



THE ACCESS AND
DELIVERY PARTNERSHIP

New Health Technologies for TB, Malaria and NTDs

STATUS REPORT 2018



*Empowered lives.
Resilient nations.*



From the People of Japan

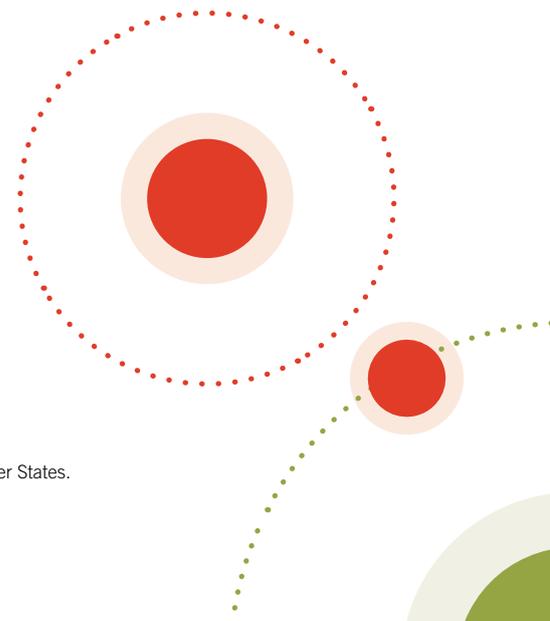
The ADP partners

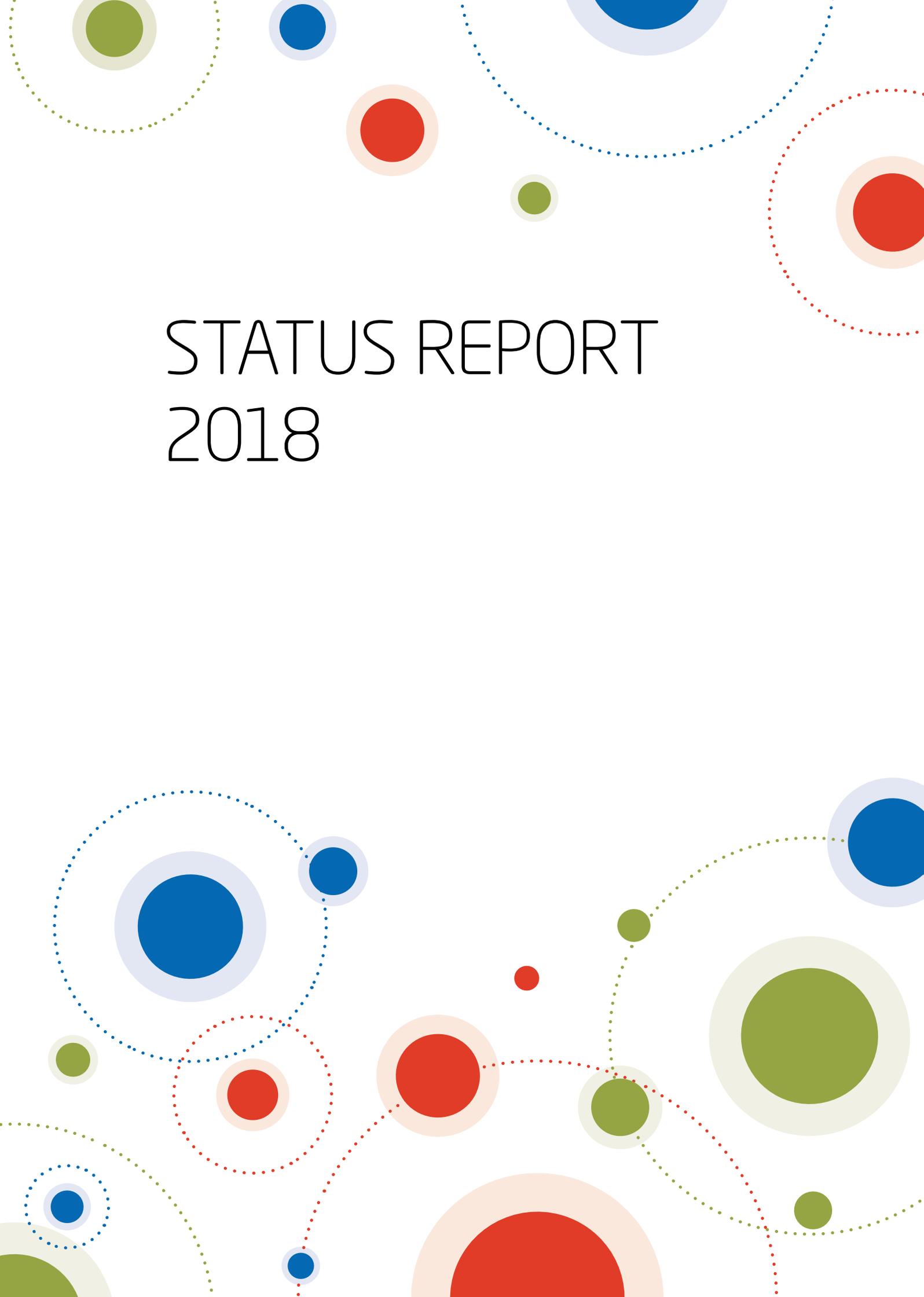
The **United Nations Development Programme (UNDP)** partners with people at all levels of society to help build nations that can withstand crisis, and to drive and sustain the kind of growth that improves the quality of life for everyone. On the ground in more than 170 countries and territories, UNDP offers a global perspective and local insight to help empower lives and build resilient nations.

The **Special Programme for Research and Training in Tropical Diseases (TDR)** is a global programme of scientific collaboration that helps facilitate, support and influence efforts to combat diseases of poverty. It is hosted at the World Health Organization (WHO), and is sponsored by the United Nations Children's Fund (UNICEF), UNDP, the World Bank and WHO.

PATH is an international non-governmental organization that drives transformative innovation to save lives and improve health, especially for women and children. PATH works to accelerate innovation across five platforms — vaccines, drugs, diagnostics, devices, and system and service innovations — that harness entrepreneurial insight, scientific and public health expertise, and passion for health equity. Working together with countries, PATH delivers measurable results that disrupt the cycle of poor health.

The collaboration between the **Government of Japan** and UNDP is a strategic partnership to promote R&D and to increase access to and delivery of health technologies used to address NTDs, TB and malaria.



The background of the page is a white canvas decorated with an abstract pattern of colorful circles and dotted lines. The circles are in shades of blue, red, green, and light grey, and vary in size. Some are solid, while others have a lighter, semi-transparent outer ring. Dotted lines in blue, red, and green connect the circles, creating a network-like structure. The overall aesthetic is clean, modern, and geometric.

