

Keeping the Promise:

Product Development Partnerships' Role in the New Age of Health Research and Product Development

EXECUTIVE SUMMARY



Product Development Partnerships (PDPs) develop new products for people suffering from diseases and health threats underserved by traditional markets. This is accomplished by building partnerships between the public, private, academic, and philanthropic sectors. In the health space, PDPs have developed and introduced treatments, vaccines, diagnostics, vector controls, devices, and various other types of innovations that have led to significant progress against some of humanity's oldest and deadliest plagues, including tuberculosis, malaria, HIV/AIDS, neglected tropical diseases (NTD), and a host of other neglected diseases. In addition to saving millions of lives, the work of PDPs has helped strengthen health systems and promoted health security in endemic countries, contributed to progress toward the United Nations 2030 Sustainable Development Goals (SDGs), and increased global capacity to conduct research. Current PDP pipelines are robust and show strong promise for a new wave of global health technologies to reach people around the world in the years to come.

The PDP model has shown its efficacy in the global response to COVID-19, which makes use of many of the attributes, human capital, and approaches core to PDPs, including innovative partnerships that share the risks and rewards of product development. Further, PDPs themselves play a critical role in preventing and responding to urgent and emerging health threats, including COVID-19, antimicrobial resistance (AMR), and pandemic preparedness. Addressing these threats promotes global development and health security.

With sufficient funding, ample political will, and partnerships across various sectors, including industry, academia, governments, communities, and multilateral organizations, PDPs can continue to develop and drive equitable global access to health technologies with the potential to save millions of additional lives, help lift people out of poverty, and improve global health security over the coming decades.

PDP COALITION:



Drugs for Neglected Diseases initiative (DNDi)



European Vaccine Initiative (EVI)



Foundation for Innovative New Diagnostics (FIND)



Innovative Vector Control Consortium (IVCC)



International AIDS Vaccine Initiative (IAVI)



International Partnership for Microbicides (IPM)



International Vaccine Institute (IVI)



Medicines Development for Global Health (MDGH)



Medicines for Malaria Venture (MMV)



PATH



TB Alliance



Tuberculosis Vaccine Initiative (TBVI)



The PDP model, history, impact, and future potential in 10 bullets

PDP products and innovation have improved health and saved lives by addressing unmet needs

1

PDPs are the global leaders in developing new health technologies where lack of traditional market incentives have stalled progress.

2

PDP pipelines are robust and poised to deliver a significant number of innovative technologies in the near term.

3

PDPs achieve impact by developing products appropriate for the people and contexts in which they will be used.

Investing in PDPs is a cost-effective way to drive global development and public health preparedness

4

PDPs save money and are a cost-effective way to save lives and grow economies.

5

PDPs build local capacity to perform research and strengthen health systems.

6

The products that PDPs develop are essential to achieve universal health coverage and the United Nations 2030 Sustainable Development Goals.

7

PDPs are equipped to help prevent and respond to urgent emerging and future health threats.

Increased investment and political will are needed to realize the full promise of PDPs

8

PDPs need sustained, diverse, and flexible funding to increase their impact on global health and development.

9

Regulatory harmonization is needed to accelerate the global availability of PDP-developed products.

10

Increased investment and cross-sector collaboration are needed to ensure the widespread adoption, delivery, and implementation of new health technologies.

PDP products and innovation have improved health and saved lives by addressing unmet needs

1. PDPs are the global leaders in developing new health technologies where lack of traditional market incentives have stalled progress.

Since 2010, the coalition of twelve PDPs represented in this report have delivered more than 60 new health technologies—treatments, vaccines, diagnostics, vector controls, and devices. These products have reached more than 2.4 billion people, mostly in low- and middle-income countries (LMICs). Highlights of these innovations include the first ever drug approved for treatment of highly drug-resistant forms of tuberculosis (TB), a single dose treatment to prevent relapse of *P. vivax* malaria, and the first all-oral cure for all stages of sleeping sickness. These advances are concentrated in diseases of poverty where investment and innovation have long been stagnant. Market-driven incentives do not drive the development of lifesaving technology for these diseases that kill millions per year; PDPs, funders, and collaborating institutions achieve critical innovation and solutions that would otherwise not exist.

