PDP

ACCELERATING GLOBAL HEALTH R&D

THE ROLE OF PRODUCT DEVELOPMENT PARTNERSHIPS

GLOBAL DEVELOPMENT

ANTARA GLOBAL
— HEALTH ADVISORS —

Barbara Bulc, **Global Development**

Rohit Ramchandani, **Antara Global Health Advisors**

TABLE
OF
CONTENTS

PHOTO

Paediatric HIV medicines are saving **children's** lives;
photo by Paul Kamau, DNDi, Nairobi, Kenya

KEY MESSAGES

This brief provides an up-to-date overview of the research and development (R&D) landscape for poverty related and neglected diseases (PRNDs), with a focus on the activities and impacts of product development partnerships (PDPs). It summarizes current evidence and perspectives about the added value of this innovative public–private partnership model, established 20 years ago. The findings aim to assist funders in optimizing their critical investments to accelerate health R&D for diseases of poverty, taking into account the rapidly changing global health, pandemic preparedness and development environments. Key messages are listed below.

1. The findings confirm that the PDP model has been one of the most successful approaches to address the need for products to tackle PRNDs. Five key assumptions that underpinned the PDP model when it was established two decades ago remain valid today. These assumptions comprise: addressing market failure, utilizing a portfolio approach to R&D, maximizing cost-effectiveness, building R&D capacity, and catalysing access for health impact.

2. PDPs are a critical mechanism to address important deficiencies in the global health architecture.[1] This includes addressing both market and policy failures in the development of vital health technologies targeting PRNDs. Since their inception, the ten PDPs assessed within the context of this study have collectively brought 85 new products to market, including 3 vaccines, 27 therapeutics, 50 diagnostics or health technologies, and 5 vector control tools.

3. Partnership management for an effective product portfolio approach is essential across all phases of R&D and is **a key strength of these "virtual R&D conductors". PDPs successfully cultivate and** enhance networks of partners in industry, academia, research institutes, governments and philanthropies. Collaborations with research organizations, governments, industry, patients and communities in low- and middle-income countries should continue to be strengthened.

4. The study identified three specific areas that could substantially improve the effectiveness of PDPs and the systems within which they operate: 1) strategic development of access partnerships (an end-to-end approach), starting earlier in the R&D process;[3-5] 2) improved coordination and a more joined-up approach among all stakeholders throughout the R&D process;[6-8] and 3) strengthened product prioritization mechanisms to inform priority setting and funding allocations across the entire portfolio of PRND products.[8-10] These changes must be supported by effective and transparent data sharing and leveraging of key tools and technologies.

5. The COVID-19 pandemic has put an unprecedented spotlight on global health R&D and diseases that traverse borders and populations. Within this context, the evolving public–private PDP model provides important practices and lessons for the future of global health R&D. These circumstances represent a unique opportunity to raise awareness about the PDP model through improved communication, collective advocacy and strengthened investment cases.

6. The evidence clearly supports a need to increase, sustain and better coordinate R&D funding for PRNDs through PDPs, utilizing flexible modalities.[107] If circumstances do not allow for this, funding should, at a minimum, be continued at current levels. This would contribute to addressing funding gaps to develop existing and missing products in the R&D pipelines, with benefits to health systems and beyond.[11] This is particularly relevant given the renewed interest of public and private stakeholders in health innovation to promote global health security and is essential for achieving the Sustainable Development Goals.[12-15]

INTRODUCTION

Investment in health research and development (R&D) continues to disproportionately focus on medicines and health technologies that can demand high prices.[16,17] This excludes a significant portion of the **world's population who cannot pay such prices. Major health inequalities exist worldwide,** including 90% of funding for health research having been focused on issues that affect just 10% of the **world's population,**[18] **referred to as the "10/90 gap". The syste**ms challenges underpinning this divide persist today. Investment in poverty related and neglected diseases (PRNDs), which primarily affect low- and middle-income countries (LMICs), is less than 2% of the USD $240 billion annual global spend on health R&D.[19,20]

Despite tremendous progress over the past decade, these poverty related diseases, which include HIV/AIDS, malaria, tuberculosis (TB), pneumonia, diarrhoeal disease, and more than 20 neglected tropical diseases (NTDs), still cause more than 9 million deaths each year.[8,21,22] The lack of affordable and effective drugs and technologies for PRNDs represents both a market and a public policy failure.[23,24] Just 1.1% of new drugs were specifically approved for PRNDs between 1974 and 1999, despite PRNDs representing 12% of the global disease burden.[25] Between 2000 and 2011, the situation improved very little (to 4%), with only 1% of new chemical entities approved targeting PRNDs.[26]

One of the most innovative models designed to address this neglect has been the product development partnership (PDP). This type of public–private partnership (PPP) was first initiated in the 1990s to overcome market failures and other barriers to product R&D for PRNDs. PDPs develop products that include drugs, vaccines, microbicides, biologics, diagnostics, vector control products, devices, and multipurpose prevention technologies.[27] A 2017 study of PDPs identified more than 20 PDPs for PRNDs.[28] This study examines the past, present and future of the PDP model, including a focused analysis of ten key PDPs, listed in Annex 1: DNDi, EVI, FIND, IAVI, IPM, IVCC, MMV, PATH, TB Alliance and TBVI.

> **Product development partnerships** (PDPs) are not-for-profit R&D organizations that develop health products and technologies for people who have been underserved by traditional markets. They focus on one or more neglected diseases and develop products suitable for use in LMICs. PDPs adopt a science- and need-based approach to product research and implementation. They facilitate global collaborations between the public, private, academic and philantropic sectors. They generally use private sector approaches in their R&D activities, while leveraging mainly public and philanthropic funds and working with external partners. This allows for sharing of risks and benefits in pursuit of a common goal that would not otherwise be attainable.

Crucially, health innovation that emerges from PDPs contributes towards attaining the Sustainable Development Goals (SDGs) and Universal Health Coverage (UHC).[29,31] Moreover, PDPs provide an essential global function of R&D health cooperation that goes beyond the boundaries of individual nations to address transnational issues.[32] The COVID-19 pandemic has brought the importance of such functions into sharp focus.

ASSESSMENT OF THE KEY ASSUMPTIONS OF THE PDP MODEL

This study reviewed and analysed the current validity of key assumptions that were the basis for the PDP model when it was established approximately two decades ago. Five key assumptions were selected based on the literature and include: market failure, portfolio approach to product R&D, cost-effectiveness, R&D capacity building, as well as access and health impact.[33-36] The findings drew on interviews and surveys with 64 key informants from governments, industry, PDPs, academia, research institutions and philanthropies, combined with a comprehensive literature review (see Annexes 2, 3, 4 and 11: methodology, interview questions, interviewees and bibliography, respectively). Selected insights from the survey and the results of the SWOT analysis of the PDP model can be found in Annexes 5 and 6, respectively.

The assessment confirmed that the five key assumptions that originally underpinned the PDP **model remain valid today.**

The findings are summarized below and include a current assessment as well as opportunities for strengthening the continuously evolving PDP model.

FIVE KEY ASSUMPTIONS FOR THE PDP MODEL AND THEIR DEFINITIONS

Market failure: It is assumed that PDPs represent a critical approach for addressing the market failure that exists for PRND products. Market failure occurs when conventional market mechanisms, such as those driven by intellectual property (IP)-based incentives, do not correspond with the nature of demand for treatments of these diseases. The market will fail by not supplying the socially optimal amounts of such innovations. A key factor is the limited purchasing power of both governments and patients in the countries where such diseases predominate.[37]

R&D portfolio approach: It is assumed that PDPs effectively utilize a product portfolio approach.[38] This refers to an R&D process that simultaneously develops multiple candidates to minimize risks associated with product failures during the lengthy development process and helps facilitate a greater number of appropriate products and combinations of products passing through the pipeline.

Cost-effectiveness: It is assumed that the PDP approach to R&D is more cost-effective than traditional approaches taken by the biomedical industry. Cost-effectiveness analysis (CEA) is intended to compare the relative R&D costs and related health outcomes of different approaches, in this case R&D costs of products targeting PRNDs and related health impact.[39]

R&D capacity building: It is assumed that PDPs facilitate and strengthen R&D capacity building in LMICs. Research capacity building equips individuals and organizations with the sustainable abilities and skills required to conduct high quality research.[40] In other words, it is a country's ability to effectively generate and utilize technologies appropriate to their needs.[41]

Access and health impact: It is assumed that PDPs improve access to products addressing PRNDs, particularly in LMICs. Access refers to a coordinated set of activities needed to ensure that developed products will achieve equitable public health impact at scale. This impact requires products to be available, affordable and acceptable to end-users, and adopted by LMIC health systems.[42]

ASSUMPTION 1: MARKET FAILURE

CURRENT ASSESSMENT

Survey respondents unanimously agreed that market failure to tackle PRNDs persists, hampering the development of health technologies by the private sector. Industry has limited economic incentive, such as intellectual property rights (IPRs), to develop drugs or technologies for conditions like PRNDs, which primarily affect the poor.[43] Recent research suggests that the biomedical market continues to disproportionately focus on diseases that mainly affect high-income countries (HICs).[44] The current system for R&D is inadequate for meeting the needs of a population with little purchasing power and primarily living in LMICs, where the PRND burden is the highest.[45] For NTDs alone, it is estimated that more than 1.7 billion people require treatment for at least one NTD every year.[46] This situation continues to motivate the need for public action, including public financing.

Investments in PDPs have been a game changer. The ten PDPs assessed as part of this study alone have launched 85 products since their inception (see Annex 9, PDP products: two decades in review). Respondents noted that these products were unlikely to have been developed without the crucial input of PDPs. However, while PDPs solve part of the problem, bottlenecks remain in delivering, scaling-up and integrating developed products into countries' health systems (see Assumption 5, below). In addition, governments and other donors continue to underinvest in global common goods for health[32], which include products targeting PRNDs. The amount received for PRND product R&D has remained relatively stagnant over the past decade, as has the proportion of total health R&D funding received by the ten PDPs (see Annex 8, Table 6). Between 2007 and 2018, funding to all PDPs reviewed by G-finder fluctuated between USD $467 and $667 million annually.[27,47] This level of change is meagre when one considers the success of the PDP model and the gap in funding, further discussed in the Portfolio section below.

FUTURE OPPORTUNITIES

Both public and private sector efforts to address systemic, long-standing problems with health R&D and equitable access remain insufficient.[43,48,49] The PDP model represents one of the best investment options for addressing market failure for PRND-related R&D. However, this can only be achieved by solving access bottlenecks. Therefore, addressing market failure must involve solutions beyond PDPs. This extends to improving systemic issues such as coordination and product prioritization,[8] as well as leveraging other R&D incentives and de-linking R&D costs from product prices.[50] Part of this includes reinvigorated discussions around the financing and provision of global public goods[51] and a recent call to action for common goods for health by WHO[52], which present further opportunities for collective action by public and private actors. PDPs are well-placed to contribute.

ASSUMPTION 2: PORTFOLIO APPROACH TO R&D

CURRENT ASSESSMENT

The findings confirmed that the overall number of products developed for PRNDs has increased considerably since the introduction of PDPs, reflecting their effective use of a portfolio management approach. This approach represents an important competency for PDPs. The product pipeline for PRNDs has more than doubled in size since 2010.[53] The ten PDPs reviewed for this study had 300

products in their R&D pipelines as of November 2019 (Annex 9). Recent, in-depth studies of the PDP pipeline have highlighted the following:

- There are between 522 and 754 products for PRNDs in the R&D pipeline, depending on which diseases and product categories are included.[8,53,54] PDPs are developing almost 70% of all public–private partnered candidates.[55]
- A large drop-off of candidates, from phase II to III, partly reflects the very high costs of phase III trials. As of August 2019, just 49 of 522 candidates (9.4%) in the pipeline for PRNDs were in phase III (excluding diagnostics).[8]
- An estimated 207 product launches, at a total cost of USD $21 billion, could be yielded from the complete 2019 pipeline by 2031.[54] **In this scenario, there would still be 16 "missing products" that** would cost an additional USD $5.5 to $14.2 billion to develop.
- It is anticipated that five PDPs, collectively, will have more than 50 products exiting their pipelines within the next 5 years.[3]
- To date, very few PDPs have launched new vaccines for PRNDs. The malaria (currently being piloted under the malaria vaccine implementation programme),[56] meningitis[57] and rotavirus vaccines[58,59] from PATH and partners are the most notable.

R&D is an inherently iterative process, faced not only with unexpected challenges but also continuous scientific advances and related opportunities. Overall, the ten PDPs interviewed have successfully managed these risks and opportunities through their use of a portfolio approach to R&D. A portfolio approach enables the creation of synergies between different products, benefiting their development under the umbrella of a single portfolio. A key advantage of such an approach is the possibility to **choose the "best" project and direct resources towards leading candidates. This effectively diversifies** and de-risks investments for donors who may not have the scientific expertise to perform this task themselves, offering the opportunity to invest in a complete pipeline of ideas rather than in a single product or project. The approach also increases the likelihood of overcoming barriers to developing combination therapies.[60]

FUTURE OPPORTUNITIES

Findings from the interviews identified five main ways to maximize the opportunities afforded by a PDP portfolio approach.

