN's Millennium Development Goals (MDGs). This strategy is linked tightly with Japan's Healthcare and Medical Strategy, also launched in 2013. The Government of Japan's (GOJ) 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 welcomed the GOJ increased participation in the global health sector. As elaborated upon in the 2013 GHIT Project Document, GHIT will support partnerships of Japanese research and development entities with international organizations and PDPs with funding from the BMGF, certain Japanese

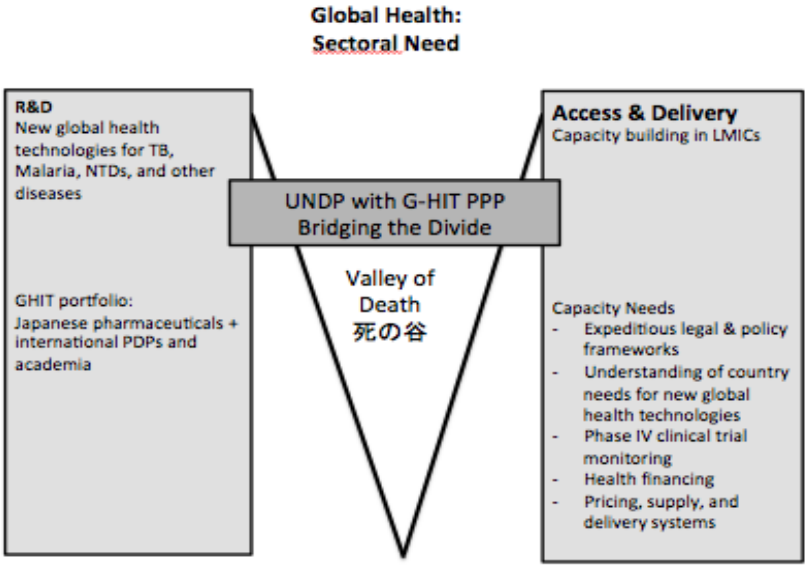
[5] Oxfam. Oxfam Briefing paper: Ending the R&D Crisis in Public Health: Promoting pro-poor medical innovation (2008).
[6] MDG Gap Task Force Report: The global Partnership for Development: Making Rhetoric a Reality (2012).
[7] PDP Support of Country Decision Making: A Discussion paper. W.Wells (TB Alliance), A. Brooks (PATH). October 2012.

Pharmaceutical companies, and the GOJ working with UNDP. GHIT's work presents UNDP with the opportunity to provide policy advice at various stages of product development: from pre-clinical to Phase IV, or from design to assisting the new global health technologies' adoption in LMICs.

In partnership with WHO/TDR, PATH and other relevant technical partners, UNDP's work on access and delivery complements the work of GHIT to support the development of new global health technologies. UNDP's work also supports the access and delivery of new health technologies not developed by GHIT, which may be introduced in LMICs in the coming years.

UNDP, through the project's first phase, has worked with WHO/TDR, PATH and other technical partners to strengthen the capacity of select LMICs ensuring appropriate policy and regulatory frameworks; safety monitoring; health financing; pricing, supply and delivery systems for better access and delivery of these new global health technologies for TB, Malaria, NTDs, and other diseases. This innovative partnership is not just anchored within MDG 8.E, but within the UNDP Strategic Plan 2014-2017, Outcome 3 focuses on the capacity of institutions to lead the development process and deliver justice, security and other basic services to all women and men, including the most marginalized. In particular, Output 3.3 aims to strengthen national institutions, systems, laws and policies for equitable, accountable and effective delivery of HIV and related services.

UNDP's partnership with GHIT offers a unique opportunity for UNDP to contribute to the discovery and development of health technologies within the innovative PDP GHIT in order to strengthen linkages between the process of health technology innovation on the one hand and access and delivery of the said health technologies on the other. In turn, GHIT will have access to policy and technical advice on the public health impact of its activities with proposals as to how these can be optimised to promote the adoption of their portfolio in LMICs, which is a key stated objective of GHIT's mission as articulated in its access policy.



Results of First Phase Project:

In the first phase of the project (2013-2014), the Access and Delivery Project undertook a range of activities at the global, regional and country levels, including the building of partnerships for effective project implementation. Project partners agreed to focus on countries in Africa and Asia, where the burden of TB, malaria and NTDs is high and where the project is likely to contribute significantly to improving health outcomes. Project partners undertook an extensive assessment of countries against agreed criteria, comprising four categories of indicators: political will and commitment, existing in-country or domestic capacity, availability of information and the potential for high impact and South-South cooperation. **Indonesia, Thailand, Ghana and Tanzania** were selected for the initial set of focus countries.

Through a cross-cutting and multidisciplinary approach, extensive efforts were made to consult with important national stakeholders (including the Ministries of Health, Trade and Industry, Science and Technology National Agencies of Drug and Food Control and local pharmaceutical industries) in each country and to establish partnerships and ownership across the board. The integrated package of capacity building activities proposed by the ADP project was warmly welcomed in Tanzania, Indonesia and Ghana, where on-going technical and financial support from the Government of Japan has already made significant inroads in the public health field.

The positive and supportive reactions from government stakeholders set the basis for country visits to three of the selected countries - Tanzania, Indonesia and Ghana[8] - between October and December 2013, with a view to engaging key government officials, policy makers and technical partners at the national level to assess the country situation with regard to the implementation of project activities and to identify potential synergies and linkages with national priorities and needs. The project plans and related results presented below are the outcome of Project Planning and Inception meetings that were subsequently conducted in February and March 2014 in Indonesia and Tanzania.

At the formal launch of the Access and Delivery Project in Indonesia, the Special Advisor to the Minister of Health speaking on behalf of the Government of Indonesia expressed his great hope that the partnership would assist different branches of government to increase coherence required across the public health system to increase access to health technologies in Indonesia. UNDP is working closely with several government ministries to improve the legal, policy and regulatory environment in Indonesia. In Tanzania, the Access and Delivery partners were requested to support the strengthening of the regulatory and policy environment, the monitoring of epidemiological studies, the commercialisation of new health technologies and the strengthening of supply chain management systems. The Government Spokesperson noted that: "the capacity building and strengthening activities will prove to be important interventions which will have a positive influence on the Government's health programming." It is anticipated that once the political situation stabilizes, the partnership will commence with project implementation in Thailand.