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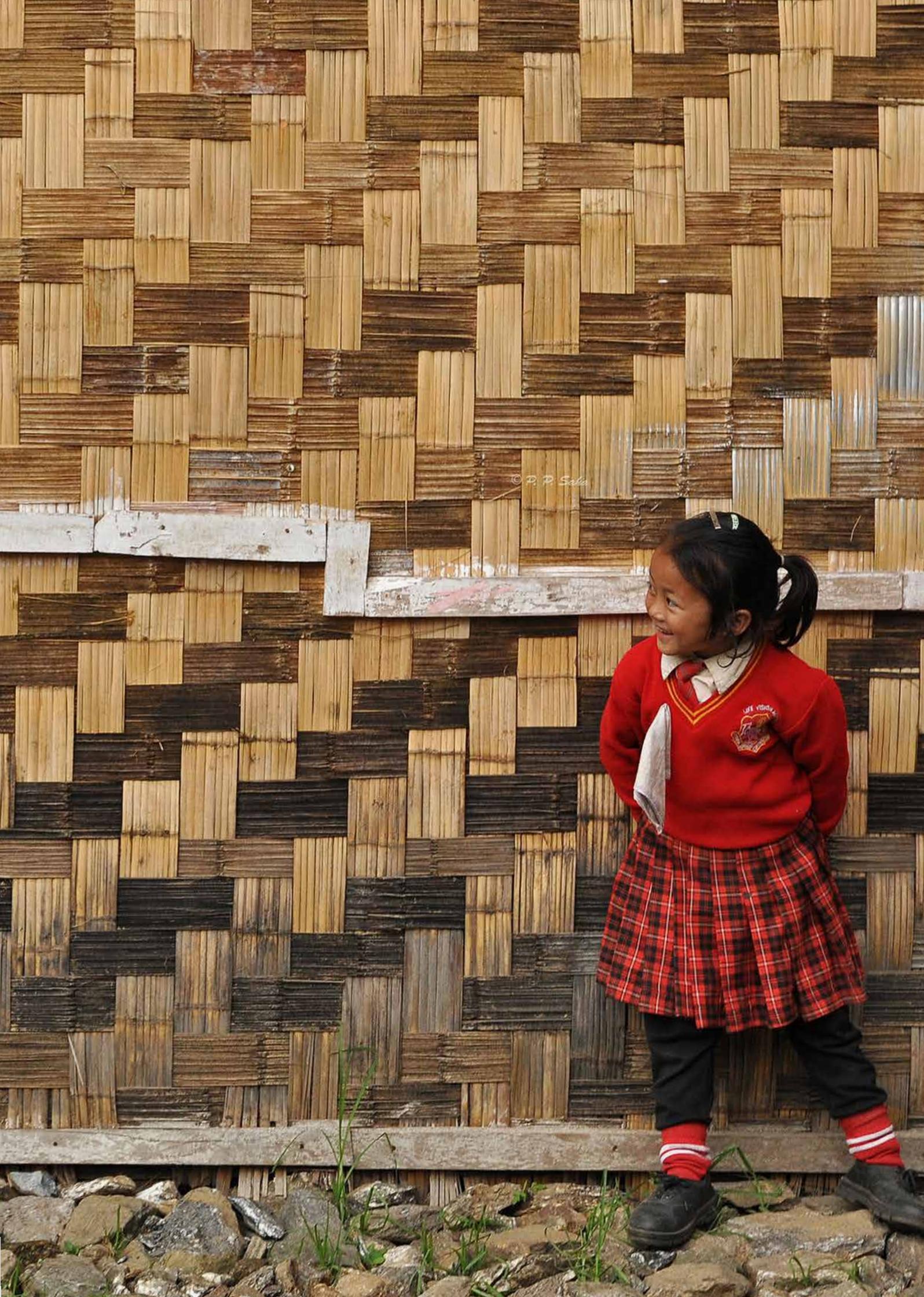
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Foreword

“Leaving no one behind”, the unifying pledge of Agenda 2030 and its Sustainable Development Goals, inspires scrutiny of global health initiatives through the lens of equity. It is no longer sufficient to assess health and development needs or progress by simply monitoring the burden of disease or population-based life expectancy.

Nor can we rank health interventions according to their broad cost-effectiveness or impact on anonymized disability-adjusted life years. A focus on equity requires us to engage from the perspective of fairness, social justice and universality.

The target of *universal* health coverage – including “financial risk protection, access to quality essential health-care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all” (SDG target 3.8) – epitomizes the principles of equity and universality in which the SDGs are grounded. As with the adoption of the SDGs, the pursuit of UHC is ultimately a political choice. But it also requires a fundamental redefinition of what comprises an ‘enabling environment’.

Leaving no one behind ultimately requires health systems are sufficiently robust to include the most vulnerable and key populations in society. Latest figures confirm that this remains a distant goal in many countries. Despite recent progress, over 500 million people in need of preventive chemotherapy for NTDs do not have access. Only one-in-ten of those with multidrug-resistant TB receive treatment. Estimates also show that each year more than one-tenth of households globally incur out-of-pocket health costs exceeding 10% of their total income. To fill these gaps and make significant progress towards UHC by 2030, countries can make better use of South-South learning and exchange with peers with similar health-related, political and economic contexts.

This report outlines some of the main ways the Access and Delivery Partnership (ADP) has supported focus countries on this journey. Over the five years, ADP has helped low- and middle-income countries identify, strengthen and ‘connect the dots’ between the policies, human capacities, systems and regulations that are essential to ensuring access to medicines, vaccines and diagnostics. ADP also provides a link to the efforts to stimulate health R&D and innovation through its on-going collaboration with the Global Health Innovative Technology (GHIT) Fund.

The United Nations Development Programme (UNDP) commends the Government of Japan for its strategic vision in supporting both the GHIT Fund and ADP. Promoting R&D of health technologies, alongside facilitating their access and delivery ensures that new medicines, vaccines and diagnostics ultimately reach the people who need them. Our shared conviction that health and development are mutually reinforcing joins us in our efforts work towards progress in both as the foundation for the achievement of human security.

From 2018 to 2023, ADP has ambitious plans to scale up the impact, scope, coverage and sustainable development. To help achieve this, the current core partners – UNDP, the Special Programme for Research and Training in Tropical Diseases (TDR) and PATH – will be joined by the World Health Organization (WHO) as a new and key partner.

We hope the report provides an accessible summary of ADP’s efforts to date, and that it inspires you to join us in supporting countries as they make progress towards UHC and deliver on their pledge to leave *no one* behind.

W. Dhaliwal

Dr Mandeep Dhaliwal
Chair of the ADP Advisory Group
Director, HIV, Health and Development Group
Bureau of Policy and Programme Support, UNDP

Abbreviations

ADP	Access and Delivery Partnership	MoLHR	Ministry of Law and Human Rights (Indonesia)
ADR	adverse drug reaction	MPPR	Medicines policy and regulatory reforms
AMA	African Medicines Agency	NEML	National Essential Medicines List
AMRH	African Medicines Regulatory Harmonization	NEPAD	New Partnership for Africa's Development
ASEAN	Association of Southeast Asian Nations	NHIS	National Health Insurance Scheme
BPOM	<i>Badan Pengawas Obat dan Makanan</i> (Indonesian National Agency for Drug and Food Control)	NIHRD	National Institute of Health Research and Development (Indonesia)
CFGEC	Community Development, Gender, Elderly and Children (MOH Tanzania)	NICE	National Institute for Health and Care Excellence (UK)
COSTECH	Commission for Science and Technology (Tanzania)	NMP	National Medicines Policy
ESRD	end-stage renal disease	NTD	Neglected tropical disease
FDA	Food and Drug Administration	P2JK	<i>Pusat Pembiayaan dan Jaminan Kesehatan</i> (Indonesia Centre of Health Insurance)
GHIT Fund	Global Health Innovation and Technology Fund	PDP	Product development partnership
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria	PMDA	Pharmaceutical and Medical Devices Agency (Japan)
HITAP	Health Intervention and Technology Assessment Programme (Thailand)	PRICELESS	Priority Cost Effective Lessons for System Strengthening (South Africa)
HTA	Health Technology Assessment	PSU	Pharmaceutical Services Unit (Tanzania)
iDSI	International Decision Support Initiative	PV	Pharmacovigilance
IR	implementation research	R&D	research and development
JICA	Japan International Cooperation Agency	SDG	Sustainable Development Goal
JKN	<i>Jaminan Kesehatan Nasional</i> (Indonesian National Health Insurance Scheme)	STG	Standard treatment guidelines
KPPU	<i>Komisi Pengawas Persaingan Usaha</i> (Indonesian National Competition Authority)	TB	Tuberculosis
LKPP	<i>Lembaga Kebijakan Pengadaan Barang Jasa Pemerintah</i> (Indonesian National Public Procurement Agency)	TDR	Special Programme for Research and Training in Tropical Diseases
LMIC	Low- and middle-income country	TFDA	Tanzania Food and Drug Authority
M&E	monitoring and evaluation	TWG	Technical working group
MDA	Mass drug administration	UGM	Universitas Gadjah Mada
MDR-TB	Multidrug-resistant tuberculosis	UHC	Universal health coverage
MOH	Ministry of Health	UNDP	United Nations Development Programme
		WHO	World Health Organization







The evolving global health context

The foundational frameworks of global health and sustainable development have undergone a dramatic evolution in recent years. Many of the factors that threaten health and well-being, and cause illness and death, are increasingly acknowledged as being beyond individual control.¹ The myriad social, economic and commercial determinants of health that affect communities and populations can lead to alarming inequities in access to health care and preventive services. Overcoming such challenges requires coordinated efforts and systemic change. Strong, sustainable and resilient health systems are critical to protect the health, well-being and economic productivity of populations.