First, most therapeutic products in PDP portfolios involve the short-term re-use or repurposing of products. There has been little growth in recent years in the number of candidates that are new chemical entities.[27,54]

Second, as products move into late phases of the R&D pipeline, PDP funding requirements are growing. Increased, sustained and well-coordinated funding will become critical if earlier investments are to be fully realized. This is particularly relevant for vaccines, where later phases of development are responsible for 70% of total vaccine development costs.[61]

Third, respondents noted that there is a need for an independent, scientific process for prioritization, particularly across the broader global pipeline of products. Prioritization globally should be informed through scientific consensus and consultation with endemic country systems. While health impact (i.e. burden of disease) and technical feasibility are considered the two most important criteria, development of technologies for the most neglected diseases should also be considered. These criteria

have been described as part of a larger aggregation function, which could help channel funds more effectively to various stages of the development-to-access continuum, minimizing recognized gaps (e.g. identification of new chemical entities, late stages of the pipeline).[8]

Fourth, PDPs have a unique capability to develop and manage complex global R&D partnership networks, as illustrated by the heat maps produced with DNDi, showing their partners and locations across R&D phases (Annex 7, Figure 4). PDPs could improve cross-sharing of these networks, as well as continue strengthening partnerships in LMICs. This would help ensure that only products with maximum utility in LMICs are put through the R&D process.

Fifth, several PDP respondents highlighted that a longer term, core funding modality would be immensely beneficial to their work. Core funding, as opposed to project-based funding, enables dynamic and flexible management of scientific portfolios and rapid responses to changing priorities and unforeseen opportunities. A full comparison of these funding approaches was beyond the scope of this study. A more detailed analysis should be conducted in the future, as there is also a lack of evidence in the literature comparing different funding modalities.

ASSUMPTION 3: R&D CAPACITY BUILDING IN LMICs

CURRENT ASSESSMENT

Respondents confirmed that PDPs play an important role in health research capacity strengthening in LMICs. This is especially true in countries where PDPs support R&D activities such as clinical trials. PDPs partner with local research institutions, improve research infrastructure, provide training in scientific skills, engage and mobilize communities, and support advocacy efforts, including policy-maker engagement.[62] While clinical trials in LMICs have increased, the focus has varied by stakeholder.[2]

Several PDPs have staff and research facilities in LMICs, working in laboratories, conducting clinical trials and coordinating activities with regulatory bodies. DNDi, for example, has focused on building R&D capacity through its network of eight regional offices, six of them in LMICs, with the aim of establishing strong partnerships and leveraging existing national and regional expertise, including through clinical trials (Figure 1). Heat maps showing the distribution of DNDi research partners and activities in LMICs are presented in Annex 7, Figures 5 and 6. IPM has built and strengthened medical research capacity at more than 15 research centres across sub-Saharan Africa, having trained more than 600 clinical staff, including community engagement teams, equipping them to conduct effective HIV prevention activities and rigorous clinical trials. IVCC has supported seven field sites in Africa to attain full good laboratory practice (GLP) accreditation.

R&D capacity developed in collaboration with PDPs has been effectively pivoted to operationalize local efforts to tackle COVID-19. For example, FIND is co-leading the diagnostics pillar of the Access to COVID-19 Tools Accelerator (ACT-A)[63] and helping to build capacity that ensures access to high-quality diagnostic tests for the virus that causes COVID-19. Respondents also highlighted that the capabilities of PDPs such as MMV are currently being leveraged to provide assets and expertise to help lessen the impacts of COVID-19 (e.g. assays, compounds, and modelling expertise), as well as contributing to data collection, while safeguarding access to antimalarials.[64]

FIGURE 1: DNDI network map - DNDi stakeholders (dots) performing various R&D activities (lines); based on the DNDi database of 485 contractual and 205 non-contractual partners

© 2021 Mapbox © OpenStreetMap
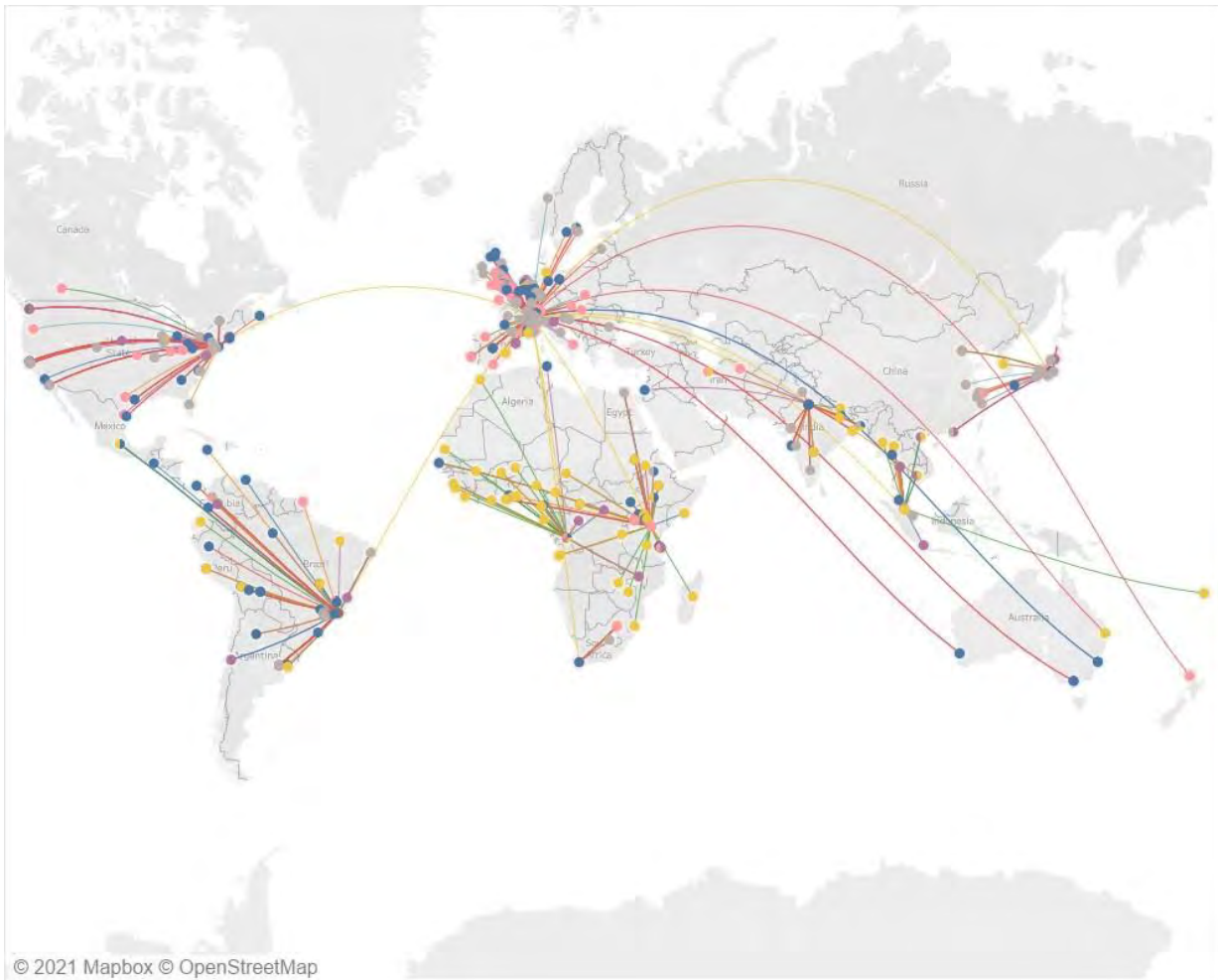
Activity Type
- Discovery
- Translation
- Clinical Development
- Pharmaceutical Development and Manufacture
- Registration
- Access & Advocacy
- DNDi Geneva - DNDi Regional Offices

Stakeholders
- Academia
- MOH/Government
- Non-profits
- PDPs
- Private Industry
- Not Categorised

SOURCE: Developed with DNDi for this study; dataset derived from all DNDi contracts and agreements (e.g. collaborations, clinical trials, fee-for-services, MTAs, MoU/LoI) signed between January 2003 and October 2020 with third parties, covering one of the activity types, with a limited set of non-contractual activities of key third parties developing access to treatment or accelerated R&D. Disclaimer: these are summary data and interpretations should be made with caution.

FUTURE OPPORTUNITIES

PDPs, working together, are in a unique position to further strengthen R&D capacities, critical for overcoming PRND and global health challenges. Respondents noted there were opportunities to improve coordination and collaboration with regards to health research activities conducted by PDPs in LMICs. The current model is, in some cases, one of **"boom and bust".** Respondents suggested that efforts should be made to map existing capacities in LMICs and explore relevant synergies. This could avoid the situation where research capacities established through vertical, disease-specific approaches often fade away once a particular clinical trial concludes. In these instances, capacity must subsequently be re-built for the next trial. PDPs could achieve efficiencies and build sustainable R&D capacity by exploring potential overlaps among product-specific expertise and infrastructure requirements. In addition, respondents suggested that PDPs could adopt policies that ensure recruitment of scientists, researchers and implementers from, and living in, LMICs. Funding through the European & Developing Countries Clinical Trials Partnership (EDCTP) was seen as a strong catalytic model and a platform for supporting collaborative research and clinical research capacity building in sub-Saharan Africa. It has created Regional Networks of Excellence and a Fellowship Program, enabling countries to share expertise, coordinate activities and undertake major, multi-centre international trials. So far, EDCTP has provided EUR €752.74 million of funding to EU–Africa research partnerships, involving 41 African and 19 European countries. The first two EDCTP programmes have funded more than 184 clinical trials to date. A new programme will be operationalized in 2021.[65]

ASSUMPTION 4: COST-EFFECTIVENESS

CURRENT ASSESSMENT

The findings showed that the concept of cost-effectiveness analysis (CEA), as applied to PDPs, varied among stakeholders. While the PDP model has clear cost advantages over more traditional product R&D approaches, most of these advantages have been demonstrated on the grounds of R&D cost-efficiency, typically defined as minimizing the total cost of production for a given output level, in this case a health product or technology. PDP R&D costs are much lower compared with pharmaceutical industry expenditure and have been estimated to range between USD $115 and $240 million versus USD $800 million for industry.[66] A more recent study found that the average cost for drug-makers to gain approval for a new prescription medicine was USD $1.4 billion per approval with pre-tax out-of-pocket costs.[67] In comparison, DNDi recently published updated cost estimates for developing **and registering new combinations or formulations of existing treatments at EUR €4 to €32 million** and a new chemical entity at EUR **€60** to **€190** million.[68] Only two PDPs of the ten we assessed, DNDi and MMV, were able to provide costing data for their products (Annex 9). Although PDP R&D costs cannot be compared directly with those of the pharmaceutical industry, the difference in scale between PDP and industry costs is striking and underscores the need to give alternate models serious consideration.[43]

Much of the actual cost-effectiveness data linked to PDPs is related to the implementation of specific products within a health system and does not account for R&D costs. Also, cost-effectiveness data for the PDP model more generally, as opposed to for specific products, are limited. For example, the cost-effectiveness and even cost-savings of hookworm, leishmaniasis and Chagas disease vaccines have been confirmed through modelling studies by health economists.[69-71] Another study showed that, relative to the status quo, the Cepheid **Xpert®** MTB/RIF rapid test for drug resistant TB had an

estimated cost-effectiveness of USD $959 ($633–$1,485) per disability-adjusted life-year (DALY) averted over 10 years. Its adoption was deemed to offer reasonable value-for-money based on conventional benchmarks for cost-effectiveness.[72] One of the few analyses uncovered during the review that actually compared the cost-effectiveness of PDPs with other interventions found that the costs per DALY averted for new PDP-developed technologies were well within the acceptable range of USD $15 to $120 and favourable in comparison with investment in scaling-up existing technologies.[73] Studies have shown that cost-effectiveness does not necessarily translate to products being affordable to end-users, which is the public-health prerogative.[39]

FUTURE OPPORTUNITIES

Currently, there are very few CEAs of a consolidated PDP approach to R&D, with empirical studies and rigorous evaluations being scarce or not easily accessible.[74-76] This is likely due to a lack of transparent and standardized product-specific costing information, as well as a lack of health impact data. Funding for PDPs frequently takes the form of project funding and is often mixed with funding for other activities (e.g. training and capacity development). This can make it difficult for PDPs to determine the final costs of developing individual products. The long-term nature of R&D, from inception to delivery, uptake and measurement of impact, also contributes to the difficulty in conducting true CEAs of the PDP model. In addition, the variety of health products and the variability in the end-to-end R&D approach, even within individual product categories (e.g. therapeutics, vaccines, etc.), makes comparability difficult. When it **comes to the PDP model, there is no "one-size fits all". For example,** there are obvious differences in the R&D pathways for diagnostics and vaccines.