[8] The country visit to Thailand planned for December 2013 had to be postponed due to the uncertain political situation in Bangkok. Project Partners have however begun a dialogue with key stakeholders in Thailand, including the Ministry of Public Health, the Health Intervention Technology Assessment Program (HITAP) and International Health Policy Program (IHPP) and WHO Thailand, to discuss potential areas of collaboration.

II. Strategy

Each partner through its mandate and programming history brings an important and unique contribution to the work of the partnership. UNDP, working with WHO/TDR, PATH and other technical partners, can provide a broad range of technical skills necessary to build capacity in LMICs to optimise the ability of LMICs to access and deliver new health technologies for TB, Malaria, NTDs, and other diseases. With its commitment to the MDGs, presence in 166 countries, strong track record in health and inclusive sustainable development issues, and strength in policy, operations, and capacity building, UNDP is well positioned to leverage its mandate and core strengths of providing technical advice 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 (GFATM), where UNDP manages approximately 10% 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.

As the specialised Health Agency within the United Nations system, WHO's leadership in setting overall policy and direction; it's oversight of the multilateral pre-qualification programme for new health technologies as well as its long-standing expertise in research, mapping, and understanding of diseases in LMICs makes it an important partner for the effective implementation of the access and delivery partnership. TDR is a global programme of scientific collaboration that helps facilitate, support and influence efforts to combat diseases of poverty. TDR is hosted by the WHO and sponsored by the United Nations Children's Fund (UNICEF), UNDP, the World Bank and WHO. The fact that UNDP as a co-sponsor of TDR presents a mutually beneficial opportunity to leverage an existing institutional partnership to strengthen the capacities of LMICs to deliver global health solutions.

As with WHO/TDR, PATH's mission is to foster new technologies for global diseases. With 40 years of experience in health technology development and delivery PATH has a proven track record of accelerating the delivery of vaccines, devices, diagnostics, drugs, and system and service innovations with a focus on affordability and product design for ease of access and use in LMICs. PATH's work in LMICs includes capacity building for understanding of market size and demand, pricing, supply chain, and delivery. By mobilizing partners around the world, PATH takes innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Working together with countries, PATH delivers measurable results that disrupt the cycle of poor health. UNDP, WHO/TDR 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 make progress in achieving health related 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 advice to strengthen capacity in a select number of LMICs for the access and delivery of new global health technologies for TB, Malaria, NTDs, and other diseases. Working with WHO/TDR, PATH and other technical partners, UNDP as overall project manager is uniquely qualified to provide the following:

Capacity building in LMICs:

To ensure that country capacity will be adequate for the access and delivery of GHIT portfolio products, UNDP, WHO/TDR and PATH 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 work across the value chain with a focus on the development of a conducive policy and legal environment, effective disease control and drug regulatory systems, sustainable financing for public health innovation and procurement of health technologies, and proficient procurement and supply chain management. Project activities are thus aimed at making interventions across five key outputs:

Output 1: Coherent policy and legal frameworks for expedited access and delivery of new health technologies:

The development of an enabling policy and legal environment that addresses the intersections of public health and industrial and fiscal policies, including approaches to social determinants of health, technological innovation and intellectual property rights, is integral to ensuring sustainable access to and delivery of affordable medicines and treatments. The focus of strategic pathway 1 will be strengthening capacities for the development and implementation of an integrated public health, innovation and industrial policy framework. Key national partners would include government authorities responsible for the various legal and regulatory environments, the pharmaceutical industry and civil society

Output 2: Enhanced capacity to identify and address country-specific health system needs for effective access and delivery of new health technologies

Epidemiological surveillance systems are an integral part of a health care system; they provide health authorities a basis to make decisions about their priority health events, whether acute or long-standing. Ideally, functioning systems should be able to evaluate the impact of interventions on disease burden. This entails detecting and reporting bottlenecks and barriers causing inefficiencies or failure of interventions, and responding appropriately. Activities under strategic pathway 2 will focus on strengthening national capacities to use epidemiological population-based data to identify needs and enhance target populations' access to new health technologies. The main partners at the national level would include government authorities responsible for disease control and surveillance, and the authorities responsible for operational research protocols.

Output 3: Strengthened capacity to monitor and respond to safety issues associated with new health technologies

Phase IV clinical trials are undertaken after a new pharmaceutical product has been brought to market. Their purpose is to gather data on the effect of the product in various populations, and to identify any side effects associated with long-term use. These clinical trials can strain the data management and surveillance systems of LMICs and affect some countries' abilities to mobilize resources to sustainably expand and extend their capacity. Strategic pathway 3 focuses on strengthening the health sector's capacity to collate and analyze safety data related to newly introduced health technologies. Activities will focus on training health care professionals in pharmacovigilance and the importance of reporting adverse drug reactions. Key national partners include government agencies responsible for research protocols and public safety, the pharmaceutical industry and prescribing physicians from all sectors.

Output 4a: Improved capacity to ensure sustainable financing for new health technologies

Many countries do not have the capacity to develop policies and structures to ensure sustainability and self-sufficiency in financing the procurement of new health technologies. Capacities for financing research and development for TB, malaria and NTDs also remain problematic. LMICs require support to integrate mechanisms that foster financial sustainability within the health system. These include tools like health technology assessments to inform coverage or pricing, inclusion into insurance benefit packages and the government resource allocation process. Strategic pathway 4a focuses on strengthening capacity for the development of processes that support sustainable financing for new health technologies, through review of existing resources and maximization of use of resources. Key national partners include government authorities responsible for finance and budgeting and science and innovation policies; academic research organizations; and knowledge management stakeholders.