PDPs DELIVER INNOVATION

Many PDPs were established around the turn of the century. This past decade has seen the fruits of previous investment.

Products developed and marketed by PDP coalition

2000–2009: 9

2010–2020: 66

PRODUCTS DEVELOPED BY THE COALITION
OF PDPs HAVE REACHED MORE THAN
2.4 BILLION PEOPLE AROUND THE WORLD



2. PDP pipelines are robust and poised to deliver a significant number of innovative technologies in the near term.

The PDPs in this coalition have more than 375 potential new technologies in their pipelines, with approximately 25% of those products in late-stage development. These efforts are driven significantly by partnerships across various sectors and geographies and represent a critical opportunity to make considerable progress against or eradicate some of the world's deadliest and most persistent threats to global health, including those that disproportionately impact women and children.

3. PDPs achieve impact by developing products appropriate for the people and contexts in which they will be used.

To maximize impact, PDPs closely and continuously engage with local communities, care providers, researchers, and policy makers to ensure they are designing products for use in the settings where they are most needed, which are often low-resource environments. This means prioritizing product attributes such as the low cost of goods, manageable dosing schedules, oral versus injectable treatment, stability in warm environments without need for refrigeration, sustainable low-footprint methods of production, resistance-breaking mechanisms, and long shelf lives.

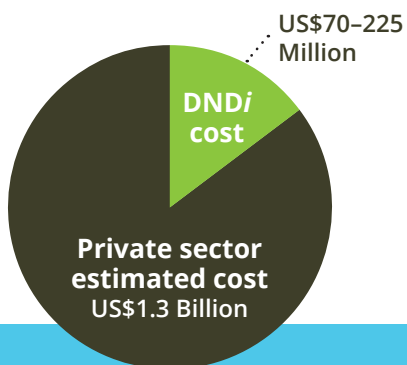
THE PDPs IN THIS COALITION HAVE MORE THAN
375 POTENTIAL NEW TECHNOLOGIES
IN THEIR PIPELINES



Investing in PDPs is a cost-effective way to drive global development and public health preparedness

4. PDPs save money and are a cost-effective way to save lives and grow economies.

The products that PDPs develop provide tremendous value for money and a strong return on investment. PDPs are consistently able to develop products at costs below that of the private sector. For example, DNDi documented the full costs for its research and development of a new chemical entity at US\$70–225 million, a figure substantially lower than that estimated by private industry. Adaptations of existing drugs can cost as little as US\$7 million. By pooling and leveraging funding from multiple sources, PDPs spread risks across multiple investors and research programs. This means investing in PDPs is a safe and impactful way to save lives, strengthen health systems, and promote economic development, health security, and stability around the world.