A rigorous CEA[39] should be performed to determine whether PDPs are more cost-effective than other R&D models. This would form a useful addition to any future investment case and would likely support investment in PDPs. CEAs should be conducted by a neutral body using full, end-to-end financial input data, including all in-kind costs, measured against health outcomes. Drug re-purposing is common among PDPs. Thus, it is essential for any CEA to compare like with like, taking similar product types and subtracting R&D costs incurred by the innovator organization before it became part of a PDP portfolio. To help facilitate CEA of the PDP model, donors could require and fund market uptake activities as well as health impact assessments for products that have gone to market. PDPs could contractually require manufacturers to track and report on market uptake data. These data would also help build investment cases. A meta-analysis of PDP product-specific CEAs could then be performed to assess the cost-effectiveness of the PDP approach to R&D more broadly.

ASSUMPTION 5: ACCESS AND IMPACT

CURRENT ASSESSMENT

Respondents agreed that PDPs have been instrumental in developing products that increase access to the prevention, diagnosis and treatment of PRNDs. PDPs have also achieved health impact, particularly over the last decade, as more products have come to market. Examples of successful implementation are presented below and in Annex 9. Tackling downstream access and obtaining related data remains a challenge for many products, and presents an important opportunity for improvement. In 2019, at a first-of-its-kind meeting that brought together innovators and implementers, Tackling Bottlenecks That Impede Access to Health Innovation[3], **key stakeholders recognized that "uptake of new innovations is** still variable and access is not embedded into innovation pathways until later stages, often leading to

delays." Respondents agreed that coordinated, collective action will be essential for delivering existing products and those emerging from PDP pipelines at scale in the coming years. The Access to Medicine Foundation (AMF), whose remit is to stimulate and guide pharmaceutical companies to do more for people living in LMICs, has noted that PDPs **"are extremely successful in incentivizing access**-friendly R&D, for example by mitigating risk, pooling resources in priority disease areas and ensuring future access is taken into account early in the product development **process."**[77]

It is important to note that almost all respondents in this study, including PDPs, donors, researchers and other stakeholders, seem to have different understandings of access and their own role in improving it. Some respondents see access as falling within the remit of PDPs. Some PDPs have accordingly strengthened their access strategies and organizational functions in this area. Others **believe the expertise and core competencies of PDPs lie in R&D and that they should "stay in their lane".**

Across the ten PDPs interviewed, our analysis found 85 products that have been collectively launched since their inception, including 3 vaccines, 27 therapeutics, 50 diagnostics or health technologies and 5 vector control tools (see Annex 9). These products were launched through partnerships, and include, for example:

- **TB Alliance's** first-line paediatric dispersible tablets, which sell for less than USD $16 for a 6-month course of a four-drug combination therapy, with more than 1 million treatment courses sold across 93 countries since 2016.
- **IVCC's** three new insecticide products, which led to the reintroduction of indoor residual spraying (IRS) in several African countries. The use of third-generation IRS (3GIRS) has protected 119 million people since 2016, resulting in a 20% to 47% decrease in malaria incidence in countries where evaluations have taken place. It is estimated that between 4.6 and 9.2 million malaria cases have been averted, with 14,000 to 28,000 lives saved through NgenIRS[78]-supported IRS campaigns.
- **PATH's** meningitis-A vaccine (MenAfriVac), which costs less than USD $0.50 per dose and was distributed through Gavi[79]-supported programmes in 26 countries of the African meningitis belt during 2010 alone. Overall, MenAfriVac has been delivered to more than 315 million people in Africa. In one nine-country study, the incidence of suspected meningitis cases declined by 57% in vaccinated compared with unvaccinated populations (99% in fully vaccinated populations).[80]
- **MMV's** dispersible form of malaria treatment (Coartem), formulated especially for children, of which more than 390 million doses have been delivered in over 50 countries since its launch in 2012. Overall, MMV estimates that more than 2.2 million lives have been saved by MMV-supported medicines.

One important feature of the PDP model that has contributed to product access, in addition to availability and acceptability, is product affordability. This includes de-linking R&D costs from product prices, facilitated in the PDP model by the leveraging of public funds and the freedom from having to recoup R&D costs. This is based on the premise that costs and risks associated with R&D should be rewarded and incentives for R&D provided by means other than through the price of the product. GlaxoSmithKline, for example, has committed to sell **PATH's** malaria vaccine (Mosquirix; RTS,S) at just 5% above cost price and to reinvest profits into research for tropical diseases. However, the WHO Consultative Expert Working Group on R&D: Financing and Coordination (CEWG) identified that, for now, de-linking approaches remain ad hoc, fragmented and limited. Current initiatives lack a reliable, sustainable mechanism to generate sufficient funding for research, rely heavily on donor financing and priorities, and cover a limited set of diseases.[43,81]

FUTURE OPPORTUNITIES

Even with multiple products having come to market, significant population health benefits from PDP R&D are yet to be realized. This includes scaling-up of approved products, launch of multiple late-stage products in the next few years (see Portfolio section), and continued development of product pipelines. Ensuring broad, equitable access for target populations remains a challenge; specifically, ensuring high distribution coverage; affordability, particularly for the poor; and adoption at provider and end-user levels.[82] Deeper collaborations with both health providers and end-users should be a priority, particularly around design and delivery. PDPs must continue to develop capacities in end-to-end product management, whether through more hands-on activities in market shaping and product delivery (e.g. NGenIRS led by IVCC in collaboration with the Global **Fund, US President's Malaria** Initiative, Abt Associates and PATH) or through collaborations with various access partners (e.g. **PATH's** meningitis and rotavirus vaccines through Gavi in collaboration with WHO, UNICEF, Serum Institute of India, and partners in LMICs). The 2021 Access to Medicine Index (ATM) found that eight leading pharmaceutical companies are moving to make access planning part of a systemic approach to R&D,[14] which presents additional opportunities for collaborations with PDPs, public and philanthropic funders and LMICs.

Some of the most important opportunities lie in achieving the full benefit of this assumption. Our analysis indicated three areas in particular that should be addressed:

First, it is essential to establish a shared understanding of what access means for PDPs within a broader health ecosystem. This is regardless of the strategic direction that PDPs choose (i.e. direct involvement in access or through partnerships). Ample experience and literature on access to innovations in global health should provide a basis for establishing this shared understanding, as well as related activities.[42,83,84,85,86]

Second, while PDPs have filled part of the market failure gap by developing products, they cannot solve the entire problem alone. Access partnerships, including with new and emerging players, are essential to solve key bottlenecks in the health system. There is an urgent need for a global conversation about how to improve access to products and achieve health impact. Many do not see this as a direct responsibility of PDPs, but it is certainly an area where PDPs have an important role to play. The July 2019 Tackling Bottlenecks That Impede Access to Health Innovation meeting,[3] held under the auspices of the SDG Global Action **Plan's** Accelerator 5[85] and the Uniting Efforts for Innovation, Access and Delivery (Uniting Efforts) initiative,[86] while not specific to PDPs, represented a helpful starting point for these conversations. This should continue, ensuring participation of diverse industry and LMIC representatives often lacking in such meetings. PDPs do not need to have a blanket approach. Some PDPs may be well-positioned to play a more direct role in access, while others may rely more on their access partnerships. The end-to-end requirements approach must be fully considered by all stakeholders involved to achieve health impact.

Third, tracking the access and health impact of their products following licensure is challenging for many PDPs. Delivery, access and uptake information is necessary to effectively assess access, health impact and cost-effectiveness. Mechanisms for tracking and sharing these data would need to be established.

PDPs IN A CHANGING R&D LANDSCAPE

This section discusses the PDP model within a changing global R&D landscape. PDPs, along with their partnership networks, are closely interwoven in the R&D landscape and cannot be discussed in isolation from the systems within which they operate. A detailed analysis of the R&D landscape was outside the scope of this study; however, some relevant themes from the interviews are highlighted below. They include the funding landscape for supporting the pipeline of products for PRNDs; new R&D organizations, tools and technologies; the influence of the COVID-19 pandemic; and the evolving PDP model.

FUNDING LANDSCAPE

Strikingly, only USD $4.05 billion (<2%) of the estimated $240 billion annual spend on health R&D is for poverty-related diseases. In 2015, WHO estimated that USD $18 billion in total expenditure would be needed to achieve its NTD roadmap by 2020; however, by 2018, less than USD $200 million a year had been provided, a shortfall of 94%.[87]

Between 2007 and 2018, PDP funding ranged annually between approximately USD $467 and $667 million.[27,47] The relative stagnation in annual funding levels seems misaligned given the success of the PDP model, the funding gap for PRNDs, and the total amount spent on health research annually. In addition, there has been limited donor diversification. In 2018, 97% of all PDP funding came from just twelve donors, up from 93% in 2009. In 2018, 38% of all PDP funding came from the Gates Foundation, 22% from DFID (now FCDO), and 21% from NIH and USAID combined. For the ten PDPs analysed in this study, the cumulative amount invested over 12 years was USD $4.9 billion. Study respondents identified a need to increase and diversify funding sources and attract new funders. This should include more private sector and LMIC funding (especially from BRIC nations, i.e. Brazil, Russia, India and China), as well as funding from established and new philanthropies. New HIC donors and innovative financing **mechanisms should also be pursued. Further funding insights can be found in Annex 8 and in the "Key facts"** box.

The portfolio approach section of this brief highlights the total cost and funding gap to bring the entire pipeline of products targeting PRNDs to market. However, even if the focus were limited to late-stage clinical trials alone, a large funding gap would remain. Recent analysis shows that, annually, about USD $1.7 billion is needed for such late-stage clinical trials; however, current spending on these trials only amounts to an estimated USD $700 million.[8] Accordingly, there is an annual funding gap of around USD $1.0 billion. While this is a significant gap, it is not unfeasible for such an amount to be raised by the global community. Despite increasing interest in the end-to-end approach to R&D for PRNDs by all stakeholders, funding estimates or scenarios are not yet available.

NEW R&D ORGANIZATIONS

Several new entities that have recently entered the global health product R&D space share key features of the PDP model. This was intentional and reflects the success of the model in developing products for PRNDs. While they may not refer to themselves as PDPs, these entities share many similarities

KEY FACTS

R&D FUNDING AND DISEASES OF POVERTY

- **USD $240 billion** total global investment in health R&D per year
- **USD $4 billion** (<2% total) investment in R&D for PRNDs per year
- **USD $21 billion** needed to develop the existing pipeline of PRND products
- **USD $5.5–$14.2 billion** needed to develop 16 identified missing PRND products
- **USD $1.7 billion** required to advance products in late-stage clinical trials
- **USD $553 million** contributed annually to PDPs (14% of total PRND investment)
- **USD $4.9 billion** invested over two decades in the ten PDPs examined in this study

GLOBAL DEATHS FROM DISEASES OF POVERTY

- **1.7 billion people** affected annually by NTDs
- **9 million deaths** annually from PRNDs
- **2.6 million deaths** annually from HIV/AIDS, malaria and TB (2018)
- **500,000 additional deaths** from HIV/AIDS due to COVID-19 in sub-Saharan Africa[88]
- **380,000 additional deaths** from malaria due to COVID-19 in sub-Saharan Africa[89]
- **280,000 additional deaths** annually from TB due to COVID-19 globally[90]

SOURCES: WHO/UNAIDS 2020; Stop TB Partnerships 2020; G-Finder 2019; Bandara et al, 2020; Friends of Global Fund Japan, 2020; IHME, 2019; additional deaths due to COVID-19 are modelled estimates

with PDPs. They include organizations such as the Coalition for Epidemic Preparedness Innovations (CEPI),[92,93] the Global Antibiotic Research and Development Partnership (GARDP),[94] the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X),[95] and the Bill & Melinda Gates Medical Research Institute (MRI),[96] **which one respondent described as being "a PDP model in all but name".** While these organizations adopted design aspects from the PDP model during their establishment, there are also opportunities for PDPs to draw lessons from their models. For example, it has been suggested that PDPs could collectively benefit from a funding model similar to that of CEPI, which is based on annual dues from contributing countries.

Another example is the WHO Global Observatory on Health R&D, established in part to identify health R&D priorities by providing a consolidation, monitoring and analysis function to support coordinated actions on health R&D.[97] The Global Observatory on Health R&D has been severely underfunded, however, and while a few countries pledged funds to this pooled mechanism early on (e.g. Switzerland, USD $6 million; Norway, USD $1.3 million; and Brazil, USD $1 million), the mechanism has failed to gain traction.[8] Since then, the advantages of an aggregator with some governance and other processes similar to those of CEPI have been highlighted.[8] Key functions would include product

prioritization; mobilization and allocation of funding for late-stage trials; targeted investment in building manufacturing capacity in LMICs; coordination and knowledge sharing; and accountability for supported trials. This builds on previous reviews that concluded that a global health R&D coordination platform is needed and garnered a high degree of support from stakeholders.[8] This aggregator should: (1) be publicly owned and managed, covering a broad base of stakeholders; (2) have independent coordination and financing functions; (3) develop platforms covering multiple diseases; (4) link global and national efforts; (5) develop an international roadmap for conducting R&D; and (6) ensure sustainability for a platform secretariat.[6] Any such mechanism must clearly have functions not already being performed by PDPs and should ensure it does not reduce or divert funds for existing PDPs. Rather, it should build on their successes rather than duplicate their efforts.