Output 4b: Developed capacity for commercialization of health technologies to ensure appropriate pricing and adequate supply

Introducing new health technologies can be expensive, and LMICs may lack the resources to adequately quantify and qualify their needs with regard to pricing and sustainable supply of such technologies. Strategic pathway 4b focuses on strengthening capacities in LMICs to ensure access to health technologies at appropriate pricing, such that supply meets demand. This may include support for the development of

structured technology selection processes, as well as the development of a centralized mechanism or process for coordinating technology introduction. Key partners include government authorities with responsibility for health technology selection, regulation, and supply; authorities responsible for infrastructure development, government procurement policies and disease control strategies; civil society stakeholders involved in procurement and supply of health technologies; and pharmaceutical and diagnostic device manufacturers

Output 5: Enhanced capacity in supply chain management

In many LMICs, bottlenecks in the planning, procurement and distribution functions disrupt public health programmes. These bottlenecks can occur at any point in the supply system, but the risk of disruptions or delays may be greatest when a new health technology is introduced. Often new technologies may also require the procurement of other items to support its use (e.g. new diagnostic equipment will likely require consumable reagents, annual calibrations, special warranties and staff training on use). Strategic pathway 5 focuses on increasing integration and strengthening the supply chain disciplines, resulting in a system more capable of introducing new products without disruption. Key national partners would be the government authorities responsible for procurement policy, commodities planning, public sector procurement commodities storage and delivery, as well as civil society actors involved in health service delivery.

Output 6: Policies influencing pharmaceutical innovation and access and delivery of Health Technologies reviewed

UNDP and its partners will undertake an in-depth analysis of the policy levers influencing pharmaceutical innovation and access and will also undertake periodic analysis of new vaccines, medicines and diagnostics in the innovation pipeline of various PDPs which are likely to be introduced into LMICs over the next decade. By so doing, UNDP and its partners will provide GHIT with information which may be useful in the helping to identify and select prospective grantees. This analysis will also include 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 bias whatsoever to a particular product or geography.

Output 7: Efficient and Effective Management of Project

UNDP will serve as the project manager of the access and delivery partnership. The functions to be performed by UNDP as part of its efficient and effective project management responsibilities include assuming responsibility for the refinement and updating of the Project business plan, providing strategic direction for the project, strengthening of project operations, building and maintaining strong partner relations, managing the interface with current and potential donors as well as exploring mobilization of additional funding by donors.

The recipient LMICs for capacity building will be chosen by UNDP and the Advisory Group. The selection of recipient countries will be based on a careful analysis which includes criteria such as the epidemiological data and specific burden of disease, the potential impact of the project on national public health outcomes, the political will expressed by the government as well opportunities to leverage the project's impact beyond a specific country.

III. RESULTS AND RESOURCES FRAMEWORK

Intended GP Outcome: Strategic Plan Outcome 3: Countries have strengthened institutions to progressively deliver universal access to basic services.				
GP Outcome indicators: Number of countries with strengthened capacity in accessing and delivering new global health technologies for Neglected Tropical Diseases (NTDs), Tuberculosis (TB), Malaria and other diseases. Baseline; 0 Target: 4				
Applicable Key Result Area (from 2014-2018 UNDP Strategic Plan): Outcome 3, Output 3.3: National institutions, systems, laws and policies strengthened for equitable, accountable and effective delivery of HIV and related services See also 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 partner with the WHO/TDR and PATH, a leading NGO in health and other technical partners as required. UNDP will act as Project Manager, with WHO/TDR and PATH contributing complimentary technical skills for a full range of capacity building activities. Total budget amount: Approximately US$3.5 million annually for 4 years.				
Project title and ID (ATLAS Award ID): Capacity Development for Access and Delivery of New Global health technologies for NTDs, TB, Malaria, and other Diseases				
INTENDED OUTPUTS	**OUTPUT TARGETS FOR (2014-2018)**	**INDICATIVE ACTIVITIES**	**RESPONSIBLE PARTIES**	**INPUTS**
Access and Delivery **Output 1** Legal and policy frameworks strengthened in target LMICs to expedite access and delivery of new global health technologies for NTDs, TB, Malaria, and other diseases. *Indicators:* *1. # of polices and laws reviewed/finalized per LMIC* *Baseline: 1 in Indonesia, 1 in Tanzania and 2 in Ghana* *Target: 3 per target country* *2. # of R&D learning networks established (disaggregated by LMIC)* *Baseline: 0* *Target: 1 per region* *3. # of stakeholders trained on:*	**Targets Years 1 to 4:** • Establishing R&D learning networks between countries and development partners • Developing stakeholder capacity on innovation models • Capacity development on IP, licensing, and enabling legal environment. • Technical assistance to public sector R&D organizations in country and region to develop R&D capacity • Capacity development on negotiating technology transfer agreements	**Activity Results:** • Establish networks between eligible R&D learning centers and partners • Develop capacity on innovation models, intellectual property and enabling legal environment • Develop capacity for government officials and research institutes to negotiate licensing and technology transfer agreements • Develop an implementation action plan to enact legal, policy and regulatory environments that facilitate access and delivery of new health technologies **Actions:** • Arranging meeting between eligible research centers in target LMICs and partners • Trainings on various forms of innovation (from publications, data sharing, material transfer and patent licensing) • Establishing mechanisms and networks to	UNDP and relevant technical partners	$2,300,000

i) licensing *ii) Innovation models* *iii) Intellectual property* *iv) Enabling legal and regulatory environments that promote R&D* *Baseline: 0* *Target: 10 per target country* *4. # of mechanisms/networks created for knowledge sharing and skills transfer* *Baseline: 0* *Target: 1 per target country*		ensure knowledge sharing, skills transfer, and promotion of communities of practice. • Trainings on IP management, development oriented licensing agreements and enabling legal environment to promote R&D • Trainings between LMICs and developing partners on enabling legal and regulatory environment conducive to developing R&D capacity • Review of policy and legal coherence		
Output 2 Capacity of selected LMICs strengthened in identifying country specific needs for new global health technologies, potential market size, and patient perspective**.** *Indicators:* *1. # of country health systems assessments finalized* *Baseline: 0* *Target: 1 per target country* *2. #of country plans developed to address health system needs* *Baseline: 0* *Target:1 per target country* *3. # of trainings held (including # and type of participants in each training) on:* *i. health system assessment*	**Targets Years 1 to 4:** • Assisting countries to identify and review existing data to estimate the burden of disease. • Identifying needs for additional evidence and/or country specific information needs. • Assisting target LMICs to develop a plan to address information needs. (This may include demonstration projects of the product in the country.) • Identify product decision making process (in collaboration with Output 1). • Implementation of study plans • Assist countries in the interpretation of the results of the study and facilitate the decision making and implementation planning. • Strengthen the ability of countries to develop an	**Activity Results:** • Review and interpret country data • Assess Country health systems related to potential implementation of target products • Conduct demonstration projects of target products within country. • Assist in the development of Product specific national policy support **Actions** • Strengthen capacity in epidemiological data review and interpretation. • Promote participation of women in decision making and activities • Provide technical training in health systems assessment related to potential implementation of scenarios of target products. • Strengthen capacity in identification of country specific data needs and ways to develop a study plan. • Strengthen capacity in design and implementation of market, epidemiological and/or cost studies.	WHO/TDR	$1,200,000