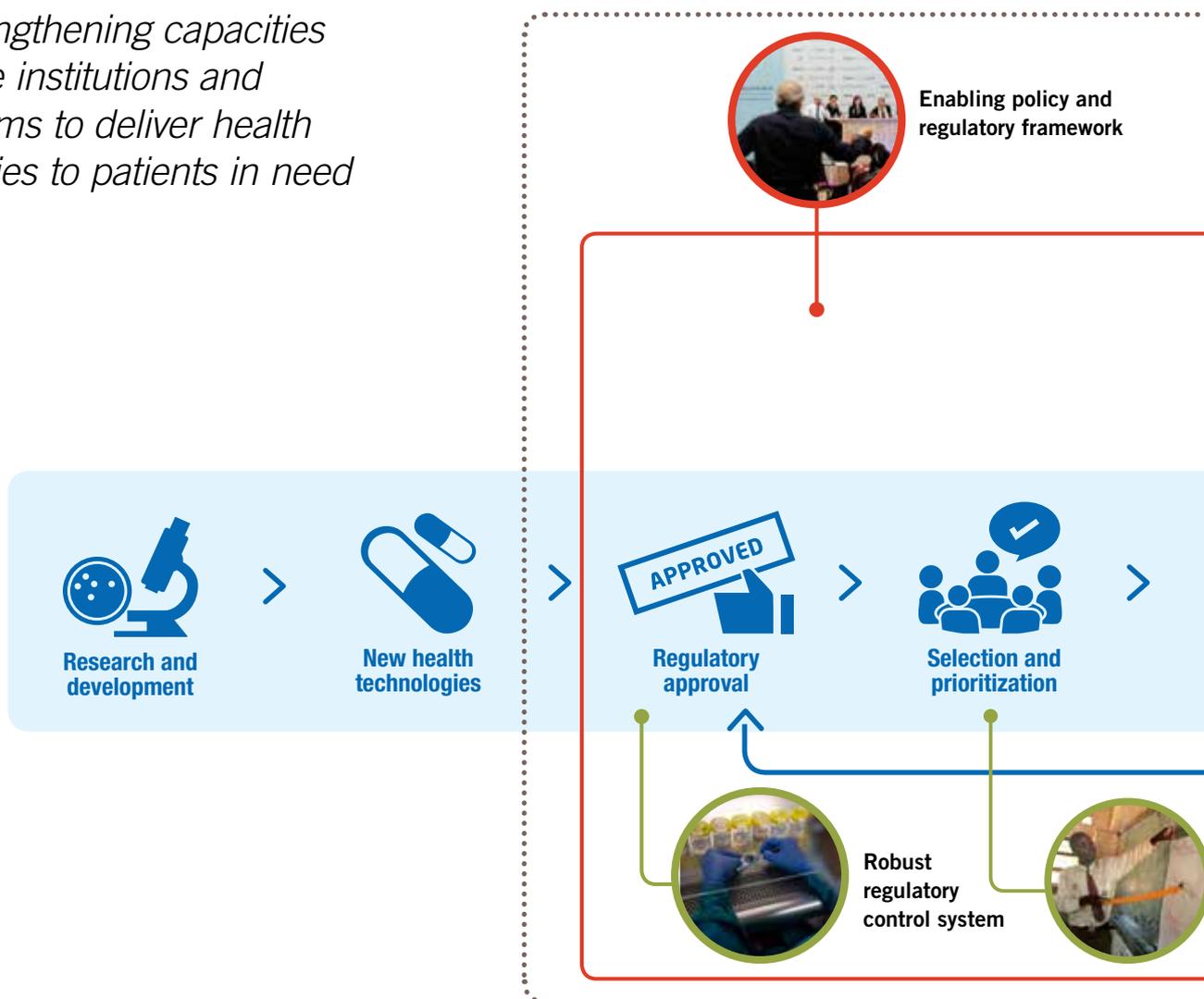
Health as the foundation of prosperity and security was recognized in the *Basic Design for Peace and Health* of the Government of Japan.² This framework for global health cooperation formed the guiding precept for the subsequent *Ise Shima Vision for Global Health 2016*, in which the Group of Seven (G-7) leaders set out a road map to scale up global interventions to maximize health impact.³ *The Berlin Declaration of the G20 Health Ministers: Together Today for a Healthy Tomorrow of May 2017* also acknowledged that strong, sustainable and resilient health systems are the basis for prosperous and stable societies.⁴ The United Nations Development Programme (UNDP) Strategic Plan: 2018–2021⁵ and its *HIV, Health and Development Strategy 2016–2021* similarly recognize resilient and sustainable health systems as a critical building block of health and development.

Meeting the goals and targets set out in the 2030 Agenda for Sustainable Development will require substantial strengthening of the means of

implementation and a concerted effort to enhance policy coherence between a range of sectors. Underlying Agenda 2030 is the principle that the 17 Sustainable Development Goals (SDGs) are universal, interlinked and indivisible: progress in one goal will be made only with simultaneous progress in other goals. The inclusion of universal health coverage (UHC) as a specific target of the SDGs underscores the contribution of health and well-being to the overarching goal of achieving equity and meeting the pledge of 'Leaving no one behind'. Yet, UHC also raises complex questions about how, in which order and by whom multiple factors affecting health and its determinants can be best managed, both now and for the future. Similarly, close linkages must be designed between established disease-specific programmes and the integrated systems required to achieve and sustain UHC. Simultaneously, health systems must strive to optimize the mechanisms and efficiencies to ensure that people can access the life-saving health services, medicines, vaccines, and diagnostics that they need. Of itself, UHC is insufficient to achieving health – the test of quality UHC will be in the degree to which optimally suited health services and products reach the most vulnerable and neglected in any society, where they live, and with a minimum burden.

- 1 WHO (2017). Promoting health: Guide to national Promoting health: Guide to national implementation of the Shanghai Declaration.
- 2 Government of Japan. Basic Design for Peace and Health (2015).
- 3 G-7 Ise-Shima Vision for Global Health (2016).
- 4 Berlin Declaration of the G20 Health Ministers (2017).
- 5 UNDP Strategic Plan 2018–2021.

ADP: Strengthening capacities of multiple institutions and mechanisms to deliver health technologies to patients in need



Despite the ambitious goals and targets that United Nations Member States set for themselves, some dimensions of global health have not changed at the same pace. Tuberculosis (TB), malaria, and neglected tropical diseases (NTDs) persist as diseases of poverty and inequality. They disproportionately impact the poorest and most vulnerable people and communities. At the UHC Forum 2017 (Tokyo, 12 to 15 December 2017), new data revealed that half of the world's population still lacked access to essential health services, and 100 million people suffered impoverishment every year as a result of out-of-pocket health expenses.⁵ Achieving UHC requires substantial shifts towards policy coherence, and scaling up partnerships and investments. The Government of Japan is partnering with UNDP through two initiatives that address both sides of the health equation in low- and

middle-income countries (LMICs): promoting research and development (R&D) for unmet health needs; and promoting access and delivery to health care. This strategy demonstrates that policy coherence can be achieved when a defined set of objectives are pursued simultaneously and treated as potential synergies rather than contradictory policy priorities.