NEW TOOLS AND TECHNOLOGIES

A variety of new tools and technologies have already or will soon enhance the way in which PDPs and other stakeholders across the R&D landscape operate. These include the Technical Product Profile Directory (TPPD), the P2i tool, artificial intelligence (AI), platform technologies for PRND tools development, open-source methods[98-100] and data sharing, to name a few that were mentioned during the interviews.

Technological advances, such as AI, should continue to be leveraged and expanded to increase the efficiency of screening compound libraries. Interviewees emphasized their expectations of more open-source and collaborative science, including more transparent sharing of high-quality data and models. This should include data on failed product candidates to avoid duplication and wasting resources.[101] Collaborations will be of utmost importance during pre-competitive stages, which are likely to shift to a later stage of R&D. PDPs are well positioned to facilitate this given the broad collaborations they already have in place.[102] Improving IP bottlenecks by leveraging open-source platforms, patent pools, IP sharing through royalty-free licences or other mechanisms are yet to be scaled up in any significant way, although there are initiatives making headway, such as the Medicines Patent Pool[103]. Evaluation or stock taking of such tools – what works, why, for which disease types, in what combination or circumstance – is still required.[104]

THE COVID-19 PANDEMIC PRESENTS BOTH OPPORTUNITIES AND CHALLENGES

Amid the many discussions taking place globally right now about preparing for a post-pandemic future, there are opportunities for PDPs to carve out a niche. For example, it has been noted that in rebuilding pandemic prevention and response systems to prepare for potential future crises (surveillance systems, manufacturing capacity, etc.) there will be a need to keep these systems "warm" and busy by focusing on other pressing health needs that are present between pandemic threats. PDPs and the many needs for countermeasures against PRNDs could play a role in filling this niche. The systems that PDPs work with on a day-to-day basis and their relational capital could be leveraged and designed to provide surge capacity during times of crisis.

The COVID-19 pandemic presents opportunities not seen before. However, the economic downturn caused by the pandemic, combined with other circumstances, has led some countries, such as the UK, to cut aid budgets in 2020. In 2018, the UK was the second-biggest donor of public funding for R&D into PRNDs.[27,105] PDPs may be at particular risk unless policy makers are aware that investing in PDPs offers good returns on their investment and can promote wider health security. PDPs are completely independent, but they can choose to invest some of the money they receive from donors back into

R&D that is carried out in the donor country.[105] This is often the case and has occurred for countries including the UK, Switzerland, Netherlands, Germany, Japan and Australia.

THE EVOLVING PDP MODEL

The PDP model has been one of the most successful public–private partnership approaches to date with regards to product R&D for diseases of poverty. PDPs and the R&D system they operate in continue to evolve. The first two operational decades of the PDP model were mainly focused on the development of a portfolio of viable products. While the development of individual portfolios will continue, the focus has now shifted to late-stage clinical trials, regulatory reviews and preparing for product delivery at scale. Access to products and health impact, which were not considered strategically until recently, must be integrated within the planning of the R&D process. This can be accomplished by a variety of innovative approaches, including expanding access collaborations with a wide range of public and private partners in the health ecosystem as well as strengthening access capacities within PDPs (see Access Assumption section for more). Other key factors for the success of the evolving PDP model, as highlighted by the respondents, are presented in Annex 5: Insights from the survey. These factors reflect the important influence of the systems within which PDPs operate and include a need for greater regulatory harmonization efforts, open-source R&D, coordination, and collaborative alliances. Additionally, this requires increasing and diversifying funding sources.

Study respondents also identified that there is a lack of familiarity with the PDP model among decision-makers in both the public and private sector. The COVID-19 crisis has triggered interest and openness from multiple stakeholders, including the general public, to reshape global health systems, including R&D, for better public health outcomes.[106] Within this context, there is an opportunity for improved communication, awareness and advocacy of the PDP model. This should include developing PDP investment cases to mobilize resources through collective advocacy and communications campaigns.

Out of 15 alternative models for improving global health R&D considered by the CEWG, PDPs were one of the most promising and feasible solutions, being best placed to draw further attention and support.[48] The model has proved to be successful. PDPs are now in a position to continue shaping the global health R&D system for equitable access to health technologies. However, PDPs cannot be viewed or evaluated in isolation. Learning from the pandemic, governments investing in PDPs now have an opportunity to shift from a **"market**-correcting **role"** to rethinking how public value is imagined, practised and evaluated to achieve public purpose.[49] This can only be achieved in collaboration with other stakeholders.

The continuing evolution of PDPs within a broader R&D system and the potential roles of key stakeholders are summarized in Annex 10: The evolving PDP model. The PDP model of the future will require more of a systems thinking approach.[107,108]

CONCLUSION

The findings confirm that the PDP experiment has been one of the most successful in accelerating the development of products and technologies for poverty related diseases. Five of the key assumptions that were the basis of the PDP model when it was established 20 years ago – market failure for PRNDs, a portfolio approach to product R&D, capacity building in LMICs, cost-effectiveness, and access towards health impact – are still highly relevant today. After two decades, this innovative public–private partnership model provides strong capabilities and relational capital that uniquely position PDPs within the evolving health innovation ecosystem. These virtual R&D conductors can be viewed as enablers of an emerging health R&D system for better and more equitable public health outcomes.

Given the funding gap for diseases of poverty, and with COVID-19 prompting a renewed focus on global health R&D and security, now is an opportune moment for governments, philanthropies and the private sector to strengthen their commitments to PDPs. Accordingly, strengthened coordination and leadership among these partners will be paramount in ensuring this model continues to meet its potential in helping fulfil the human imperative of health for all.

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ANNEXES

PDPs EXAMINED FOR THIS STUDY

We examined ten product development partnerships (PDPs) in detail for this study: DNDi, EVI, FIND, IAVI, IPM, IVCC, MMV, PATH, TB Alliance and TBVI. They are new forms of collaborative, not-for-profit R&D organizations, developing new health technologies for poverty related and neglected diseases. PDPs employ a portfolio approach to R&D and work as virtual conductors with governments, industry and research institutions. They leverage predominantly public and philanthropic funding and mitigate costs and risks for industry and governments.

A brief description for each of these PDPs is shown in Table 1, with further details about their R&D activities in Annex 9.

TABLE 1: The ten PDPs examined for this study and their primary R&D activities

Product Development Partnership (year established)	R&D activities
DNDi (2003)	Drugs for Neglected Diseases Initiative: developing new affordable treatments for a wide range of neglected diseases.
EVI (1998)	European Vaccine Initiative: supporting global efforts to develop effective and affordable vaccines against diseases of poverty and emerging infectious diseases.
FIND (2003)	Foundation for Innovative New Diagnostics: accelerating the development, evaluation and delivery of high-quality, affordable diagnostic tests for poverty-related diseases.
IAVI (1996)	International AIDS Vaccine Initiative: exploring new approaches to developing vaccines and other means of preventing HIV infection and AIDS.
IPM (2002)	International Partnership for Microbicides: exploring ways to prevent HIV transmission by accelerating the development and availability of a safe and effective microbicide for use by women in developing countries.
IVCC (2005)	Innovative Vector Control Consortium: facilitating the development and delivery of new and improved vector control tools to prevent malaria and other neglected tropical diseases.
MMV (1999)	Medicines for Malaria Venture: reducing the burden of malaria in disease-endemic countries by discovering, developing and facilitating delivery of new, effective and affordable antimalarial drugs.
PATH (1977)	PATH: transforming health products innovation and delivery in a wide range of areas, including for PRNDs.
TB Alliance (2000)	Tuberculosis Alliance: facilitating the discovery and development of new, faster-acting and affordable tuberculosis medicines.
TBVI (2008)	Tuberculosis Vaccine Initiative: facilitating the discovery and development of new, safe and effective TB vaccines that are accessible and affordable for all people.

METHODOLOGY

The methodology behind the development of this report was based on a participatory assessment process. It included information from 64 individuals from 46 organizations representing 8 stakeholder groups (21 direct interviews with key stakeholder organizations and 25 online surveys), combined with an extensive literature review. A SWOT (strengths, weaknesses, opportunities, threats) analysis for PDPs was developed, again in a participatory manner, with all interviewees invited to contribute to an openly shared online version. Two consultations were held with the PDP Funders Group (PFG). The PDPs provided and verified all product information. Full details are provided below.

PHASE 1

Interviews, literature, & preliminary SWOT analysis

- Initiated in Feb 10, 2020
- Set up participatory assessment process
- Literature review
- Established critical questions for direct interviews
- Developed online questionnaire & created tool for direct Key Informant interviews
- Identified priority key informants to be interviewed across sectors (21)
- Consulted with DFID to review work plan (i.e validate questions and interview list)
- Preliminary SWOT analysis July 13, 2002

PHASE 2

Data collection, analysis, updated SWOT analysis & preliminary report

- Quantitative data collection based on information provided by PDPs, SWOT analysis, secondary research, and online survey
- Qualitative data gathered: 21 direct key informant interviews and 25 online surveys (Google Forms), 100+ online questionnaires sent out (25% response rate)
- SWOT analysis with feedback
- Data from all sources, analysed and triangulated
- Preliminary report
- PFG discussion July 13

PHASE 3

Final synthesis report & recommendations

- Final draft report developed based on feedback from FCDO and PFG
- Consolidated brief with key messages and annexes developed for FCDO

LIMITATIONS

- The COVID-19 pandemic and changing environment caused various difficulties for this project:
  - Delays in data collection and communications
  - Some interviewees could not participate, e.g. representatives from LMIC health authorities, Gavi, and Global Fund
  - Shifting donor priorities and organizational changes (e.g. establishment of FCDO)
- Data gaps and transparency challenges associated with various PDP-related metrics:
  - Tracking downstream access and market data
  - Cost-effectiveness and health impact data
  - Confidentiality restrictions on funding by product

INTERVIEW QUESTIONS

1. **Are the assumptions that were the basis of the PDP model 20 years ago, when the model was established, still valid? What evidence do we have with regard to:**
   a. **Market failure.** Considering major global shifts (e.g. transitions from low- to middle-income countries, emerging diseases, changing burden of disease, etc.), is there still a significant market failure (e.g. 10/90- gap) for products targeting Poverty-Related and Neglected Diseases (PRNDs)? Please provide insights and examples from your organization or otherwise.
   b. **R&D portfolio approach.** Has the portfolio approach to R&D been beneficial (i.e. have the rate and number of products developed for PRNDs increased since the PDP model was introduced)? Please provide examples from your organization or otherwise.
   c. Cost-effectiveness. Has the PDP approach been more cost-effective than traditional models (e.g. public research institutes, industry, etc.)? Please share analysis and evidence.
   d. **Improved access - lives saved or improved.** Have lives ultimately been saved or improved as a result of PDPs (e.g. improved product access and adoption at scale)? Please provide examples.
   e. **R&D capacity in low- and middle-income countries (LMICs).** Has the PDP model increased R&D capacity in LMICs? Please provide examples.
   f. Are there other key assumptions you would add to this list, and are they still valid today?

2. **How do PDPs continue to add value in the current R&D landscape for PRNDs?**

3. **Are the assumptions that were the basis of the PDP model 20 years ago, when the model was established, still valid? What evidence do we have with regard to:**
   a. What are the benefits of funding through:
      - PDPs
      - Other non-PDP intermediaries (GHIT, EDCTP, CHAI, etc.)
      - Direct to researchers and developers?
   b. Based on the value-add of PDPs, should the proportion of funding from the existing external R&D funds be increased? How?

4. **Are the assumptions that were the basis of the PDP model 20 years ago, when the model was established, still valid? What evidence do we have with regard to:**
   a. An estimated ~$6B is needed annually to advance the current product pipeline (18 key missing products) for PRNDs. This translates to a funding gap of $1.5–2.8 billion per year over the next 4 years.

5. What new organizations, with promising alternative product R&D models, have entered this field in the past 10 years? What differentiates them from PDPs, and what is their added value?

6. **What complementary stakeholders within the global health system have PDPs engaged to strengthen their model and investment case? Are there additional stakeholders that should be engaged? (e.g. regulatory agencies, access partners, local SMEs, regional partnerships, patient coalitions, health technology assessment orgs, etc.) Please provide examples.**

7. **Based on your experience and insights, what key recommendations do you have to strengthen the PDP model, including product R&D coordination functions for PRNDs?**
   a. What are the benefits of funding through:
      - PDPs
      - Other non-PDP intermediaries (GHIT, EDCTP, CHAI, etc.)
      - Direct to researchers and developers?
   b. Based on the value-add of PDPs, should the proportion of funding from the existing external R&D funds be increased? How?