ii. epidemiological and/or cost studies *Baseline: 0* *Target: 4 per target country* *4. # of national policies drafted/developed related to introduced products* *Baseline: 0* *Target: 1 per target country*	introduction and implementation plan of a new product.	• Provide technical assistance in design and implementation of demonstration projects for target products. • Assist countries in developing product specific policy support.		
Output 3 Health sector capacity in selected LMICs strengthened in monitoring and responding to safety issued associated with new global health technologies for TB, Malaria, NTDs, and other diseases. *Indicators:* *1. # of staff from national pharmacovigilance center trained within regional pharmacovigilance network (Tanzania)* *Baseline: 0* *Target: 4 (Tanzania)* *2. Total # of health professionals trained per target country in safety monitoring (Tanzania and Indonesia)* *Baseline: 0* *Target: 100 per target country* *3. # of meetings/workshops/trainings or pilot research project on innovative approaches for safety monitoring* *Baseline: 0* *Target: 2 activities in total involving*	**Targets Years 1 to 4:** • Strengthening stakeholder capacity to monitor and respond to safety issue associated with new health technologies	**Activity Result:** • Develop a roadmap for strengthened pharmacovigilance (PV) • Strengthen government officials' and pharmaceutical industry's capacity on PV **Actions:** • Conduct a situational analysis and assessment of PV capacity in selected LMICs • Trainings on various aspects of PV • Strengthen regional pharmacovigilance network • Pilot innovative approaches for safety monitoring at field level	WHO/TDR and relevant technical partners	$1,000,000

target countries				
Output 4a Capacity of selected LMICs developed in global heath technologies financing mechanisms, including south-south cooperation. *Indicators:* *1. South-south networks on financing global health technologies for NTDs, TB and malaria established (yes/no)* *Baseline: No* *Target: Yes* *2. # of new South-South partnerships established per region in the area of health technologies for TB, malaria and NTDs* *Baseline: 0* *Target: 2 per region* *3. # of meetings/workshops/trainings on HTA conducted in target country* *Baseline: 0* *Target: 4 per target country* *4. # of meetings/workshops/events per target country or region between health recipient countries, regional and political groupings* *Baseline: 0* *Target: 4 per target country or region*	**Targets Years 1 to 4:** • Identifying current gaps for sustainable resource allocation for new global health technologies for TB, Malaria, NTDs and other diseases. • Support development of processes allowing for evidence based and sustainable resource planning for technology introduction	**Activity Results:** • Conduct country situation analysis and assessment of financing mechanisms for NTDs, TB, and Malaria health technologies Provide technical assistance to develop evidence based planning and resource allocation processes new health technologies • Establish and strengthen South-south networks on evidence based resource allocation for global health technologies for NTDs, TB and malaria **Actions:** • Collaborate with country governments to define capacity building needs for health financing • Capacity strengthening on the undertaking of health technology assessments (HTA) • Convening of project recipient countries and leveraging of regional and political groupings to facilitate south-south co-operation in support of evidence based resource allocation • Ongoing planning to define any other technical assistance in support of developing sustainable financing processes for health technologies for TB, malaria and NTDs	PATH, UNDP and relevant technical partners	$1,480,000
Output 4b	**Targets Years 1 to 4:** • Landscaping of population	**Activity Results:** • Strengthen capacity of government	PATH	$1,710,822.92

Capacity of selected LMICs developed on commercialisation, supply and pricing of new global health technologies *Indicator:* *# of meetings/workshops/trainings per target country on commercialisation, supply and pricing of new global health technologies conducted in target countries conducted* *Baseline: 0* *Target: 8 per target country*	need and demand and industry situation for new global health technologies for TB, malaria and NTDs • Strengthen capacity of government official and the private sector in regard to evidence-based decision making for local manufacturing and pricing of new global health technologies.	officials and private sector in decision making in manufacturing and pricing of new global health technologies based on market intelligence, including their country's need/demand, global/regional competition, and size of investment. • Inform government officials of necessary policy alignment to strengthen capacity of local pharmaceutical industry and increase access to medicines. **Actions:** • Conduct industry and market landscape analysis. • Conduct meetings with key stakeholders, including the Ministry of Health officials, to identify areas for priority health technologies and key areas that require capacity development. • Provide technical assistance to strengthen capacity in the key areas.		
Output 5 Selected LMICs' capacity in supply chain and delivery systems of new global health technologies for TB, Malaria, NTDs and other diseases strengthened *Indicators:* *1. # of meetings/workshops/trainings on distribution system readiness conducted in target country* *Baselines: 0* *Targets: 5 per country*	**Targets Years 1 to 4:** • Strengthening stakeholder capacity in strategic supply planning • Strengthening capacity in distribution system readiness	**Activity Results:** • Strengthen capacity of government authorities in evaluation and preparation of distribution system readiness for new global health technologies • Strengthen planning, quantification and procurement practices **Actions:** • Provide technical assistance to determine distribution system readiness. • Develop assessment tools for evaluating supply chain capacity to introduce new health technologies	PATH	$1,400,000