The two Government of Japan-UNDP initiatives are described below in more detail:

The Global Health Innovative Technology (GHIT) Fund focuses on investments in the discovery and development of medicines, diagnostics and vaccines (referred to in this report as health technologies) for TB, malaria, NTDs and other diseases. The GHIT Fund supports partnerships and identifies global opportunities

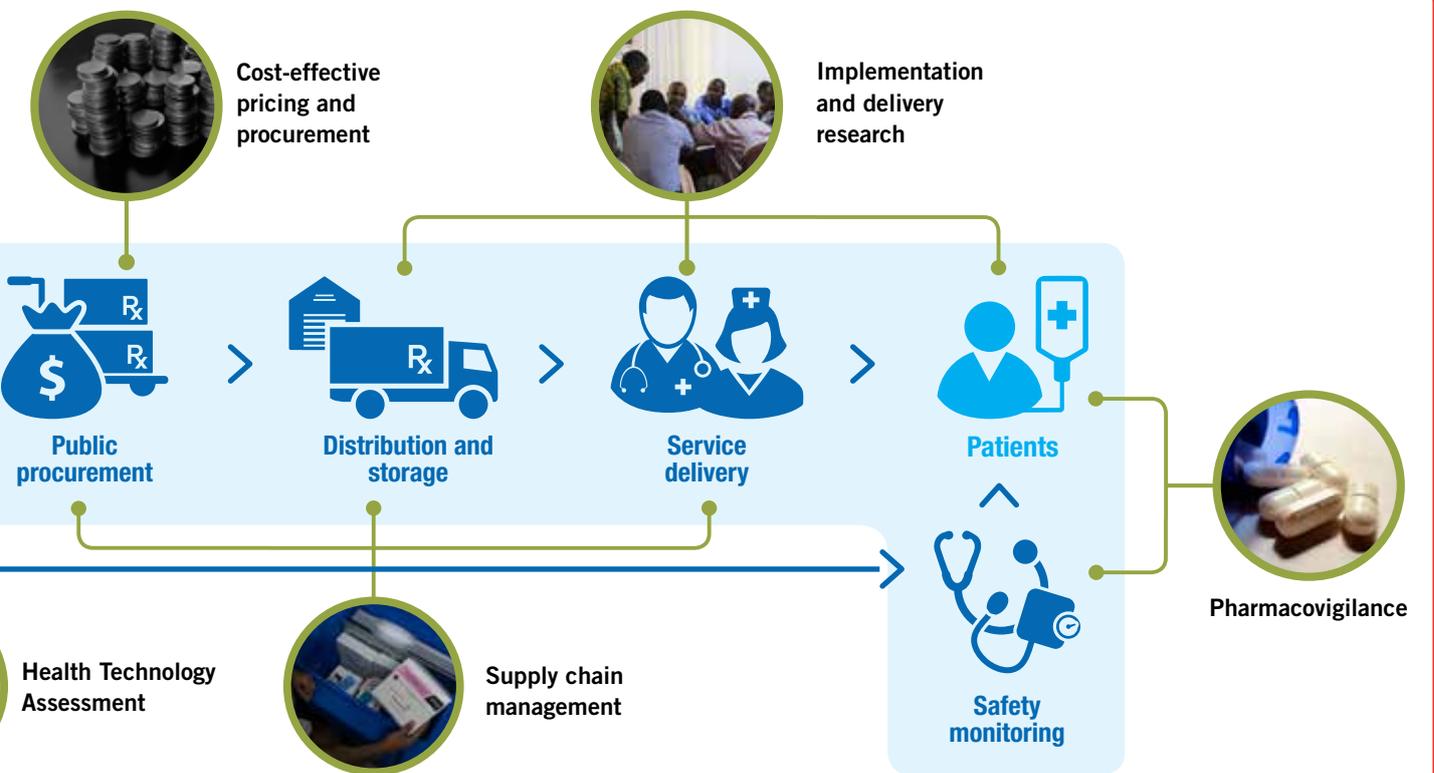
for collaboration with Japanese organizations involved in the R&D of global health technologies.

The Access and Delivery Partnership (ADP) supports countries to strengthen the policies, human capacities, systems and regulations needed to ensure that medicines, vaccines and diagnostics ultimately reach the people who need them. ADP brings together UNDP, the Special Programme for Research and Training in Tropical Diseases (TDR)⁷ and PATH in a unique partnership that helps identify and strengthen related capacity gaps in LMICs in an innovative and integrated manner.

These interlinked projects reflect more than ever the specific needs for improving health and development outcomes through strong, resilient and sustainable health systems.



THE ACCESS AND DELIVERY PARTNERSHIP



Contributing to UHC

ADP supports countries to bolster and harmonize policies and systems, and to strengthen the capacities of key stakeholders and institutions, thereby paving the way for sustainable, country-led progress towards UHC. ADP leverages the unique areas of expertise of its core and technical partners to strengthen the capacities of governments and their partners, helping to drive sustainable, long-term change.

The ADP strategic approach is responsive to the shifting global health context and informed by two key lessons gained from five years of experience in working with key stakeholders in LMICs.

First, where new health technologies are developed, their introduction

into national health systems is often constrained by country-specific situations and challenges. For example, although the approvals of two new medicines – bedaquiline and delamanid – offer promise for treatment of drug-resistant TB, there has yet to be widespread introduction of these medicines. Reasons for this delay include the absence of both active pharmacovigilance (PV) systems and strong regulatory frameworks in a number of LMICs. Hence, ADP focuses on identifying and addressing specific technical and institutional gaps that must be resolved in an integrated manner to successfully introduce and deliver new health technologies.

Second, introducing new health technologies depends on the effective and coordinated functioning

of domestic institutions. ADP has successfully implemented interventions in Ghana, Indonesia and the United Republic of Tanzania to strengthen capacity in, as well as coherence between, institutions responsible for core functions related to access and delivery of new health technologies

6 WHO/World Bank (2017). Tracking universal health coverage: 2017 global monitoring report. Geneva.

7 The Special Programme for Research and Training in Tropical Diseases (TDR) is hosted at the World Health Organization (WHO) and is co-sponsored by the United Nations Children's Fund (UNICEF), UNDP, the World Bank and WHO.

Making an impact Ghana, Indonesia and Tanzania

Over the past five years, ADP has collaborated with stakeholders in a set of focus countries – Ghana, Indonesia and Tanzania – to implement a range of capacity-building interventions. The implementation process at the country level has focused on integrated capacity strengthening of people and institutions responsible for core functions related to access and delivery of new health technologies.



The Government of Ghana has taken important steps to deliver on its commitment to achieve UHC. For example, the National Health Insurance Scheme (NHIS), established in 2004, seeks to ensure affordable, equitable access to quality essential health care for all citizens, and to provide financial protection, particularly to poor and vulnerable communities. Nevertheless, challenges remain with ensuring the population's access to basic health services. The *Health Sector Medium Term Development Plan (2014–2017)* identified the need for improvements in the health system to ensure equity in the distribution of health resources and in supply chain performance. Another major priority is the prevention and control of communicable diseases, particularly reducing the mortality and morbidity due to malaria and NTDs.⁸

In line with these priorities, the work of ADP in Ghana has focused on strengthening components of the health system by linking policy goals with interventions to strengthen institutions and build technical skills. ADP contributed to addressing key policy gaps within the health sector through the formulation of the *National Medicines Policy (NMP)* and the *National Health Research Agenda*, which provide policy and strategic guidance on promoting



access to health technologies and addressing bottlenecks to their introduction and scale up. In promoting an integrated approach, ADP worked with stakeholders to provide the needed technical support and capacity-building interventions to ensure that core functions within the regulatory and safety monitoring systems, disease control, and supply chain management were strengthened.