FULL COSTS OF R&D OF A NEW CHEMICAL ENTITY

BY DNDi: **US\$70–225** MILLION

ESTIMATED COST OF PRIVATE SECTOR BRINGING NEW

CHEMICAL ENTITY TO MARKET: **US\$1.3** BILLION*

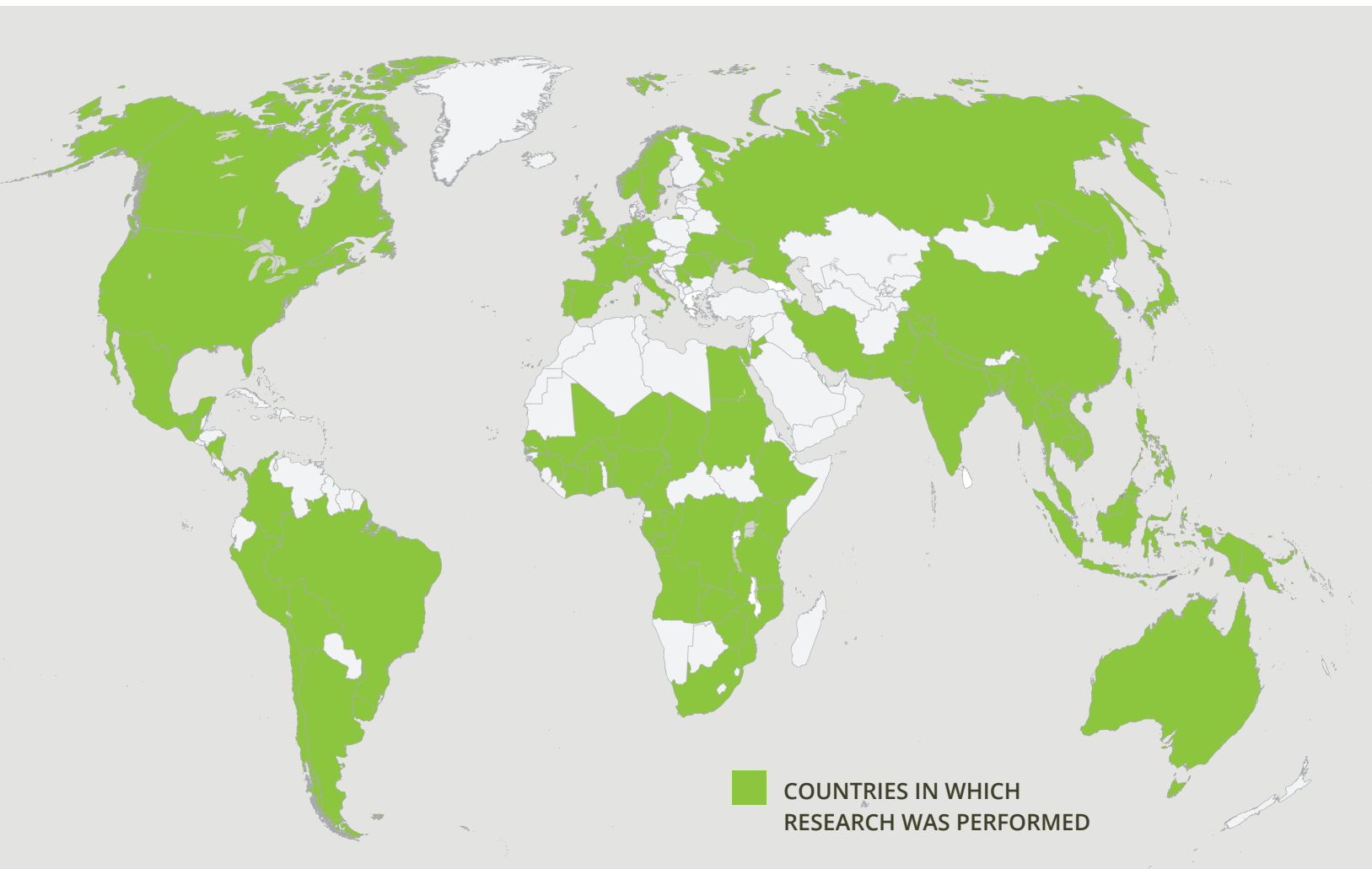


*Tufts Center for Study of Drug Development.

5. PDPs build local capacity to perform research and strengthen health systems.

PDPs have performed clinical research at more than 550 sites in more than 80 countries, mostly in LMICs. Through partnerships, training, infrastructure improvements, and the development of the next generation of researchers, disease experts, and scientific leaders, PDPs build sustainable platforms for research that better prepare countries to address emerging and future health issues and research questions. The infrastructure in many LMICs that is currently being used to operationalize local efforts to combat COVID-19 has been substantially developed through collaborative product development work with PDPs. Furthermore, the very products that PDPs develop often enhance the performance of health systems, for example, oral treatments that avoid hospitalization, and rapid diagnostics that enhance primary health care capacity to meet health needs and reduce costs.

COUNTRIES IN WHICH PDPs HAVE PERFORMED CLINICAL RESEARCH



6. The products that PDPs develop are essential to achieve universal health coverage and the United Nations 2030 Sustainable Development Goals.