8. Thinking more broadly than PDPs, how can public finance of health R&D better facilitate alignment of innovation with unmet priority **needs of PRNDs? (e.g. priority setting tools such as Portfolio to Impact Model (P2I); coordination mechanisms such as WHO Global Observatory on Health R&D, Global Research Collaboration for Infectious Disease Preparedness, etc.)**

9. **Are there any approaches to incentivize and enhance product R&D that could be better leveraged by PDPs? How? (e.g. patent pools, open source and pre-competitive R&D, equitable access licenses, priority review vouchers, regulatory harmonization, etc.)**

10. **As part of this assessment, we are asking key experts to provide inputs into a preliminary SWOT analysis of PDPs within the global health R&D environment. Please follow the link provided to review and provide your comments.**

11. **Do you have anything else to add?**

OPTIONAL:

- **What radical changes are required to ensure products for PRNDs are developed, an essential step in achieving the SDGs?**

- How might the COVID-19 Pandemic influence PDPs and the approach to product R&D?

INTERVIEWEES

We interviewed 64 individuals from 46 organizations and eight stakeholder groups for this study. These groups comprised PDPs (20 individuals); government donors (13); private sector entities (9); high-income country (HIC) researchers (4); low- and middle-income country (LMIC) researchers (4); access partners (4); multilateral agencies (5); and philanthropies (5) (Figure 1). Interviews were conducted either directly (Table 2) or via an online questionnaire in Google Forms (Table 3).

FIGURE 1: Interviewees by stakeholder group (n=46*)

Philanthropies
8%

Multilaterals
8%

Access partners
6%

LMIC researchers
6%

HIC researchers
6%

Private sector
14%

PDPs
31%

Government
donors
21%
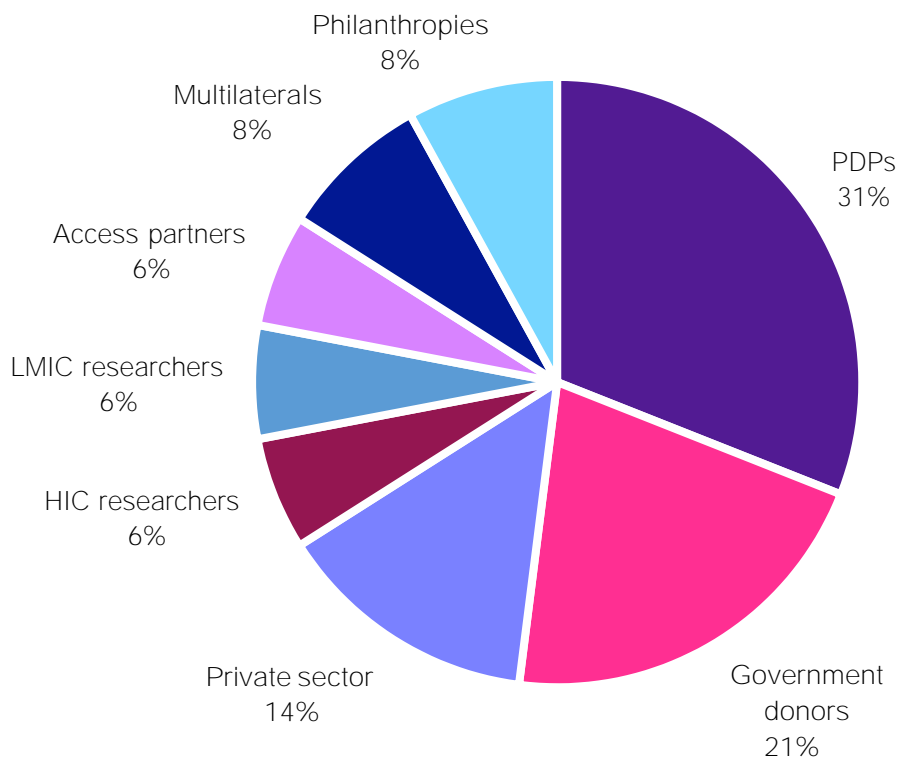
*46 Organizations

64 Individuals

8 Stakeholder groups

DIRECT INTERVIEWEES

TABLE 2: Direct interviewees from 21 organizations

	Name	Organization	Position	Stakeholder Type
1	Alexander Schulze Olivier Paz	Switzerland SDC	Co-Head of Division Global Programme Health Senior Policy Advisor & Health Focal Point, Global Programme Health	Government donor
2	Annie Vestjens	DGIS	Thematic Expert Health	Government donor
3	Jo Mulligan Dirk Mueller Emily Weston	FCDO	Senior Health Advisor, Central Research Department Senior Health Advisor, Health Research Team Deputy Programme Manager, Health Research Team	Government donor
4	Sue Kinn	FCDO	Head of Southern Africa Regional Hub for Science, Innovation & Technology	Government donor
5	Catharina Boehme Sharon Saacks	FIND	CEO Director of Operations	PDP
6	David Reddy Andrea Lucard Neil McCarthy	MMV	CEO Executive VP, Corporate Affairs VP, Head of External Relations: Executive VP of Foreign Affairs Head of External Relations Group	PDP
7	Frederik Kristensen	CEPI	Deputy CEO	PDP
8	David Kaslow	PATH	Vice President, Essential Medicines	PDP
9	Manica Balasegaram Matt Doherty	Global Antibiotic R&D Partnership (GARDP)	Executive Director (formerly MSF Access) External Relations	PDP
10	Marie Lamy	APLMA	Director Access & Polcy	Access partner
11	David Ripin Paul Domanico	CHAI	Executive Vice President of Access, Chief Scientific Officer Senior Director of Global Health Sciences	Access partner
12	Charles Clift	Chatham House	Senior Consulting Fellow, Global Health Programme	HIC researcher
13	Gavin Yamey	Duke	Director of the Center for Policy Impact in Global Health	HIC researcher
14	Bernard Pecoul Laurent Fraisse	DNDi	Executive Director Research & Development Director	PDP
15	Glenda Gray	SA Medical Research Council	President/CEO/DCP3 Advisory Committee	LMIC researcher
16	John Reeder Robert Terry	WHO	Coordinator for Research and R&D at World Health Organization Research Manager	Multilateral agency
17	Tenu Avafia Judit Rius Sanjuan	UNDP	Team Leader, Human Rights	Multilateral agency
18	Toni Hoover Bahati Ngongo	BMGF	Director, Strategy, Planning, and Management for Global Health Strategy Lead, Global Health R&D Policy and Advocacy	Philanthropy
19	Mike Strange Samantha Johnson	GSK	VP and Head, Global Health Catalyst Senior Manager of Global Health Advocacy at GSK	Private sector
20	Gary Cohen Renuka Gadde	Becton Dickinson	Executive Vice President, Global Health President Vice President, Global Health	Private sector
21	Lutz Hegemann	Novartis	COO, Global Health	Private sector

ONLINE INTERVIEWEES

TABLE 3: Online interviewees from 25 organizations

	Name	Organization	Position	Stakeholder Type
1	Peñas Jiménez	EU DG Research	Administrator - Focal Point for EDCTP	Government donor
2	Kei Katsuno	GHIT	Senior Director of Investment Strategy and Business Development	Government donor
3	Julie Wallace	USAID	Malaria Division Chief/ Agency Lead PMI	Government donor
4	Nic Notarpietro	DFAT (AUSTRALIA)	Director of Mind Garden Development Services	Government donor
5	Jens Bessai Gerald Laezer	KFW (GERMANY)	Former Head-Southeast Asia Head of KFW Office in Cambodia	Government donor
6	Michael Goldrich	IPM	Director at International Partnership for Microbicides (IPM)	PDP
7	Mel Spigelman Willo Brock	TB Alliance	CEO of TB Alliance Senior VP, External Affairs	PDP
8	Stefan Jungbluth	EVI	Head of Business Development (EVI)	PDP
9	Nick Hamon Tom McLean	IVCC	CEO of IVCC Access and New Paradigms in Vector Control at IVCC	PDP
10	Patricia Coffey	PATH	Director, D3AWN PDP	PDP
11	René Coppens	Tuberculosis Vaccine Initiative (TBVI)	Director of External Relations & Resource Mobilization	PDP
12	Hester Kuipers	IAVI	Executive Director, Europe	PDP
13	Ben Pierce	Imperial College London	Operations Manager for FVMR Hub	HIC researcher
14	Jamie Bay Nishi	Global Health and Technologies Coalition	Director	Access partner
15	Simon Croft	LSHTM	Professor	HIC researcher
16	Lara Pandya	EDCTP	Strategic Partnerships Officer	LMIC researcher
17	Bassirou Bonfoh	Centre Suisse de Recherches Scientifiques en Cote d'Ivoire (CSRS)	Director at CSRS and Director for DELTAS Africa Afrique One-ASPIRE consortium in Abidjan, Cote d'Ivoire	LMIC researcher
18	Moses Adriko	AAS	Programme / Technical Officer - DFID ASCEND Project	LMIC researcher
19	Duneton Philippe	UNITAID	Deputy Executive Director	Multilateral agency
20	Lisa Goerlitz	DSW (Deutsche Stiftung Weltbevoelkerung)	Senior Advocacy Officer	Philanthropy
21	Philippe Jacon	Cepheid	SVP Global Access	Private sector
22	Helen McDowell	ViiV	Head of Government Affairs, Global Health and Access	Private sector
23	Charles Knirsch	Pfizer	Clinical Research at Pfizer	Private sector
24	Mark Grabowsky	Pantheryx	Vice President, Public Initiatives	Private sector
25	Lorenzo De Santis Gemma Wardle	Wellcome Trust	Policy Officer Policy Officer	Philanthropy

INSIGHTS FROM THE SURVEY

The figures below present some of the key insights from the online survey respondents. They include perspectives about 1) ways to enhance R&D for PDPs, 2) priority areas for public sector investments and 3) new investment opportunities to address the funding gaps (Figure 2).

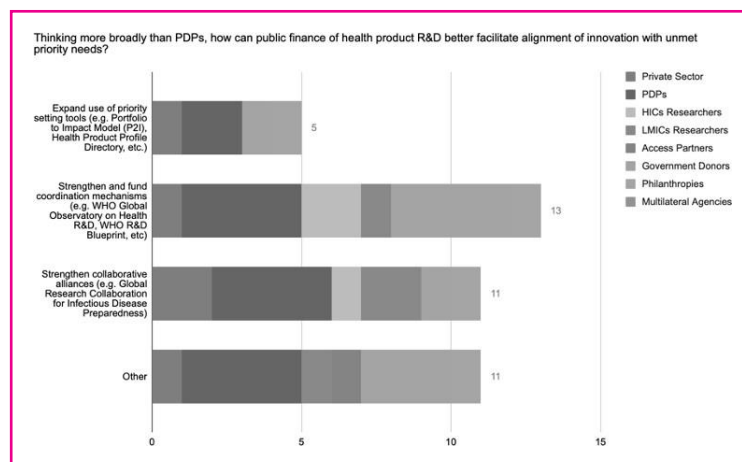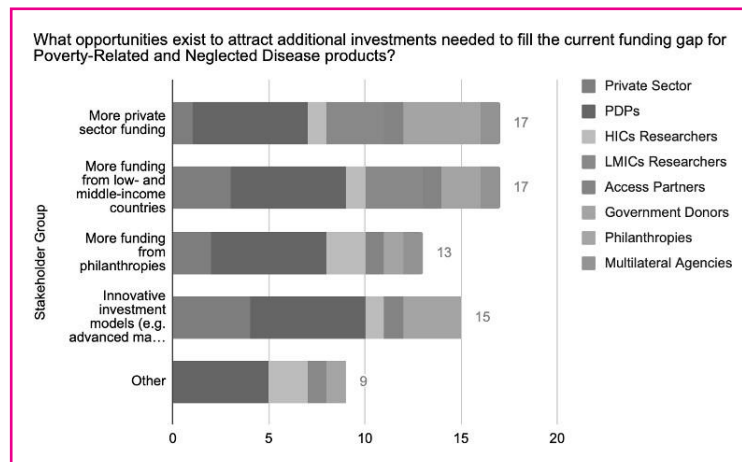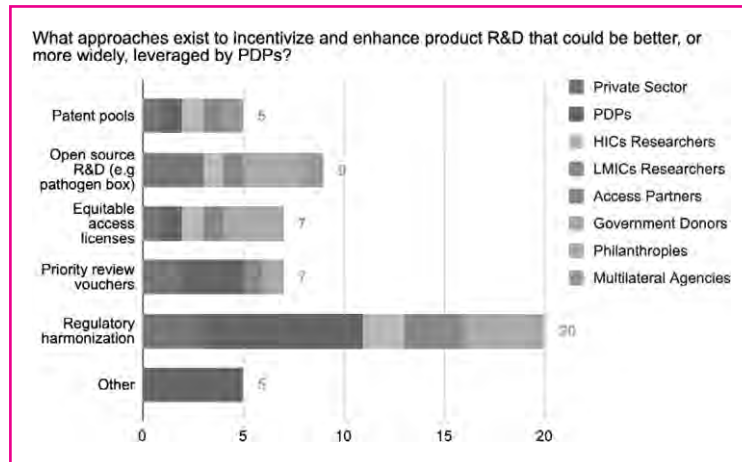**FIGURE 2:** Insights from the online surveys (n=25)