Driving change

Since the earliest stages ADP has served as a primary partner of the Ministry of Health (MOH) in establishing a multisectoral forum to promote policy and regulatory coherence for access and delivery of new health technologies. A key outcome of ADP support was the development of the NMP 3rd edition in 2017. The NMP, adopted by the Cabinet in May 2018, aims to fill an existing policy gap by setting out updated policy guidance for the governance and regulatory control of the pharmaceutical sector. The NMP is critical for the support of coordinated action across sectors and ensuring the quicker introduction and uptake of new health technologies.

ADP also partnered with the Research and Development Directorate of the Ghana Health Service to formulate



the *National Health Research Agenda 2015–2019*. The agenda provides a systematic framework and action plan to prioritize efforts and resources for research to address bottlenecks within the TB, malaria and NTD control programmes. ADP support has strengthened national research capacity together with a cohort of health researchers and programme implementers in the country's health research centres across all 10 regions in Ghana. ADP has also supported the capacity of the researchers to raise external funding. Research funding was successfully raised from the Global Fund to Fight AIDS, Tuberculosis and Malaria and the Department of International Development of the United Kingdom to investigate key priorities.

Until recently, the Ghana Food and Drug Administration (FDA) had no individual case safety report management system for pre- and post-approval safety data. Low reporting rates, coupled with a lack of doctors trained in drug safety monitoring, translated into inadequate management of safety reporting.⁹ ADP provided critical support to the introduction of a new and effective approach for drug safety monitoring. This support included the piloting and roll out of a national electronic management system for pre- and post-approval safety monitoring of health technologies, known as the 'Safety Watch' system, which was designed to incorporate patient/consumer reporting portals and reports from clinical trial sites. ADP also supported the training

of almost 1,000 health service staff across the country to ensure its effective use. As a result, the Ghana FDA is now able to effectively monitor the safety of new health technologies, including the new malaria vaccine that is being piloted in the country.

As coverage of the National Health Insurance Scheme (NHIS) expands towards UHC, national capacity and technical expertise for the prioritization and economic evaluation of new health technologies grows in importance. Since 2014, ADP has provided support to strengthen the institutional and individual capacities within the MOH, and at major universities and research institutes on the use of Health Technology Assessments (HTA). This support enables evidence-based prioritization of services and health technologies covered under the NHIS and informs price negotiations in medicines procurement and other related cost containment measures. A pilot initiative, jointly undertaken by the MOH, Priority Cost-Effective Lessons for System Strengthening (PRICELESS), International Decision Support Initiative (iDSI) and ADP, to review the standard treatment guidelines (STGs) for hypertension as a 'tracer' condition, has found the potential for significant health improvements and cost savings (of up to an estimated US\$14 million) if treatment regimens were changed to use better value first-line medicines.¹⁰ ADP will continue to support the MOH to expand the use of HTA in decision-making for a wider range of diseases and products, including TB, malaria and NTDs, with

the aim of fostering informed decision-making and policy change.

Finally, mass drug administration (MDA) campaigns for NTDs were identified as an important opportunity for improvements in logistics management. Critical capacity gaps were identified within the national NTD control programme, as a result of lack of documented protocols and training curricula for health workers. ADP helped establish a national logistics capacity-strengthening curriculum and associated materials, and also established a cadre of trainers to support sustained training on NTD MDA supply logistics management. The development of standard operating procedures and guidelines, as well as training will be rolled out in the next phase of ADP. This will contribute to the more efficient use of quality-assured medicines and increased availability for the 25 million people of Ghana, who are still at risk from at least two of the five most prevalent NTDs (namely, lymphatic filariasis, onchocerciasis, soil-transmitted helminthiasis, schistosomiasis and trachoma).

8 Ministry of Health, Ghana (2014). Health Sector Medium Term Development Plan 2014–2017.

9 Sabblah GT, Akweongo P, Darko D, Dodoo AN, Sulley AM (2014). Adverse drug reaction reporting by doctors in a developing country: A case study from Ghana. *Ghana Medical Journal* 48(4):189–193

10 iDSI (2017). Improving the quality and efficiency of healthcare services in Ghana through HTA.



In 2012, Indonesia established the goal of achieving UHC for all citizens by 2019, through enrolment of the population under the national health insurance scheme (JKN). It is one of the largest national health insurance systems in the world, and the full implementation of the system will have an estimated cost of US\$15 billion a year – about 15 percent of the central government's budget.¹¹ The financial sustainability of the health insurance scheme is clearly a priority for the country.

At the same time, health crises remain a significant determinant of economic well-being for Indonesian citizens and households. Indonesia

is one of the 22 countries with the highest TB prevalence in the world, and data published in 2018 show that catastrophic health costs are experienced in 36 percent of TB-affected families. Looking specifically at households affected by multidrug-resistant TB (MDR-TB), those levels rise to 83 percent.¹²

Given the context in Indonesia, ADP has focused on policy approaches that support and strengthen the JKN, including strengthening capacities for the conduct of HTAs. In addition, ADP has delivered capacity-strengthening interventions to the regulatory system to enable the introduction of bedaquiline, a new treatment for MDR-TB. The support of ADP to strengthening pharmacovigilance capacities paved the way for an active surveillance system that will be relevant to the introduction of other health technologies in the future. In line with the integrated approach, ADP

has worked across the various sectors to ensure that capacities and systems are strengthened, including through the conducting of IR to identify and address bottlenecks to the use of new diagnostics for TB and MDR-TB, and in improving technical and allocative efficiency in the procurement systems.

Driving change

Since the early stages of ADP, a primary outcome in Indonesia has been the establishment of a policy review mechanism that contributes towards a coherent and enabling policy and regulatory framework. ADP facilitated partnerships between the MOH, the Ministry of Law and Human Rights and the national competition authority (KPPU), as well as the National Public



Procurement Agency (LKPP) and the National Drug and Food Control Agency (BPOM) – for cross-sectoral decision-making on issues related to innovation, competition and cost-containment.

Indonesia's *National Strategy for Implementation and Operational Research for Prevention and Control of TB, Malaria and NTDs (2016–2019)* was developed through a collaboration between ADP, the National Institute of Health Research and Development in the MOH and the Centre for Tropical Medicine at Universitas Gadjah Mada. The strategy now guides the prioritization of research and training for the management and control of TB, malaria and NTDs, with the aim of enhancing introduction and scale-up of new health technologies. Arising from this, a research project was initiated to improve the use of the Gene Xpert technology to increase detection and diagnosis of MDR-TB, which is currently only at 7 percent of an estimated

32,000 new cases per year. Although it is the standard rapid diagnostic for MDR-TB in Indonesia, high operational and maintenance costs, and the need for trained personnel have been barriers to the effective use of the technology.

Indonesia is one of the first countries to pilot the introduction of bedaquiline as part of a combination therapy for MDR-TB in adults. One of two new TB medicines to be approved in 50 years, bedaquiline has the potential to offer a significant breakthrough for the treatment of MDR-TB, with a much shorter treatment regimen and higher cure rates than other treatment options.

Since WHO guidance requires active PV measures to be in place for the use of bedaquiline, active safety monitoring capacity was jointly identified by the PV unit within the BPOM and the national TB programme as a priority area. ADP support and training for 172 health care providers and pharmacists from BPOM has contributed significantly to MOH efforts to roll out bedaquiline in a number of hospitals and to updating the standard treatment guidelines for TB to include bedaquiline.

Another priority for ADP in Indonesia is the institutionalization of HTA as a systematic priority-setting process. To achieve this outcome, ADP has strengthened national capacities for economic evaluations and systematic assessment of new technologies and supported the development of a national HTA road map by the Government of Indonesia.