The development of products in PDPs' portfolios, such as improved vaccines, treatments, diagnostics, and vector controls for tuberculosis, malaria, and HIV/AIDS, and improved tools for women's and children's health is a necessary precondition for universal health coverage and the achievement of:

- **SDG #1:** End poverty in all its forms everywhere
- **SDG #3:** Ensure healthy lives and promote well-being for all at all ages
- **SDG #5:** Achieve gender equality and empower all women and girls
- **SDG #8:** Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all
- **SDG #10:** Reduce inequality within and among countries
- **SDG #17:** Strengthen the means of implementation and revitalize the global partnership for sustainable development

Continued support of PDPs is critical to achieve these goals.

7. PDPs are equipped to help prevent and respond to urgent emerging and future health threats.

The capabilities of PDPs are not limited to poverty-related diseases. PDPs have mobilized to contribute to the global response to the COVID-19 pandemic by developing vaccine and monoclonal antibody candidates, providing chemical libraries to be tested for potential efficacy against SARS-CoV-2, and applying drug discovery techniques to aid in COVID-19 product research. PDPs are staging large-scale adaptive platform trials in Africa, connecting scientists across the continent for therapeutic testing, and convening novel partnerships to accelerate the development, production, and broad, equitable access to COVID-19 tests, treatments, and vaccines that meet the needs of resource-limited contexts. PDPs are also developing products and coalitions to address looming health threats, such as antimicrobial resistance.



Increased investment and political will are needed to realize the full promise of PDPs

8. PDPs need sustained, diverse, and flexible funding to increase their impact on global health and development.

To account for the relatively lengthy timelines of medical technology development and attrition rates, PDPs require stable long-term funding and investment across every stage of the research process—from discovery and epidemiology to clinical trials and access—and sufficient latitude to shift funding across their pipelines to prioritize the most promising and impactful research programs. New innovative financing mechanisms are needed to incentivize increased participation in global health product development by the private sector. To fully unlock the potential of PDPs, increased investments are needed from all parties and sectors, including BRICS and low- and middle-income countries.



**FUNDING FOR PDPs
MUST BE:**

**INCREASED
LONG-TERM
CONSISTENT
PORTFOLIO-WIDE
FLEXIBLE**

9. Regulatory harmonization is needed to accelerate the global availability of PDP-developed products.

Inconsistent, complex, and sometimes slow processes for earning approval and registration of new products in all countries are a significant challenge to ensure they are widely and equitably available. Relieving these barriers can also serve as a financial incentive for donors and product developers, resulting in a quicker and larger health impact and return on investment. National and regional efforts to streamline and harmonize regulatory processes can accelerate the availability of lifesaving new health technologies, especially where most urgently needed. As an example, IAVI's collaboration with the East African Health Research Commission (EAHRC) to develop a policy guide to standardize the research ethics review process in six African countries helped ensure trial safety and reduced approval times by 30% for IAVI-sponsored protocols in Kenya, Uganda, and Zambia.