FIGURE 3: SWOT analysis of the PDP model

STRENGTHS

- Addresses market and government failures
- Portfolio based approach to R&D
- Develop appropriate and affordable health products for LMICs
- Catalyst of capacity building in LMICs
- Attracts new investment for PRNDs

- Major contributor to growing product development knowledge pool
- Builds multi-stakeholder partnerships leveraging capabilities, reducing risks
- Impact on lives saved and PRNDs

WEAKNESSES

- Donor funding dependency (relatively limited pool of funders)
- Siloed approaches across PDPs (e.g. capacity building, lack of best-practice sharing)
- Lack of consolidated, easily accessible and transparent information, incl. a standardized Performance Measurement Framework (PMF)

- Lack of prioritization of key medicines and diagnostics across disease areas
- Risk of private interests undermining public goals

OPPORTUNITIES

- Leverage funding trends around preparedness & health security
- Emergence of new funding entities (e.g. GHIT, GHIF, etc.) & sources (e.g. MICs, philanthropies, etc.)
- Greater alignment of PDP priorities with global needs & burden of disease
- Digital technologies & AI , open source approaches
- Enhancing access for end users & scaling up products (end-to-end approach)

- Inclusion & expansion of new partners (academia, patients, access partners, etc.)
- Create shared performance measurement framework
- Adopt longer time horizons
- More evidence around cost-effectiveness of the PDP model
- Replenishment or similar model for funding

THREATS

- Funding sustainability (e.g. waning interest from industry and others: new priorities (AMR, pandemic prep, etc.)
- Complex and fragmented international funding sources and pathways
- Limitations on accessibility due to environmental and geopolitical factors
- Most industry related R&D and market information is confidential

- Low awareness and demand among healthcare professionals and end users in countries
- Inconsistent prequalification and regulatory processes
- Unreliable or late demand forecasting
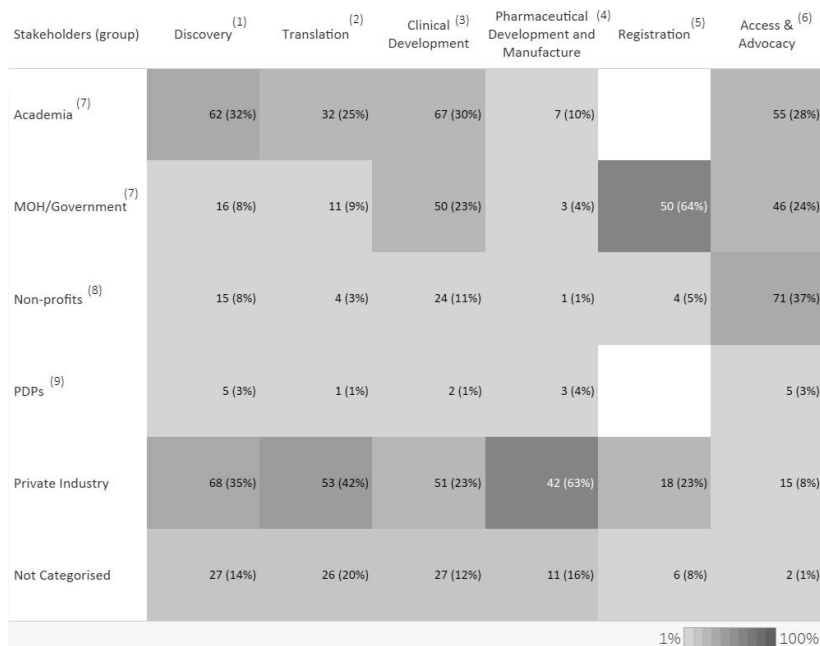- Inconsistent alignment between centralized and local regulators

PDP SWOT ANALYSIS
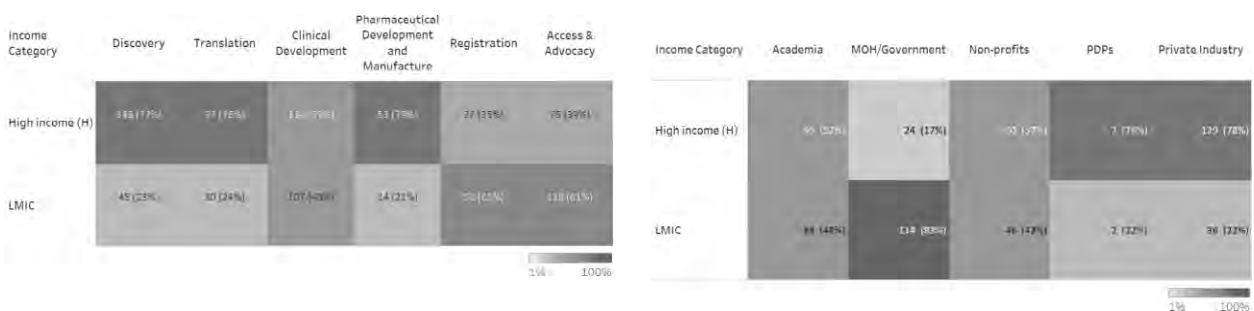
HEAT MAPS OF PDP R&D PARTNERS
DNDi ILLUSTRATIVE EXAMPLE

The heat maps below show the distribution of R&D partners and activities across all phases of research and access for DNDi (Figure 4). They also show the pattern of partners and R&D activities that are conducted predominantly in HICs or LMICs (Figures 5 and 6, respectively). These heat maps were developed with DNDi for the purpose of this study, based on the DNDi contracts database of 485 contractual and 205 non-contractual stakeholders.

FIGURE 4: Heat map of R&D activities by stakeholder type for DNDi

Stakeholders (group)	Discovery [1]	Translation [2]	Clinical Development [3]	Pharmaceutical Development and Manufacture [4]	Registration [5]	Access & Advocacy [6]
Academia [7]	62 (32%)	32 (25%)	67 (30%)	7 (10%)		55 (28%)
MOH/Government [7]	16 (8%)	11 (9%)	50 (23%)	3 (4%)	50 (64%)	46 (24%)
Non-profits [8]	15 (8%)	4 (3%)	24 (11%)	1 (1%)	4 (5%)	71 (37%)
PDPs [9]	5 (3%)	1 (1%)	2 (1%)	3 (4%)		5 (3%)
Private Industry	68 (35%)	53 (42%)	51 (23%)	42 (63%)	18 (23%)	15 (8%)
Not Categorised	27 (14%)	26 (20%)	27 (12%)	11 (16%)	6 (8%)	2 (1%)

1% ▓▓▓ 100%

FIGURES 5 AND 6: Heat maps showing types of R&D activities (Figure 5) and types of R&D partners (Figure 6) by location in HIC or LMIC, for DNDi

Income Category	Discovery	Translation	Clinical Development	Pharmaceutical Development and Manufacture	Registration	Access & Advocacy
High income (H)	148 (77%)	97 (76%)	116 (79%)	53 (78%)	77 (35%)	76 (39%)
LMIC	45 (23%)	30 (24%)	107 (49%)	14 (21%)	55 (45%)	118 (61%)

1% ▓▓▓ 100%

Income Category	Academia	MOH/Government	Non-profits	PDPs	Private Industry
High income (H)	95 (52%)	24 (17%)	60 (77%)	7 (78%)	129 (78%)
LMIC	88 (48%)	118 (83%)	46 (17%)	2 (22%)	36 (22%)

1% ▓▓▓ 100%

SOURCE: This dataset derived from all DNDi contracts and agreements (e.g., collaborations, clinical trials, fee-for-services, MTAs, MoU/LoI) signed between January 2003 and October 2020 with third parties having a scope covering one of the activity types, plus a limited set of non-contractual activities of key third parties with whom we have sustained engagement aiming to develop access to treatment or accelerated R&D. Disclaimer: these are summary data and interpretations should be made with caution.

PDP FUNDING OVERVIEW

(2007-18)

This annex provides a review of funding streams to PDPs from 2007 to 2018, as well as funding for R&D for PRNDs.

TABLE 4: Funds received between 2007 and 2018 by the ten PDPs analysed for this study. The cumulative annual amount ranged from USD $360–466 million. The total amount of funding 2007-2018 was USD $4,957.8 million. Funding prior to 2007 was not tracked annually by G-finder. (sources: G-finder 2019 (2009–2018 funding) and G-finder 2017 (2007–2008 funding*)). Funders include government donors, philanthropies and private sector entities. TB Alliance & EVI independently reported different funding figures for 2018 than those reported by G-finder.

PDP	*2007	*2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	TOTAL 2007-18
						Funds Received by PDPs - USD (millions)							
PATH	45	130	151	81	106	91	88	128	89	50	67	101	1,127.0
IAVI	85	93	79	73	67	66	64	43	70	93	86	81	900.0
TB Alliance	44	38	40	55	40	48	55	58	74	41	50	68	611.0
MMV	85	50	48	76	80	54	70	77	81	63	79	58	821.0
DNDi	28	22	34	35	38	32	35	56	33	49	57	57	476.0
FIND	26	35	17	29	24	24	25	25	17	29	27	34	312.0
IPM	46	65	36	33	15	24	31	28	27	21	40	31	397.0
IVCC	n/a	11	16	18	3.1	14	26	13	33	34	11	28	207.1
TBVI	n/a	n/a	<0.1	4.2	3.9	5.3	5.8	4.4	9	8.7	8.5	5.8	55.7
EVI	7.5	4	3.9	5.3	7.8	2.2	6.6	3.1	3.8	2	2.3	2.5	51.0
TOTAL	366.5	448	424.9	409.5	384.8	360.5	406.4	435.5	433.8	390.7	427.8	466.3	4957.8

FIGURE 7: Graphic presentation of funds received between 2007 and 2018 by the ten PDPs (Table 6) - USD (millions)
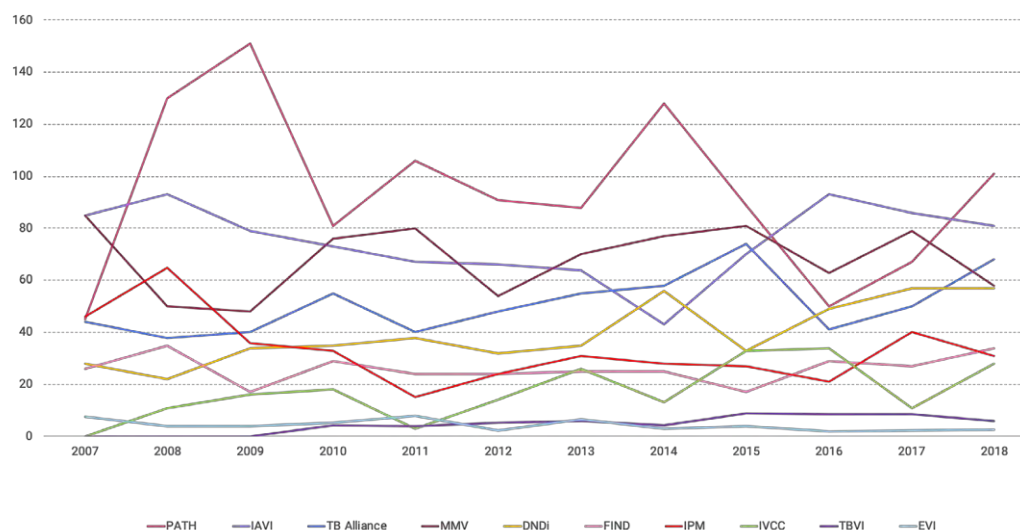
FIGURE 8: Global funding for PRNDs in 2018, showing that only around 13% of global investments in neglected diseases R&D goes to PDPs (source: G-finder 2019)
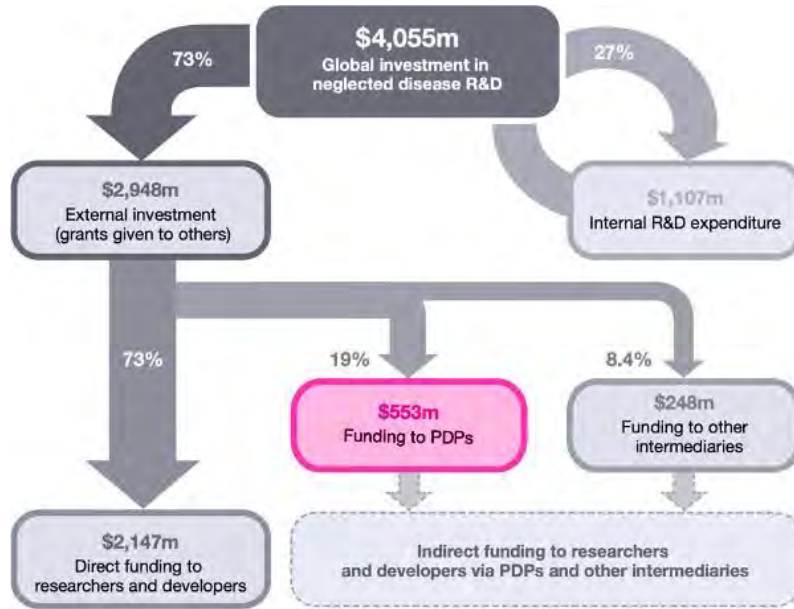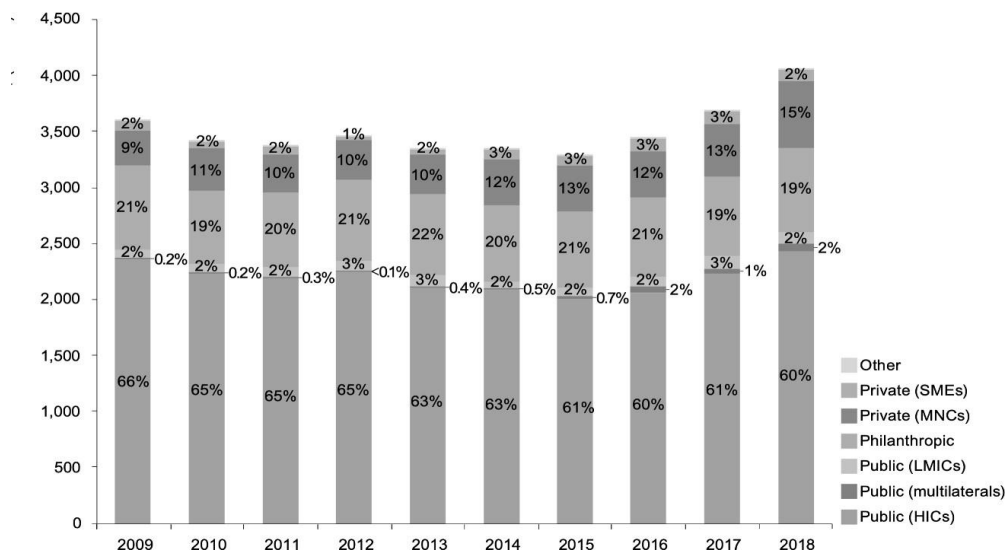