In this context, ADP has partnered with HITAP of Thailand in a South-South initiative to support the integration of HTA into priority-setting and the selection of new health technologies in Indonesia. Such South-South cooperation, along with partnerships with a consortium of technical partners, such as WHO and iDSI, has resulted in strengthened capacity within the MOH to conduct HTAs. Pilot evaluations related to end-stage renal disease (ESRD) and hypertension treatment options, conducted jointly with the MOH and the technical partners, generated evidence and recommendations on the cost-effective

selection of new treatment approaches. For example, the HTA for renal dialysis for ESRD indicated the potential for cost savings of up to IDR 86 trillion (an estimated US\$6 billion) over five years, if the first-line treatment was changed to a more cost-effective option.¹³

Since 2013, ADP has worked towards enabling regional and provincial procurement units to make effective planning and procurement decisions for new health technologies. This was achieved through strengthening the pool of experts who can support regional and provincial procurement units in planning for and procuring new health technologies.

ADP collaborated with LKPP to support procurement and supply chain management for medical equipment by improving access to information on technical and quality standards and prices.

A training module on planning and procurement of medical and laboratory equipment, developed through a partnership with LKPP, will be used in ongoing training programmes for provincial and district planning and procurement personnel. The training module will be integrated into the national procurement training programme, making it accessible to planning and procurement personnel in over 700 hospitals at the provincial and district levels.

11 Hutton J (2014). Indonesia launches world's largest health insurance system. *The Christian Science Monitor*, 10 March.

12 Fuady A, Houweling TAJ, Mansyur M, Richardus JH (2018). Catastrophic total costs in tuberculosis-affected households and their determinants since Indonesia's implementation of universal health coverage. *Infectious Diseases of Poverty* 7:3.

13 Afiatin, Khoe LC, Kristin E, Masyth LS, Herlinawaty E, Weraingyong P, et al. (2017). Economic evaluation of policy options for dialysis in end-stage renal disease patients under the universal health coverage in Indonesia. *PLoS ONE* 12(5): e0177436.



UNITED REPUBLIC OF TANZANIA

With total health expenditure more than tripling between 2002 and 2014, the health sector is a priority in the United Republic of Tanzania. Achievements in the health sector since the late 1990s have contributed to improvements in the health status of the population, including significant reduction of under-five mortality and decreases in maternal and neonatal mortality rates. Despite this progress, health outcomes in Tanzania are still lower than expected. A major priority to address in Tanzania is the high prevalence of NTDs with the most common being lymphatic filariasis, onchocerciasis, schistosomiasis, soil-transmitted helminths and trachoma. Almost the entire population is thought to be at risk of contracting at least one NTD, and millions require regular treatment and/or preventive medicines.

Since its establishment in Tanzania, ADP has responded to the priorities identified by national stakeholders to support key functions for the introduction and delivery of health technologies. These priorities include strengthening capacity for priority setting and resource allocation for the national health insurance scheme, as a contribution towards UHC, and strengthening of the national regulatory system. In light of the prevalence of NTDs, ADP has focused on two areas: to strengthen capacity for the conduct of implementation research to identify and address barriers to disease prevention and control; and to address inefficiencies in supply chain management linked to national NTD MDA campaigns, so that such large-scale distribution of quality-assured preventive chemotherapy achieves maximum coverage and minimum wastage.

Driving change

Strengthened stakeholder capacities to ensure policy coherence between public health, industrial and research and development objectives is a key outcome of ADP in Tanzania. The on-going collaboration of ADP with the Tanzania Commission for Science and Technology (COSTECH) enables a national multi-stakeholder platform to identify the most pressing access and delivery priorities in the country, including issues related to domestic regulatory capacities.

ADP has strengthened capacities of national disease control programmes to systematically identify and address barriers to the effective use of health technologies, through its support to the MOH in improving the effectiveness of disease control tools and technologies in priority areas. As an integral part of this work, ADP supported the development of the *National Agenda for Health Systems Research for TB, malaria and NTDs* in Tanzania, consolidating existing efforts to identify and address bottlenecks in disease prevention and control. ADP provided training for mid- and senior-level researchers, implementers and policy-makers, with the result that national research teams have successfully developed and received funding for projects aimed at strengthening MDA campaigns against NTDs and improving early diagnosis and treatment of MDR-TB.

ADP support to strengthening both institutional and technical capacities within the National Pharmacovigilance Centre at the Tanzania Food and Drugs Authority (TFDA) has enhanced the regulatory system to monitor and respond to safety issues effectively. In particular, TFDA has addressed the underreporting of adverse drug reactions, resulting in significant improvements in Tanzania's drug safety monitoring system, with the national reporting rate of adverse drug reactions more than doubling from 2014 to 2017. This result reflects the effectiveness of the training by ADP of nearly 500 health care providers and



master trainers from public and private health facilities across 20 districts. As another complement to its work on safety monitoring, ADP supported TFDA in the launch of a new system for direct reporting by consumers, by conducting an education campaign promoted through electronic and print media.

ADP has also supported incorporation of systematic economic evaluation into the priority-setting process in Tanzania for the National Essential Medicines List (NEML), through the introduction and establishment of a national HTA mechanism. In partnership with the Pharmaceutical Services Unit (PSU) in the Ministry of Health, Community Development, Gender, Elderly and Children (MOH-CDGEC) and the South African technical agency, PRICELESS, ADP provided technical support for the



review and revision of STGs and the NEML. Revision of the STGs and NEML, adopted by MOH-CDGEC, reflect the HTA recommendations. Successful implementation of these changes will contribute to cost-effectiveness and increased coverage of the national health insurance benefits package, which covers over 12 million beneficiaries.

The review process has ensured a South–South transfer of knowledge to the PSU and other stakeholders in Tanzania, which will be a valuable foundation for conducting future assessments and the establishment of a formal HTA mechanism in the country. PSU, PRICELESS and ADP intend to jointly publish the process of the STG/NEML review to share lessons learned and good practices for other countries to consider when undertaking similar reviews.

ADP support to strengthening supply chain management for NTD-focused MDA campaign aims to address the cost inefficiencies related to the supply chain of the \$100 million annual NTD treatment programme. A three-pronged approach was adopted: build a cadre of trainers on NTD MDA supply logistics management; develop the guidelines and training curriculum; and rollout the training programme at all levels. The training was undertaken in over 100 regional and district pharmacies in districts with the highest prevalence of NTDs, with the guidelines and training curriculum rolled out to over 3,000 health workers in 20 regions.

The development and piloting of guidelines and facilitator training materials for the management of the supply chain for NTD MDA campaigns

included the translation into Swahili, Tanzania’s national language. This ensured that the materials are accessible to all 67,000 of the front-line health care workers, community drug distributors and volunteers who deliver preventive chemotherapy to over 50 million people at risk of NTDs. Publishing in Swahili can expand the use of the booklets across much of the sub-Saharan region. As a testament to their effectiveness, the guidelines and training tools have now been adopted by the Government of Tanzania as the official documents for use in government training programmes.

Regional and South-South cooperation

Extending the reach of ADP

The ADP approach to facilitating South-South cooperation focuses on learning and exchanges on policy, programmatic and technical issues that comprise some of the most common challenges across different health systems. ADP has sought to harness the power of regional and South-South collaboration to highlight the leadership of the Government of Japan in global health, as well as strategic, technical and policy partnerships that enable capacity strengthening and the transfer of a range of technical knowledge among stakeholders at the national, regional and global levels.

ADP has established strategic partnerships with relevant regional institutions in the regions of Africa and Asia-Pacific, including the African Union (AU), New Partnership for Africa's Development (NEPAD) Agency, the East African Community (EAC) and the Association of Southeast Asian Nations (ASEAN). Through these partnerships, ADP is actively engaged in regional policy processes and collaborates on initiatives with wide implications for improving innovation, access and delivery of new health technologies. Notable initiatives include the collaboration with ASEAN on policy coherence and the partnership with the AU and NEPAD Agency on the AU Model Law on Medical Products Regulation.