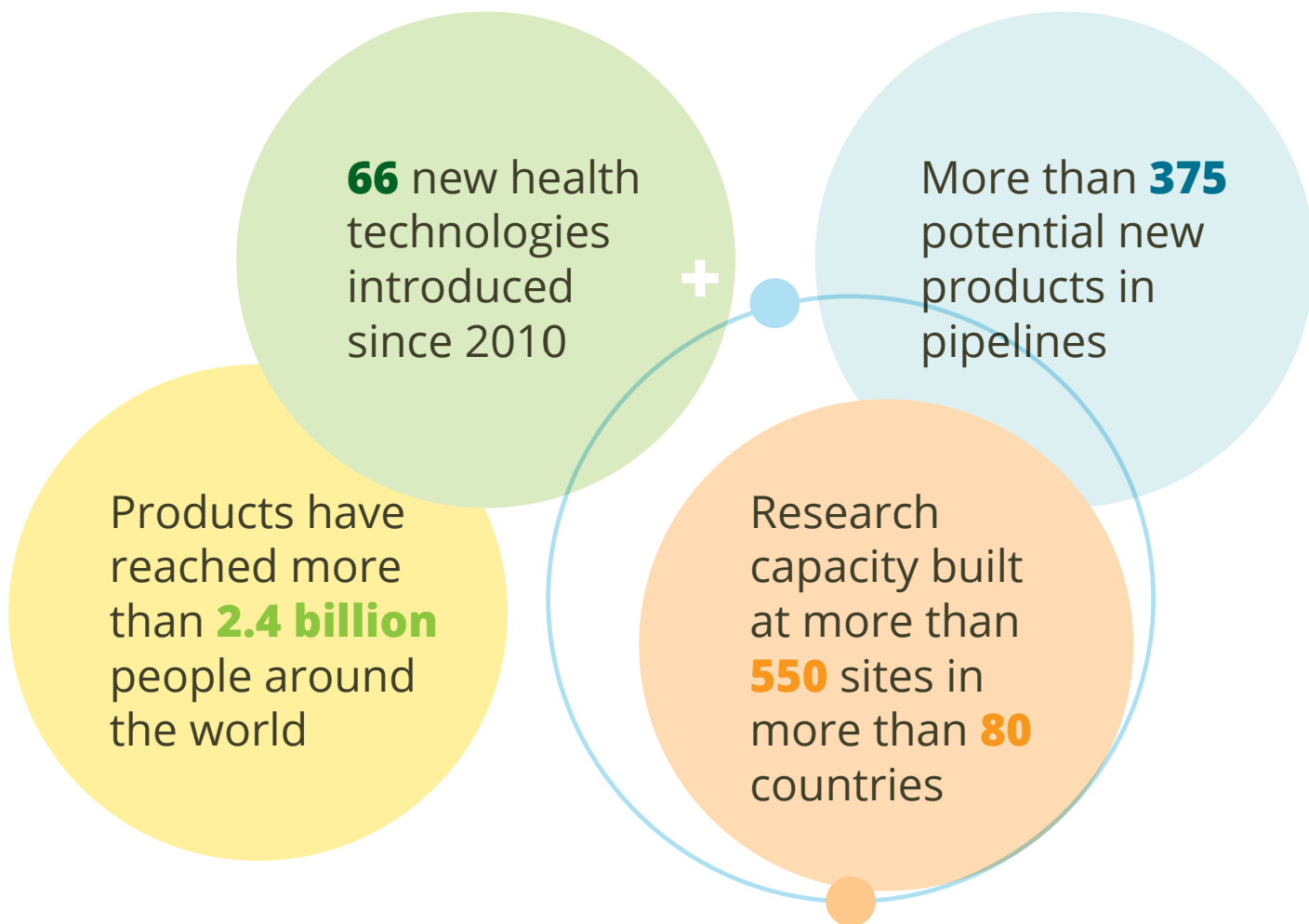
10. Increased investment and cross-sector collaboration are needed to ensure the widespread adoption, delivery, and implementation of new health technologies.

PDPs, national health systems, multilateral organizations, donors, and advocates have learned that achieving health impact requires an end-to-end approach. This includes investing to ensure products are affordable, rapidly available, and widely and equitably accessible by addressing challenges relating to manufacturing, market competition, affordability, forecasting, and training of health service providers. Accelerating and expanding access to new products requires dedicated investment and creative and multi-sectored partnerships. With more products approaching and reaching the market than ever before, the need to invest in access is increasingly critical and urgent.

**PDP COST FOR DEVELOPING A NEW DRUG
CAN BE 20% OR LESS THAN THAT OF
THE PRIVATE SECTOR**



PDPs DELIVER INNOVATION



WITH SUFFICIENT FUNDING, AMPLE POLITICAL WILL, AND PARTNERSHIPS ACROSS VARIOUS SECTORS, PDPS WILL:

- **CONTINUE TO DEVELOP AND DRIVE EQUITABLE GLOBAL ACCESS TO HEALTH TECHNOLOGIES WITH THE POTENTIAL TO SAVE MILLIONS OF ADDITIONAL LIVES,**
- **HELP LIFT BILLIONS OUT OF POVERTY,**
- **IMPROVE HEALTH SECURITY.**

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