FIGURE 9: Total R&D funding for PRNDs by sector (source: G-Finder 2019)

PDP PRODUCTS:
TWO DECADES IN REVIEW

(1 of 6)

The ten PDPs we consulted have 300 products in their R&D pipelines overall (as of November 2020); 93 products have been registered and 85 have been launched in LMICs.

Table 5 includes a quantitiative summary of these products along with information on total funding received from 2007-2018. **Table 6** provides product details for each PDP consulted, including market data (see magenta text) and estimated R&D costs per product, where available. Please refer to Assumption 4: Cost-Effectiveness and Assumption 5: Access and Impact, for related challenges.

TABLE 5: A summary of products in the R&D pipeline, registered and launched by the ten PDPs examined for this study (as of November 2020) (source: the ten PDPs examined for this study)

Product Development Partnership	Products in the R&D Pipeline (Across Phases)	Products Registered	Products to Market	Funding 2007-2018[27,47] (USD millions)
DNDi	48	9	8	476.0
EVI	24	-	-	51.0
FIND	47	27	24	312.0
IAVI	29	-	-	900.0
IPM	13	-	-	397.0
IVCC	16	5	5	207.1
MMV	37	14	13	821.0
PATH	44	32	29	1,127.0
TB Alliance	32	6	6	611.0
TBVI	10	-	-	55.7
Total	300	93	85	4,957.8

PDP PRODUCTS:
TWO DECADES IN REVIEW
(2 of 6)

TABLE 6: PDP products: two decades in review (source: PDPs examined for this study, information provided and verified as of November 2020)

Product Development Partnership (PDP)	Disease Areas	Products in R&D Pipeline	Products Registered (Year)	Products to Market (Launch Year)	Est. Costs of R&D by Product* (Currency as Provided)
DNDi (Est. 2003)	Sleeping Sickness Leishmaniasis Chagas disease Pediatric HIV Filarial disease Mycetoma Hepatitis C COVID-19	48 products in R&D pipeline Discovery: 14 Translational stage: 13 Development stage: 12 Implementation stage: 9	8 products registered (1 pending) Therapeutics 1. Malaria FDC ASAQ (WHO PQ 2008) Registered in 35 countries. 2. Malaria FDC ASMQ (WHO PQ 2012, EML and EMLc 2013) Registered in 11 countries. 3. Nifurtimox-eflornithine combination therapy (NECT) (WHO EML 2009, EMLc 2013) First-line treatment registered all 13 endemic countries (until arrival of fexinidazole, as of 2019, Second-line treatment except in cases of advanced disease. 4. SSG&PM for visceral leishmaniasis in Africa (2010, recommended by WHO as first-line treatment for visceral leishmaniasis in East Africa) Drugs for combination registered in 5 countries. 5. Benznidazole Paediatric Dosage form (Brazil, 2011, WHO EMLc 2013) Registered in 4 countries. 6. New Visceral Leishmaniasis treatments Asia (2010, recommended by WHO Expert Committee on the Control of Leishmaniases) Guideline change in 3 countries. 7. Superbooster Therapy Paediatric HIV/TB (2016), recommended by WHO in its antiretroviral guidelines) 8. Fexinidazole (T.b. gambiense) (EMA 2018, DRC 2019: WHO EML 2019) 9. 2-in-1 LPV/r pellets and ABC/3TC or AZT/3TC (Pending US FDA approval: decision expected December 2020)	8 products launched Therapeutics 1. Malaria FDC ASAQ (2007, Morocco) First registered in Morocco to enable rapid exportation to other African countries. More than 516 million treatments distributed since 2007. 2. Malaria FDC ASMQ (2008, Brazil) First registered in Brazil. More than 1.2 million treatments distributed since 2008. 3. Nifurtimox-eflornithine combination therapy (NECT) (2009, DRC) 4. SSG&PM for visceral leishmaniasis in Africa (2010, North & South Sudan) 5. Benznidazole Paediatric Dosage form (2011, Brazil) 6. New Visceral Leishmaniasis treatments Asia (single-dose liposomal amphotericin B: w/ miltefosine, w/ paromomycin) (2011, Bangladesh and India) 7. Superbooster Therapy Paediatric HIV/TB (2016, South Africa) 8. Fexinidazole (T.b. gambiense) (2019, DRC)	1. €5M 2. €6M 3. €4M 4. €10M 5. €3M 6. TBD 7. TBD 8. €55M (NCE) 9. €18M
EVI (Est. 1998)	Vaccines for: Malaria Leishmaniasis Diarrheal diseases Zika Nipah Virus In addition, EVI is involved in several horizontal, disease-overarching activities related to vaccine R&D.	24 products in R&D pipeline: Pre-clinical: 7 Phase I: 8 Phase II: 7 Phase III: 2	No products registered	No products on the market	Not available

PDP PRODUCTS:
TWO DECADES IN REVIEW

(3 of 6)

Product Development Partnership (PDP)	Disease Areas	Products in R&D Pipeline	Products Registered (Year)	Products to Market (Launch Year)	Est. Costs of R&D by Product* (Currency as Provided)
FIND (Est. 2003)	TB Antimicrobial Resistance (AMR) Hepatitis C & HIV Malaria & Fever Neglected Tropical Diseases (NTDs) Pandemic Preparedness (i.e. pathogens with pandemic-casuing potential)	47 products R&D pipeline: Feasibility: 6 Development: 16 Validation: 14 Regulatory: 8 Evaluation/ Demonstration: 3	27 products registered Diagnostics & health technologies 1. GenoType MTBDR (2005), TB 2. GenoType MTBDRsl VER 1.0 (2009), TB 3. GenoType MTBDRsl VER 2.0 (2015), TB 4. GenoType MTBDRplus VER 2.0 (2015), TB 5. NTM+MDRTB Detection Kit 2 (2016), TB 6. Xpert MTB/ RIF (2010), TB 7. Loopamp Trypanosoma brucei Detection Kit (2015), Human African Trypanosomiasis 8. SD BIOLINE HAT 2.0 (2018), African trypanosomiasis 9. Determine TB LAM Ag (2013), TB 10. Loopamp MTBC assay (2016), TB 11. Xpert MTB/RIF Ultra (2017), TB & DR-TB 12. Alere Malaria Ag P.f. (2016), Malaria 13. Xpert HIV-1 Qual (2015), HIV 14. Xpert HIV-VL (2017), HIV 15. Xpert Ebola (2015), Ebola 16. HAT RDT 1st generation (native proteins) (2012), African trypanosomiasis 17. Malaria LAMP (2014), Malaria 18. MGIT liquid culture (TB & MDR-TB) (2007), TB 19. MTB rapid speciation (2007), TB 20. iLED fluorescent (2009), TB 21. TrueNat MTB and Rif (2018), TB 22. CRP-malaria combo test (2019) 23. DPP II Asia panel (multiplex fever RDT) (2019 - not commercialised yet) 24. FUJI-SAI Rapid (2018- not commercialised yet) TB 25. AlereqFilodetect (2017 - not commercialised) Ebola 26. Xpert HCV (2018) 27. Xpert XDR (2020), DR TB	24 products launched* Diagnostics & health technologies 1. GenoType MTBDR (2005) 2. GenoType MTBDRsl VER 1.0 (2009), TB 3. GenoType MTBDRsl VER 2.0 (2016) 4. GenoType MTBDRplus VER 1.0 (2016) 5. NTM+MDRTB Detection Kit 2 (2016) 6. Xpert MTB/ RIF (2010) 7. Loopamp Trypanosoma brucei Detection Kit (2015) 8. SD BIOLINE HAT 2.0 (2018) 9. Determine TB LAM Ag (2013) 10. Loopamp MTBC assay (2016) 11. Xpert MTB/RIF Ultra (2017) 12. Alere Malaria Ag P.f. (2016) 13. Xpert HIV-1 Qual (2015) 14. Xpert HIV-VL (2017) 15. Xpert Ebola (2015) 16. HAT RDT 1st generation (native proteins) (2013) 17. Malaria LAMP (2014) 18. MGIT liquid culture (TB & MDR-TB) (2007) 19. MTB rapid speciation (2007) 20. iLED fluorescent (2009) 21. TrueNat MTB and Rif (2018) 22. CRP-malaria RDT (2019) 23. Xpert HCV (2018) 24. Xpert XDR (2020)	Not available

*FIND's GenoType MTBDR was replaced by MTBDRplus in 2016.

PDP PRODUCTS:
TWO DECADES IN REVIEW

Product Development Partnership (PDP)	Disease Areas	Products in R&D Pipeline	Products Registered (Year)	Products to Market (Launch Year)	Est. Costs of R&D by Product* (Currency as Provided)
IAVI (Est. 1996)	HIV TB EIDs Snakebite	29 products in R&D Pipeline Development: 2 Translation: 26 Discovery: 1	No products registered	No products in the market	Not available
IPM (Est. 2002)	HIV prevention Sexual and reproductive health technologies	13 products in R&D pipeline Preclinical stage: 4 Clinical stage: 9 Active development or paused: 7 Development collaboration (not IPM led): 4	No products registered	No products in the market	Not available
IVCC (Est. 2005)	Vector control, with a focus on mosquito borne diseases and malaria	16 products in R&D pipeline Lead Generation Proof of concept: 1 Lead Optimization: 3 Pre-Development: 4 Development: 3 Product Launch: 1 Product Management: 4	5 products registered Vector control tools 1. BASF Interceptor G2 (WHO PQ 2018) 2. Bayer Fludora Fusion (WHO PQ 2018) 3. Sumitomo Sumishield 50WG (WHO PQ 2017) 4. Syngenta Actellic 300CS (WHO WHOPES 2013, WHO PQ 2018) 5. K-Othrine Polyzone (WHO WHOPES 2013, WHO PQ 2018)	5 products launched Vector control tools 1. BASF Interceptor G2 (2018) 2. Bayer Fludora Fusion (2018) 3. Sumitomo Sumishield 50WG (2017) 4. Syngenta Actellic 300CS (2013) 5. K-Othrine Polyzone (2013) IVCC's use of 3rd generation IRS has protected 119 million people since 2016 resulting in a 20 - 47% decrease in malaria incidence. It is estimated that 4.6 to 9.2 million malaria cases will have been averted, with 14,000 to 28,000 lives saved through NgenIRS supported IRS campaigns.	Not available
MMV (Est. 1999)	Malaria	37 products in various R&D and clinical trial phases Research:15 Translational: 13 Product Development: 9	14 products registered Therapeutics 1. Coartem Dispersible (2012) 2. Supyra (2020) 3. SPAQ-CO dispersible (2012) 4. Larinate (60 mg for injection) (2018) 5. Artesun (2010) 6. Eurartesim (2011) 7. Pyramax (2015) 8. Pyramax granules (2015) 9. ASAQ Winthrop (2007) 10. ASMQ (2012) 11. Artecap (2018) 12. Artesunate Rectocaps (2018) 13. Kozenis/ Krintafel (2018) 14. Tafenoquine (2019)	13 products launched Therapeutics 1. Coartem Dispersible (2012) 390+ million treatments of Novartis' Coartem® Dispersible delivered to over 50 countries since launch 2. Supyra (2020) 3. SPAQ-CO dispersible (2012) 4. Larinate (60 mg for injection) (2018) 5. Artesun (2010) Fosun Pharma estimates over 120 million vials of Artesun® delivered between 2010 & 2018 6. Eurartesim (2011) 7. Pyramax (2015) 8. Pyramax granules (2015) 9. ASAQ Winthrop (2007) 10. ASMQ (2012) 11. Artecap (2018) 12. Artesunate Rectocaps (2018) 13. Kozenis/ Krintafel (2018) Over 2.2 million lives saved by MMV-supported medicines	1. 7,988,860 USD 2. 1,331,553 USD 3. 106,363 USD 4. 975,735 USD 5. 3,032,564 USD 6. 30,238,513 USD 7. 28,145,337 USD 8. 211,539 USD 9. Not avaiable 10. Notavaiable 11. Not avaiable 12. 3,950,928 USD 13. 30,822,155 USD