Given that its in-country implementation experience provides a rich source of learning, ADP has identified opportunities for South-South exchanges that enable countries to share and learn from each other. Such exchanges have enabled a greater depth of support and sustainability for national level capacity strengthening. In total, over 700 policy-makers, technical experts, academics and other stakeholders from more than 38 countries have benefited from ADP South-South learning and technical exchanges. ADP has also established strategic and technical partnerships with a broad range of national and regional organizations, as well as global institutions and networks.¹⁴

Regional and South-South partnerships extend the visibility and awareness of the approach, tools and knowledge products of ADP among an increasing array of stakeholders. Four such initiatives have created collaborative platforms that have sustained the interest and participation of stakeholders.

¹⁴ ADP has established strategic and technical partnerships with the following regional and global organizations: the African Union Commission, the Association of South East Asian Nations (ASEAN), the East African Community (EAC), the International Decision Support Initiative (IDSI), INDEPTH Network, the Joint United Nations Programme on HIV/AIDS (UNAIDS), Management Sciences for Health (MSH), NEPAD Agency, the Prince Mahidol Award Conference (PMAC), the UN Economic and Social Commission for Asia and the Pacific (UN ESCAP), the United Nations Conference on Trade and Development (UNCTAD), and WHO Collaborating Centres.



ADP FOCUS COUNTRIES

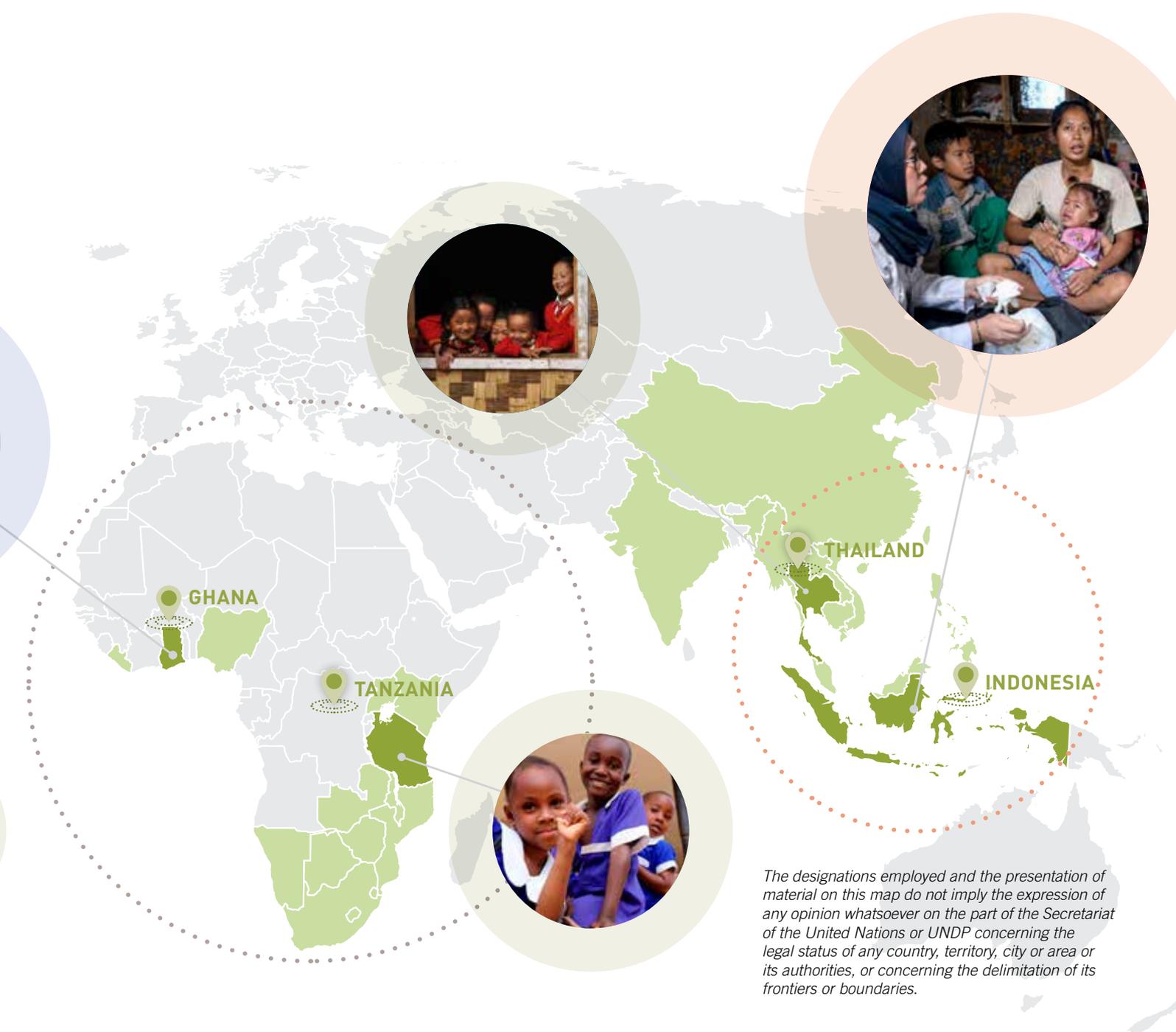


COUNTRIES THAT BENEFITED FROM ADP CAPACITY-BUILDING INITIATIVES



Regional regulatory harmonization - African Union Model Law

The AU Model Law is one of the two key pillars of the African Medicines Regulatory Harmonization (AMRH) initiative, aimed at removing regulatory barriers that hinder patient access to health technologies in Africa through regional harmonization and capacity strengthening. ADP has provided expert legal advice and technical support throughout the process of developing the Model Law.



The designations employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations or UNDP concerning the legal status of any country, territory, city or area or its authorities, or concerning the delimitation of its frontiers or boundaries.

The collaboration continues, through the provision by ADP of technical expertise and support to national-level implementation of the Model Law through the Technical Working Group on Medicines Policy and Regulatory Reforms (TWG-MPRR), comprising regulators and legal experts from the region to guide the domestication of the Model Law.

While ADP does not operate in each of the 55 AU Member States, it leverages the regional platform afforded by the AU and the NEPAD Agency to harmonize technical requirements and guidelines for the registration of medicines, with the aim of reduced registration cycles.¹⁵ Given the need for robust regulatory frameworks and safety monitoring systems for the

introduction of new health technologies, the Model Law will be an important means of enhancing capacities in the regulatory systems of the countries in the region – which account for a major share of global disease burden – and enable speedier approval and introduction of new health technologies.

ADP support in this area also extends to the provision of legal advice and technical support for the establishment of the African Medicines Agency (AMA). With the May 2018 adoption of the treaty establishing the AMA, the second pillar of the AMRH initiative is close to realization. As the specialized regional technical agency, the AMA is expected to play a major role in providing regulatory guidance and technical assistance to AU

Member States, as well as promoting the use of the AU Model Law to facilitate regulatory and legal reforms at continental, regional and national levels. In this context, ADP aims to build on the successful collaboration with AU and the NEPAD Agency, with a view to provide systematic and sustained technical support to AU Member States to accelerate the implementation of the Model Law at the national level.

¹⁵ Access and Delivery Partnership (2017). Issue brief: African Union Model Law for Medical Products Regulation: Increasing access to and delivery of new health technologies for patients in need.



HTA knowledge platform

As national health systems come under increasing pressure to rationalize the use of limited resources, sustainable health resource allocation is key to ensuring that growing demands on the health system can be met. Sustainable resource allocation relies on the consistent use of systematic priority-setting procedures. ADP promotes this approach by ensuring that national stakeholders have access to a key knowledge and capacity base for the establishment of HTA mechanisms that are relevant to their own country context.