2. # of tools for evaluating supply chain capacity developed *Baselines: 0* *Targets: 2*		• Trainings on supply chain requirements for new global health technologies		
R&D Advisory Services **Output 6:** Policies influencing pharmaceutical innovation and access and delivery of Health Technologies reviewed *Indicator:* *# of policy recommendations developed for GHIT related to increasing access and delivery of health technologies* *Baselines: 0* *Targets: 2*	**Target Years 1 to 4:** • Providing GHIT with substantive inputs on how it's grant making and policies can increase access and delivery upstream and downstream	**Activity Results:** • Greater linkages between grants making by GHIT and impact on access and delivery of health technologies for TB, malaria and NTDs in LMICs achieved **Actions** • Review all grants made by GHIT upon receipt of required information, to assess likely impact on access and delivery. All advice will be completely neutral without any preference whatsoever to a particular product or geography. • Undertake analysis of pipeline of new global health technologies for TB, malaria and NTDs •Undertake analysis of GHIT's policies and their impact on access and delivery of health technologies and make recommendations for their amendment as required.	UNDP and technical partners	$380,000
Output 7: Project Oversight Project is managed efficiently and effectively *Indicators:* *1. Business implementation plan finalized (yes/No);* *baseline: No* *Target: Yes* *2. # of new project partnerships* *Baseline: 0*	**Target Years 1 to 4:** • Develop Project business plan • Strengthen strategic direction of project operations • Build and maintain strong partner relationships • Manage interface with donors • Strengthen resource mobilization from multiple funders • Strengthen financial resource management system	**Activity Result:** • Develop robust Business and implementation Plan • Implement Partnership Agreements implemented • Well informed lead donor (GOJ) • Develop strong network of implementation and project recipient partnerships • Submit Grant applications to additional donors • Ensure strong financial management, conforming to UNDP standards	UNDP/PATH	$960,000

Target: 2 *3. System for financial management strengthened (yes/No)* *Baseline: Yes* *Target: Yes* *4. Timely reporting to donors conducted (yes/No)* *Baseline: Yes* *Target: Yes*		**Actions:** • Work with Advisory Group – partners and LMICs- plus sector thought leaders and civil society, to develop and implement a business and operational plan for global Access & Delivery Project • Work with partners, WHO/TDR, PATH and other technical partners, to implement project activities • Identify potential new funders • Develop and submit grant applications to potential funders • Strengthen systems for financial management and administration • Co-ordinate project reporting of partners to donors and undertake regular audits		

*Results and Resources Framework will be reviewed and revised annually before the commencement of each year's activity. Note that a comprehensive M&E framework will be developed in Year 2.

**** 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/TDR
*Additional information from WHO/TDR on staffing will be clarified shortly

3. PATH
* Additional information from PATH on staffing will be clarified shortly

IV. Annual Work Plan: 2014-2015
Year 1: 1 July 2014-15 May 2015

EXPECTED OUTPUTS	PLANNED ACTIVITIES List activity results and associated actions	TIMEFRAME				RESPONSIBLE PARTY	PLANNED BUDGET		
		Q1	Q2	Q3	Q4		Funding Source	Budget Description	Amount
Output 1 Legal and policy frameworks strengthened in target LMICs to expedite access and delivery of new global health technologies for NTDs, TB, Malaria, and other diseases. *Indicators:* *1. # of polices and laws reviewed/finalized per LMIC* *Baseline: 1 in Indonesia, 1 in Tanzania and 2 in Ghana* *Target: 3 per target country* *2. # of R&D learning networks established (disaggregated by LMIC)* *Baseline: 0* *Target: 1 per region* *3. # of stakeholders trained on:* *i) licensing* *ii)Innovation models* *iii) Intellectual property* *iv) Enabling legal and regulatory environments that promote R&D* *Baseline: 0* *Target: 10 per target country* *4. # of mechanisms/networks created for knowledge sharing and skills transfer* *Baseline: 0* *Target: 1 per target country*	**Activity Result** ▪ R&D learning networks established between target countries and development partners ▪ Stakeholder capacity developed on innovation policy and models ▪ Stakeholder capacity strengthened on IP, licensing negotiations and enabling legal environment **Activity Action in Asia:** ▪ Conduct regional review of policy coherence (using the common research template as Africa) ▪ Conduct review of domestic legal and policy environment in target countries ▪ Establishment of national task force on integrating R&D and access to affordable health technologies ▪ Organize capacity building and training workshop(s) for patent examiners **Activity Action in Africa:** ▪ Awareness raising/advocacy at international public health events ▪ Conduct a regional study on innovation and local pharmaceutical production in Africa ▪ Organize a regional meeting to establish R&D networks between select African countries ▪ Organize a national capacity development trainings on innovation models, licensing and enabling legal /regulatory environments	X X X X X X	X X X X X X	 X X X	 X X X	UNDP	GOJ	▪ In-country consultant support in target countries **Asia** ▪ Regional review on policy coherence ▪ National review of legal and policy environment in 2 target countries ▪ Patent examiner workshop(s)] **Africa** ▪ Consultant support on Africa activities Regional study on innovation and pharmaceutical production ▪ Regional meeting for R&D networks ▪ National capacity development trainings	**$577,450**

Output 2 Capacity of selected LMICs strengthened in identifying country specific needs for new global health technologies, potential market size, and patient perspective**.** *Indicators:* *1. # of country health systems assessments finalized* *Baseline: 0* *Target: 1 per target country* *2. #of country plans developed to address health system needs* *Baseline: 0* *Target:1 per target country* *3. # of trainings held (including # and type of participants in each training) on:* *i. health system assessment* *ii. epidemiological and/or cost studies* *Baseline: 0* *Target: 4 per target country* *4. # of national policies drafted/developed related to introduced products* *Baseline: 0* *Target: 1 per target country*	**Activity Result** In select countries: ▪ Strengthened capacity to identify and review existing data to estimate burden of disease ▪ Needs for additional data and evidence identified ▪ Strengthened capacity to promote women's participation in activities relating to Output 2 **Activity action** ▪ 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 ▪ Organize 2 stakeholder consultations to review existing information, assess needs and identify barriers/bottles necks in scale up and effective use of health technologies ▪ 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.	X X	X X	X X	X X	WHO/TDR	GOJ	▪ Training courses for skills development ▪ Stakeholder consultations for scale up and effective use of health technologies	**$302,451**