Capacity transfer in relation to conducting and institutionalizing the HTA approach has been facilitated between the Indonesia MOH and HITAP in Thailand; and between the Tanzania Pharmaceutical Services Unit and PRICELESS in South Africa. These country-to-country examples are closely linked to ADP collaboration with national agencies, such as National Institute for Health and Care Excellence (NICE) in the United Kingdom, and with global learning networks on

priority-setting and HTA platforms, such as iDSI and HTA International Asia.

To expand the knowledge base on HTA institutionalization for other LMICs to draw on, ADP knowledge products include documentation of the country experiences and lessons learned in Ghana, Indonesia and the United Republic of Tanzania, as well as the processes and findings of pilot evaluations. ADP will continue its collaboration with HITAP and other key actors, to sustain the growing number of resources that LMICs can draw on to understand the key steps and challenges to establish a national HTA mechanism. This will enable an increasing number of countries to accelerate institutionalization of HTA methodologies, driving technical and allocative efficiencies that align closely with national health policy priorities and disease burdens.

Strengthening national PV capacity

The deployment and use of new technologies may encounter unanticipated or adverse reactions; hence, an effective monitoring

system that can detect, assess and manage such events within the health system is critical. As ADP works on strengthening human and institutional capacities to enable national PV systems to be set up for this purpose, it also promotes active exchanges of experiences and knowledge on PV between interested LMICs.

To promote good practice and sustainable capacity-strengthening for PV beyond its focus countries, ADP has supported networking and South-South exchange between PV experts across 13 countries in the Africa and Asia-Pacific regions.

Based on the experience of strengthening national PV systems in its focus countries, ADP has also developed and disseminated related knowledge products for use by an extended set of countries. The experience and lessons generated from implementing active safety monitoring of bedaquiline in Indonesia is a core element of this approach and is being documented as a guide for supporting other LMICs when introducing bedaquiline and/or other health technologies in their own settings.

ADP has helped to strengthen national PV centres and disease control programmes through study placements and regional technical



exchanges on safety monitoring. This work has included training on cohort event monitoring for adverse event surveillance of new medicines, carried out in partnership with the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, based at the University of Ghana Medical School. The technical capacities developed by focus countries for safety monitoring and PV will be crucial to facilitate the introduction of new health technologies in their own national settings.

A review of the policy and legal frameworks related to mandatory reporting of adverse drug reactions in selected LMICs, for example, enables countries to identify viable options that can facilitate the introduction of mandatory reporting of adverse drug reactions and inform the strengthening of relevant laws and policies in other countries.

ADP continues to develop this growing repository of relevant resources, helping a broad set of countries to pool financial and technical information on PV, so that this information can be readily available to interested national authorities to help strengthen the capacity of their PV systems.

Research to identify and address barriers to introduction of new health technologies

'Real life' and country specific investigation of challenges in the introduction of new health technologies is an important way of identifying and addressing barriers in access, delivery and optimal usage of new health technologies. ADP supports expanded use of such implementation research approaches, tools and mechanisms in and beyond ADP focus countries to facilitate the adoption and use of new health technologies.

Central to this strategy has been the development of a comprehensive Implementation Research Toolkit to help LMICs strengthen IR capacity for identifying and addressing barriers to the effective use and scale-up of new technologies. The new toolkit uses an online modular learning approach, which is available in both English and French.¹⁶ In the first six months following its launch, there were 2019 users from

26 countries (18 from LMICs) and 3,642 unique sessions.

Beyond the toolkit, the lessons learned and good practices of ADP support, including those gained through the development of national IR strategies and agendas, have been well documented and provide the basis for South-South sharing and learning for other LMICs in their process of strengthening IR capacities.

ADP has strengthened IR capacities in non-ADP focus countries including India, through a collaboration with the Indian Council of Medical Research (National Institute for Research in Tuberculosis), and in Vietnam, in partnership with the INDEPTH Network.

¹⁶ The IR toolkit is available online at <http://adphealth.org/irtoolkit/>

Future directions

Scaling up ADP

As important advances take place in health research and product development, it is crucial to ensure that promising new technologies in the pipeline can be successfully brought to market through continued and strategic investments. Despite a historical emphasis on R&D, it is now widely recognized that R&D is essential but not sufficient to drive access to new health technologies in countries and communities in need. Alongside R&D investments, it is critical that health system strengthening efforts continue apace, to ensure that once new technologies are available, they can be swiftly introduced and reach people in need. Strengthening these linkages contributes to amplifying the impact of the GHIT Fund and highlighting the leadership of the Government of Japan on UHC and in the global health field. These factors provide the rationale as well as impetus for the next phase of the GHIT Fund and ADP.

From 2018 to 2023, ADP will be scaling up its country coverage, in a number of ways. First, ADP is pleased to add WHO as the fourth core partner, deepening the technical assistance and capacity strengthening that ADP will be able to offer to countries, particularly on the key aspects of regulatory control. With four core partners consolidating the broad scope of experience and expertise, ADP is well-positioned to provide expanded policy and technical support to other LMICs in order to help them optimize access and delivery of health technologies. ADP also intends to expand further the range of technical partners that it engages with, in order to meet country needs. One priority will be to enhance the use and reach of Japanese technical expertise through building collaborations with Japanese

technical agencies. ADP will continue to provide a range of support for an increasing number of focus countries. During this period, ADP will also extend and deepen its impact in the current focus countries, introducing new interventions and/or increasing intervention quality, scope and reach.

The experience of the past five years will help ADP maintain focus on strengthening national capacities to access and deliver new health technologies in accordance with the needs and priorities identified by and within each country. Despite wide-ranging differences in national health and development contexts, some common challenges and capacity gaps continue to endure across the health technology value chain of many LMICs. Some are prerequisites for promoting the availability and affordability of essential health technologies, ensuring their quality and safety, and facilitating their reliable supply and timely introduction within the national health system.

Drawing on achievements and lessons during its first phase, ADP will continue to support health system strengthening, with the aim of ensuring effective access to medicines, vaccines, diagnostics and other health technologies, and supporting the concerted drive for UHC. It will achieve this through the following objectives and outcomes:

1. Strengthen policy and regulatory harmonization and coherence. While an effective regulatory framework is vital for improved health outcomes, policy functions related to the selection, prioritization and use of health technologies must also be aligned. There is also a need for effective



procurement, supply chain management and delivery systems to ensure that health technologies reach the people and communities that need them most, and in a timely way. A harmonized policy and regulatory environment enables these functions to work in tandem for the successful introduction, use and delivery of new health technologies within a national health system.

2. Strengthen institutions for accelerating health technology introduction and access. In many countries, an urgent need exists for targeted capacity development within national institutions or mechanisms in order to support the effective introduction of new health technologies. In its scale-up phase, the ADP will tailor capacity



strengthening to individual country-specific needs, effectively addressing critical capacity gaps within national health systems. ADP will leverage the expertise and experience of each core partner organization, to provide capacity strengthening that ensures the effective functioning of the entire health technologies value chain.

3. Establish and contribute to regional and global platforms for technology preparedness.

ADP will collaborate with the GHIT Fund and other product development partnerships (PDPs) to identify and bring together key actors within the health technology R&D and delivery fields. The aim is to ‘crowd in’ a growing global network of PDPs and delivery focused organizations to serve as a major learning platform for

information exchange on late-stage candidates in R&D pipelines, and to promote common approaches to health technology preparedness in LMICs. The learning and exchange from such a platform will enable the identification and design of effective interventions to address major barriers to technology introduction at the national level, while simultaneously allowing for these interventions to inform the product development processes at earlier stages, with the ultimate goal of accelerating access and introduction of new health technologies for TB, malaria and NTDs.



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