Output 3 Health sector capacity in selected LMICs strengthened in and responding to safety issued associated with new global health technologies for TB, Malaria, NTDs, and other diseases. Indicators: *1. # of staff from national pharmacovigilance center trained within regional pharmacovigilance network (Tanzania)* *Baseline: 0* *Target: 4 (Tanzania)* *2. Total # of health professionals trained per target country in safety monitoring (Tanzania and Indonesia)* *Baseline: 0* *Target: 100 per target country* *3. # of meetings/workshops/trainings or pilot research project on innovative approaches for safety monitoring* *Baseline: 0* *Target: 2 activities in total involving target countries*	**Activity Result** In select countries: ▪ Strengthened health sector capacity for monitoring and responding to safety issue of newly introduced health technologies (medicines and diagnostics) ▪ Engagement in regional or global pharmacovigilance networks **Actions** ▪ Organize 1 stakeholder consultations for needs and capacity assessment and sensitization of resource persons in target countries ▪ Organize courses for health sector on pharmacovigilance ▪ Organize training for key staff of the national pharmacovigilance cetner ▪ Facilitate linkages with WHO programme for international drug monitoring and other similar bodies for continuous learning and improvement	 X X	 X X X	 X X X	 X X	WHO/TDR		▪ Stakeholder consultations for needs and capacity assessment ▪ Trainings on pharmacovigilance ▪ Workshop in innovative approaches for safety monitoring	**$262,451**

Output 4a Capacity of selected LMICs developed in global heath technologies financing mechanisms, including south-south cooperation. Indicators: *1- South-south networks on financing global health technologies for NTDs, TB and malaria established (yes/no)* *Baseline: No* *Target: Yes* *2. # of new South-South partnerships established per region in the area of health technologies for TB, malaria and NTDs* *Baseline: 0* *Target: 2 per region* *3. # of meetings/workshops/trainings on HTA conducted in target country* *Baseline: 0* *Target: 4 per target country* *4. # of meetings/workshops/events per target country or region between health recipient countries, regional and political groupings* *Baseline: 0* *Target: 4per target country or region*	**Activity Result** In select countries: ▪ Capacity developed for assessment of country capacity and options for funding of new global health technologies for TB, Malaria, NTDs and other diseases **Actions** ▪ 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 [cont'd in Year 2]	X X X	 X	 X	 X	PATH UNDP	GOJ	▪ Study on existing R&D financing mechanisms ▪ Study on new R&D mechanisms ▪ Situation analysis on financing policy in target countries ▪ Analysis of financial bottlenecks ▪ Plan of action for capacity development Capacity building workshops	**$322,451**

Output 4b Capacity of selected LMICs developed on commercialisation, supply and pricing of new global health technologies Indicator: *# of meetings/workshops/trainings per target country on commercialisation, supply and pricing of new global health technologies conducted in target countries conducted* *Baseline: 0* *Target: 8 per target country*	**Activity Result:** In select countries: ▪ Tools developed and pilot tested to assess demand/market for potential new global health technologies for use by target countries and partners ▪ Generic tools developed to assess country's existing conditions to support local manufacturing of new health technologies and to assess manufacturing capacities **Actions** ▪ Gather and review existing tools, including through literature review and survey of PATH and other relevant PDPs ▪ Develop appropriate assessment tools for adoption and uptake of potential new technologies (as identified by Output 6) ▪ Organize consultation meeting with key stakeholders to obtain feedback on feasibility of the tools ▪ Adopt plan for piloting application of the tools in one or two target countries	X X	 X	 X X X	 X	PATH	GOJ	▪ Review and survey of existing tools ▪ Assessment tool for adoption and uptake of new technologies ▪ Stakeholder consultation meeting ▪ Action plan for pilot implementation ▪ In country consultancy support	**$382,451**

Output 5 Selected LMICs' capacity in supply chain and delivery systems of new global health technologies for TB, Malaria, NTDs and other diseases strengthened Indicators: *1. # of meetings/workshops/trainings on distribution system readiness conducted in target country* *Baselines: 0* *Targets: 5 per country* *2. # of tools for evaluating supply chain capacity developed* *Baselines: 0* *Targets: 2*	**Activity Result** In select countries: ▪ Stakeholder capacity in strategic supply forecasting strengthened ▪ Stakeholder capacity in procurement of new technologies strengthened ▪ Capacity in distribution system readiness strengthened **Actions** ▪ Produce framework and technical paper on Pathways to Procurement for New Technologies ▪ Create supply systems assessment tool for adoption of new technologies ▪ Organize workshops on strengthening supply systems for introduction of new health technologies in target countries	X X X	X X	X	X	PATH	GOJ	▪ Framework and technical paper on procurement pathways ▪ Systems assessment tool for adoption of new technologies National supply capacity assessments in target countries ▪ Workshops on strengthening supply systems for introduction of new health technologies	**$392,451**
Output 6 Policies influencing pharmaceutical innovation and access and delivery of Health Technologies reviewed Indicator: *# of policy recommendations developed for GHIT related to increasing access and delivery of health technologies* *Baselines: 0* *Targets: 2*	**Activity Result** ▪ Policy framework developed for enhanced access and delivery of emerging health technologies for global health, focusing on products from public-private partnerships ▪ Strategic interventions identified to improve access and delivery within a range of technology landscapes **Actions** ▪ Produce advisory report(s) on impact of upstream decisions in R&D pipeline on downstream access and delivery ▪ Mapping of catalytic interventions including piloting of approaches to pharmaceutical innovation that enable delivery of affordable health technologies in LMICs ▪ Analyze in conjunction with relevant partners, bottle necks and opportunities for changing the enabling policy environment for pharmaceutical innovation	X X X	X X X	X X X	X X X	UNDP	GOJ	▪ Advisory report(s) on impact of upstream decisions ▪ Interventions map and pilot approaches ▪ Analysis of bottlenecks and opportunities for pharmaceutical innovation ▪ Pipeline analysis of new global health technologies for NTDs, TB and malaria	**$80,000**

Output 7 Project is managed efficiently and effectively Indicators: *1. Business implementation plan finalized (yes/No);* *baseline: No* *Target: Yes* *2. # of new project partnerships* *Baseline: 0* *Target: 2* *3. System for financial management strengthened (yes/No)* *Baseline: Yes* *Target: Yes* *4. Timely reporting to donors conducted (yes/No)* *Baseline: Yes* *Target: Yes*	**Activity Result** ▪ Strengthened strategic directions for project implementation ▪ Strong partner relationships developed and built **Action** ▪ Organize 3 Project Partners meetings for development, coordination and implementation of work plan ▪ Organize 1 Advisory Group meeting ▪ Develop and implement communications strategy ▪ Develop monitoring and evaluation plan ▪ Project management and coordination (incl. implement resource mobilization strategy)	X X X X	X	X X	X X	UNDP PATH	GOJ	▪ Partners meetings + technical briefing ▪ Advisory Group meeting ▪ Communications consultant] ▪ M&E consultant ▪ Project management and coordination support ▪ Audit fees	**$288,000**

Note: AWP will be reviewed and revised annually before the commencement of each year's activity. The project period for Year 2 is from 16 May 2015 to 31 March 2016, for Year 3 is from 1 April 2016 to 31 March 2017 and for Year 4 is from 1 April 2017 to 31 March 2018 respectively.

Access and Delivery Summary Budget 2014-2018:

			Government of Japan	UNDP Contribution
Requested Total for Years 1-4 Capacity Building			US$ 13, 712 047	$507, 204.00
Capacity Building in select Countries: (see budget notes)				
Project Oversight with operational business plan, partnership agreements, and resource mobilization for building access and delivery capacity in select LMICs.	$960,000			
1. Strengthen legal and policy frameworks to expedite access and delivery of new global health technologies for TB, Malaria, NTDs and other diseases	$2,300,000			
2. Strengthen capacity for epidemiological study review and market needs assessment	$1,200,000			
3. Strengthen health research capacity in monitoring of Phase IV trials	$1,000,000			
4a. Strengthen capacity within LMIC Government to ensure the financing for new global health technologies	$1,480 000			
4b. Build capacity on commercialisation to ensure that new global health technologies are priced appropriately, and supply meets population demand	$1,710,822.90			
5. Strengthen capacity of delivery systems including supply chain of new global health technologies for TB, Malaria, NTDs and other diseases	$1,400,000			
6. Robust review of grant applications to determine if the proposed product is viable for access and delivery in LMICs	$380,000			
Sub Total for Advisory and Capacity Building Activities (A)			**$10,430,822.92**	
Staff Costs (Breakdown)				
Level	**Salary/yr**	**Time**		
Director Level 1 in New York	$326,168.09	30%		$391,401.72
P5 l in Bangkok	$279,491.48	100%	$1,117,965.90	
P3 in New York	$197,228.34	100%	$788,913.36	
General Staff G6 in New York	$96,501.90	30%		$115, 802.28
Sub Total for Staff (B)			**$1,906,879.26**	**$507, 204.00**
UNDP corporate:				
General Management Services			$1,096,963.76	
Implementation Support Services (for UNDP's portion only)			$277,381.07	
Sub Total (C)			**$1,374,344.83**	
GRAND TOTAL BUDGET (A) + (B) + (C)			**$ 13 712 047.01**	**$507, 204.00**

Notes:

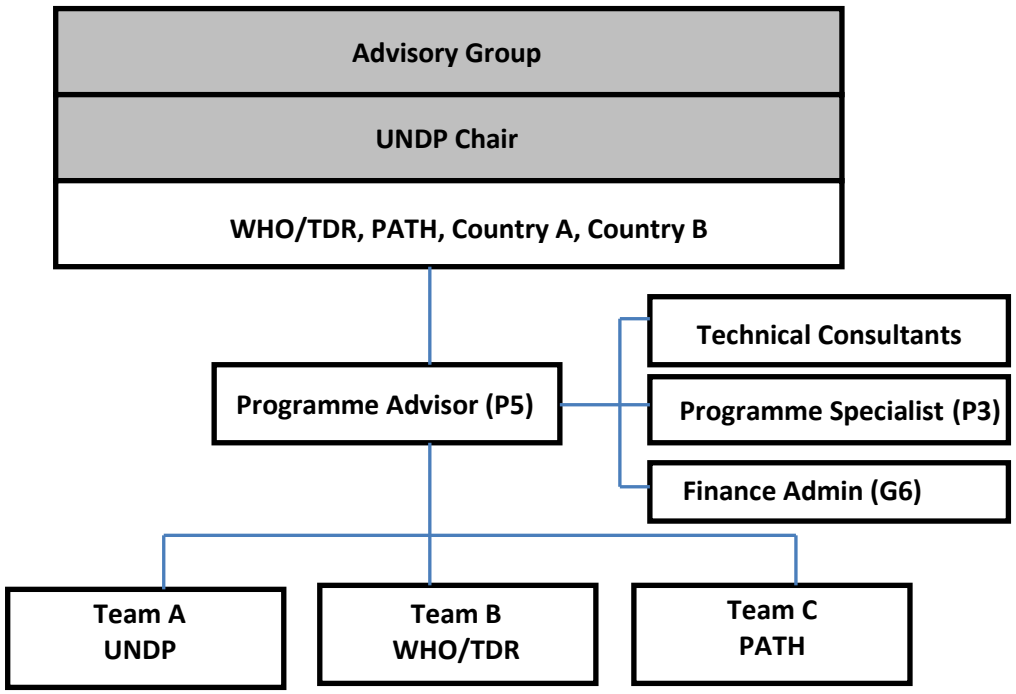
1) Figures based on estimated numbers from UNDP, PATH, and WHO. Costs will vary depending on selected countries

2) The estimated costs will need to be refined during the course of project development

3) UNDP plans to build capacity in 4 countries for greater impact. Additional funds will be required for this.

V. MANAGEMENT ARRANGEMENTS

Access and Delivery
Advisory Group Structure



- **Project Implementation Modality**

Using UNDP's NGO implementation (execution) modality, PATH will be implementing the project, together with WHO/TDR and UNDP as the responsible parties. Under this modality, PATH, WHO/TDR and UNDP will be responsible for the implementation of their assigned components of the project. UNDP's HIV, Health and Development Practice will oversee the project on a day-to-day basis, with support of the Advisory Group, and in collaboration with Partner Country offices. The Advisory Group will be responsible for providing the implementing partners with strategic direction on the project, the proposed design of project activities and risk management of the proposed project activities.

UNDP will serve as the Project Manager of the Global Access and Delivery Project, thereby chairing the Advisory Group. The Advisory Group will comprise of UNDP (BPPS, a representative of BERA or a Regional Bureau), WHO/TDR, PATH, representatives with key experience and substantive knowledge on various aspects of the Access and Delivery Partnership and representatives of regional economic communities, patient groups and/or developing country institutions. The Programme Advisor assigned by BPPS will report to the Chair of the Advisory Group, UNDP's Director of HIV, Health and Development. The Programme Advisor will oversee the technical advisory services both for GHIT and the recipient countries, as well as partnership relationships and the management of financial resources. Supervised by the Programme Advisor, the Programme Specialist assigned by BPPS will be responsible for financial and project management. Project assurance will be done according to UNDP modalities.

- **Roles and responsibilities of Advisory Group**

The Advisory Group will provide policy guidance, review progress on a periodic basis in terms of the delivery of project results and benefits, and providing guidance on risk management to ensure that project milestones are managed and completed.

The Advisory Group will be composed of:

- Representative from the BPPS HIV, Health and Development Group (Chair);

- Representatives with key experience and substantive knowledge on various aspects of the Access and Delivery Partnership (Senior Suppliers)
- Representatives of regional economic communities, patient groups and/or developing country institutions (Senior Beneficiaries)
- UNDP representative (Ex officio)
- PATH representative (Ex officio)
- WHO/TDR representative (Ex officio)

Additional members may be invited at the discretion of the Advisory Group. The Advisory Group will meet virtually or physically at least once per year. The Programme Advisor will act as secretariat for the committee, being responsible for convening the meetings, preparing the agenda and overseeing preparation of materials for presentation to the meeting and for preparing and distributing minutes of the meetings. If the Advisory Group meeting does not take place virtually or physically, the Programme Advisor will ensure that consultation is carried out with the Advisory Group members.

The Programme Advisor (P-5) and Programme Specialist (P-3) assigned and managed by BPPS will be responsible for delivering the two interlinked projects "GHIT: Research and Development (R&D) of New Global Health Technologies for TB, Malaria, NTDs and other Diseases for Patients and Citizens of LMICs" and "Building Capacity for Access and Delivery of New Global Health Technologies for TB, Malaria, NTDs, and other Diseases in LMICs" within UNDP. They are responsible for project delivery by supervising the activities in the selected program countries on a day-to-day basis communication with country operations. They will coordinate with GHIT project that deals with medicine development by the PCA framework by communicating with the Project Manager assigned by GHIT. They will communicate closely with BERA/RPC/Japan Unit and concerned Regional Bureaux.

Visibility

The executing agency will make every effort to identify UNDP and the Government of Japan as the partners and disseminate information about this project program whenever possible. The following visibility actions are incorporated and will be taken into action:

- Banners including the collaborating partners logo in all seminars/ workshops
- Material depicting the collaborating partners logo 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 the beginning of Year 2, a Monitoring and Evaluation framework will be jointly developed and agreed by the project partners. Each partner will be responsible for monitoring its own contribution at the output level; however, the overall outcome will be monitored by all the partners. One of the partners will be assigned the responsibility to coordinate among the partners.

For UNDP outputs, 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 (to be complete following the signing of the Project Document).
- An Issue Log shall be activated in Atlas and updated by the Programme Manager to facilitate tracking and resolution of potential problems or requests for change.
- Based on the initial risk analysis submitted (see annex 1), 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 Programme Advisor to the Advisory 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 Programme Advisor and shared with the Advisory Group. As a minimum requirement, the Annual Review Report shall consist of the Atlas standard format for the Quarterly Progress Report (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 Advisory Group 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.

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 SBAAs 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 executed by UNDP, WHO/TDR and PATH 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

Risk Analysis.

OFFLINE RISK LOG

Project Title: Access and Delivery Partnership 2014-2018	**Award ID:**	**Date:** 8 August 2014

#	Description	Date Identified	Type	Impact & Probability	Countermeasures / Mgt response	Owner	Submitted, updated by	Last Update	Status
1	GHIT may not have products ready for Phase IV or country access in Year 2, 2015.	1 March 2013	Operational	P= 4 I = 3	• UNDP has commenced with capacity strengthening activities in three LMICS to prepare not only for possible products funded by GHIT, but for potential health technologies in the innovation pipeline generally.				
2	GHIT may not produce products for Phase IV access and delivery in the next four years.	1 March 2013	Operational	P= 4 I = 3	• By building capacity in select 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	1 March	Legal	P = 4	• UNDP cannot participate				

	of UNDP to influence GHIT's operational and management decision-making	2013		I = 2	on any of GHIT's executive or management structures, either in a voting or non-voting role. Advisory Services will be provided directly to the GHIT CEO and Board directly.				
4	UNDP being incorrectly understood as a donor	1 March 2013	Political	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. P= 3 I = 4	• 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 with GHIT is to raise issues affecting LMICs by providing advisory services to GHIT and capacity development to LMICs.				
5	Insufficient funding to purchase new global health technologies once introduced	1 March 2013	Operational	Need for health financing resources. P= 3 I= 5	• 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	1 March 2013	Operational	While GHIT was established a year ago, it has secured a strong	• To be justified through an unqualified audit report.				

	GHIT, which is a recently established organization			reputation as a PDP through the direct involvement and support by Government of Japan, the Gates Foundation and has established a high profile Advisory Broad of eminent experts in the field P= 3 I = 3					
7	New global health technologies are not affordable for LMICs.	1 March 2013	Operational	New global health technologies must be affordable for developing countries. P = 3 I = 5	• The Access and delivery Partnership will strengthen the capacity of LMIC governments to control and reduce the cost of health technologies and to negotiate and conclude licenses where the supplier of health technologies is the sole, or one of a limited number of producers				