PDP PRODUCTS:
TWO DECADES IN REVIEW

Product Development Partnership (PDP)	Disease Areas	Products in R&D Pipeline	Products Registered (Year)	Products to Market (Launch Year)	Est. Costs of R&D by Product* (Currency as Provided)
PATH (Est. 1977)	Malaria Rotavirus Meningitis Pneumococcal Enteric diseases PPH PE, etc.	44 products in R&D pipeline Implementation: 7 Development: 7 Translation: 18 Discovery: 12	32 products registered Therapeutics & vaccines 1.. **MenAfriVac®** (2010) 2.. **PNEUMOSIL®** (2019) 3.. RTS,S/AS01 (2015) 4.. ROTAVAC (2014) 5.. ROTASIIL (2017) Diagnostics & health technologies 6. STANDARD G6PD (2018) 7. The Ellavi Uterine Balloon Tamponade (2019) 8. Unijet Injection System (2000) 9. Vaccine Vial Monitors (1996) 10. Soloshot Syringe (1990) 11. Ceramic Water Filters 12. **Woman's** Condom (2010) 13. Caya Diaphragm (2013) 14. Clean Delivery Kit (1980's) 15. LifeWrap Non-Pneumatic Anti-Shock Garment (2014) 16. BIRTHweigh (mid 1980s) 17. Nevirapine pouches (2007) 18. MSR SE 200 Community Chlorine Maker (2015) 19. C1 Common Interface (2012) 20. Nifty Cup (2016) 21. Intradermal Adapter (2017) 22. Freeze-Safe Vaccine Carrier (2018) 23. Tropis Jet Injector (2018) 24. 7.1% Chlorhexidine for umbilical cord care (2012/2013) 25. Blow-Fill-Seal (BFS) container 26. Rapid falciparum malaria test (1998) 27. Care HPV (2012) 28. Alere Malaria Ag P.f test (2017) WHO PQ 4/2019 29. P4 Rapid test (2018) 30. SD BIOLINE Onchocercaiasis, Lymphatic Filariasis and bioplex IgG4test (2014 & 2016) 31. Bag mediated filtration systems (BMFS) (2019) not registered 32. PrCr (2019) registered in South Africa in 2018. No longer US FDA listed, but is CE Marked (self-certified)	29 products launched* Therapeutics & vaccines 1. **MenAfriVac®** (2010) More than 315 million people vaccinated across Africa; meningitis A has virtually disappeared wherever it has been used. In 2016, Sudan became the first country to incorporate MenAfriVac® into its routine national immunization programme. it has since begun routine immunization in more than 10 countries. 2. ROTAVAC (2015) 3. ROTASIIL (2018) Diagnostics & health technologies 4. STANDARD G6PD (2018) In 2019, 70,350 tests were distributed to malaria-endemic countries where the product is registered. 5. The Ellavi Balloon Tamponade (2018) 6. Rapid falciparum malaria test (1998) 7. Care HPV (2012) 8. Alere Malaria Ag P.f test (2017) WHO PQ 4/2019 9. P4 Rapid test (2018) 10. SD BIOLINE Onchocercaiasis, Lymphatic Filariasis and bioplex IgG4test (2014 & 2016) 11. Bag mediated filtration systems (BMFS) (2019) not registered 12. PrCr (2019) registered in South Africa in 2018. No longer US FDA listed, but is CE Marked (self-certified) 13. Unijet Injection System (2000, also used in DMPA-SC) 14. Vaccine Vial Monitors (VVM) (1996) 15. Soloshot Syringe (1990) 16. Ceramic Water Filters 17. **Woman's** Condom (2010) 18. Caya Diaphragm (2013) 19. Clean Delivery Kit **(1980's)** 20. LifeWrap Non-Pneumatic Anti-Shock Garment (2014) 21. BIRTHweigh (mid 1980s) 22. Nevirapine pouches (2007) 23. MSR SE 200 Community Chlorine Maker (2015) 24. C1 Common Interface (10+ different product brands, 2012) 25. Nifty Cup (2016) 26. Intradermal Adapter (2017) 27. Freeze-Safe Vaccine Carrier (Multiple products, first: 2018) 28. Tropis Jet Injector (2018) 29. 7.1% Chlorhexidine for umbilical cord care (2012/2013)	Not available

*7 PATH products were discontinued:
1. HIV Dipstick (1993): Older technology replaced by newer with better, characteristics. 2. Rapid Hepatitis B test (1998): outdated technology. 3. Rapid falciparum malaria test (1999): Performance issues – see WHO/FIND evaluations. 4. Rapid falciparum malaria test (2001): Performance issues – see WHO/FIND evaluations. 5. Retinol Blinding Protein ELISA Test (2003): Insufficient and inconsistent demand for use. 6. TB MODs Test Kit (2010): Product was released around the same time as the Cepheid GeneXpert received WHO endorsement, an automated TB molecular test that diagnoses TB and also drug resistance to first line drugs and takes 2 hrs to run, MODS takes up to 2 weeks but is cheaper and more sensitive. 7. Alere Malaria Ag Pf HRP2 ELISA (2017) was purchased by Abbott and removed as SKU in Q1 2019
PATH also developed ancillary products including: - Recombinant human antibody for Ov16 (2015). - Q-Plex Micronutrient Array (2017) not registered. - Custom antibodies for malaria diagnostics (2017) not registered. - Q-Plex Malaria 5-Plex Array (2019) not registered.

PDP PRODUCTS: TWO DECADES IN REVIEW

Product Development Partnership (PDP)	Disease Areas	Products in R&D Pipeline	Products Registered (Year)	Products to Market (Launch Year)	Est. Costs of R&D by Product* (Currency as Provided)
TB Alliance (Est. 2000)	Tuberculosis	32 products in R&D pipeline Discovery: 18 Translation: 4 Development: 3 Implementation: 7 *current pipeline October 2020	6 products registered* Therapeutics 1. Pretomanid (2019) -- in combination with bedaquiline + linezolid for DR-TB 2. Pretomanid pediatric product 3. Pediatric HR (isoniazid + rifampin) 4. Pediatric HRZ (isoniazid + rifampin + pyrazinamide) 5. Pediatric E (ethambutol) 6. Pediatric H (isoniazid) *The pediatric products are counted separately as they are separately manufactured, sold/used alone or in various combinations for different indications for treatment for both active and latent TB in children.	6 products launched* Therapeutics 1. Pretomanid (2019) - in combination with bedaquiline + linezolid for DR-TB 2. Pretomanid pediatric product (2020) As of the end of 2019, 150 countries can access pretomanid through regulatory waivers thanks to its inclusion in the GDF catalogue. Partner Mylan is on track to file pretomanid in 25 countries plus European Union member states in the first year, with filing in India and South Africa already complete. 3. Pediatric HR (isoniazid + rifampin) (2015) 4. Pediatric HRZ (isoniazid + rifampin + pyrazinamide) (2015) 5. Pediatric E (ethambutol) (2015) 6. Pediatric H (isoniazid) (2015) *The pediatric products are counted separately as they are separately manufactured, sold/used alone or in various combinations for different indications for treatment for both active and latent TB in children.	Not available
TBVI (Est. 2008)	Tuberculosis	10 vaccine candidates in various R&D and clinical trials Preclinical: 6 Phase I: 1 Phase IIa: 2 Phase IIb: 0 Phase III: 1 Previously supported 3 vaccine candidates: Phase I: 1 Phase IIa: 2	No products registered	No products in the market	Not available

THE EVOLVING PDP MODEL

The continuing evolution of the PDP model within a broader R&D system and the roles of key stakeholders are presented below. Achieving the future state of the PDP model will require more of a systems thinking approach.[107,108]

FIGURE 10: The evolving PDP model and stakeholder functions, with examples

Stakeholders	PDP model (current state)	PDP model (future state)
High-income countries (donors)	Continuous but stagnant and not well coordinated funding of PDPs; some donor-driven priorities; project-specific funding and core funding; 3-5 year grants; some geographic specificity; limited donor diversification; informal PDP Funders Group (PFG), mainly exchanging information; PFG has limited leadership and influence	Increased and converged or pooled funding of PDPs; PDP funding is well linked with other funding flows in the R&D system; longer-term investments; core funding modality increased; funders aligned on investing in common goods for health; additional policy and other incentives to industry; close collaborations with LMICs; funders proactively champion PDPs, an end-to-end approach and collective actions; take a systems view of R&D and access; use mapping as a tool to optimize R&D and health system funding; new champions; environmentally conscious
Foundations (donors)	Continuous but fragmented funding of PDPs; limited diversification; donor-defined priorities; project-specific funding and core funding; 3-5 year grants; geographically and topic specific	PDP funding is well linked with other funding flows in the R&D system; pooled funding; longer-term investments; flexible or core funding modality increased; alignment on investing in common goods for health; new champions engaged; environmentally conscious
Product development partnerships	Successful R&D of new products and technologies; focused on R&D partnerships (development, late-stage clinical trials and regulatory reviews); often repurposing products as a cost-effective and quick way to deliver products; majority of research partners in HICs, and expanding research in LMICs; limited access functions and partnerships; selected disease areas; limited but increasing collaborations among PDPs; increasing use of new technologies and tools; emerging open innovation (e.g. MMV Open, Open Source Drug Discovery; FIND Specimen Bank etc.) and awareness about PDPs and the model's added value	R&D focused with an integrated end-to-end strategy; LMIC partners included from the start; stronger access functions and partnerships; use of network maps of R&D and health systems to identify partners and opportunities for collective action; diagnostics and therapeutics PDPs and partners working closer together; possible joint ventures or other governance modalities; increased collaborations among PDPs, including for R&D capacity building in LMICs; other collaborations across R&D and health systems improved (e.g. regulators and access partners including the Global Fund and Gavi); optimal use of emerging tools and technologies (e.g. AI, open source, data management, platform technologies); the PDP public-private model is well recognized and scaled-up for PRNDs and beyond; environmentally conscious
Multilaterals	Approaches to prioritization of products and technologies for PRNDs are well known but not enacted; limited leadership and coordination to foster health innovation including R&D for PRNDs; slow regulatory processes	Clear prioritization of global health innovations including technologies for PRNDs; improved information management and sharing (e.g. fully funded and actionable Global Health Observatory, Health Product Profile Directory); fit-for-purpose pathways for regulatory approval; use of mapping of R&D and health systems as a tool to mobilize collective, multi-stakeholder action; increasingly unified support for common goods for health; systems leadership; environmentally conscious
Private sector	Limited investment in PRNDs; key partner for PDPs in the discovery, registration, manufacturing and implementation phases; types of industry include primarily pharmaceutical, life sciences, medical devices and diagnostics, clinical research, chemical manufacturing, contract manufacturing	Increased investment in PRNDs; incentivized by public sector mechanisms and investment frameworks (e.g. environmental, social and governance); participation of a wider range of industries (distributors, health supply chains, ICT, insurance; private health providers, design; media and communication); commitment to common goods for health; environmentally conscious
Research institutes and academia	Highly fragmented field with often piecemeal medical solutions; primarily organizations from HICs, but LMIC partners are increasing; neglected role of R&D for diagnostics and health technologies; lack of collective efforts in R&D for diagnostic tests and therapeutics accross partners' ecosystems	Expanded open research and innovation for collective impact; greater involvement of research institutes form LMICs in all phases of R&D processes and implementation; greater role of training and education to researchers in LMICs; use mapping of R&D capacity building activities to mobilize collective impact; contribution to repositories like the Health Product Profile Directory; commitment to common goods for health; environmentally conscious
Low- and middle-income countries	Involvement mainly in clinical trials through public or private research institutes; rarely included in early phases and thoughout the R&D process; LMIC governments and research institutions are often not aware of opportunities for collaboration with PDPs; limited investments in R&D for PRNDs and lack of cross-national collaborations; slow regulatory approvals and lack of harmonization	Increased investment in health R&D including PRNDs; national needs and priorities to inform regional and global strategies; LMICs as active participants from the start of the R&D process; incentivised and funded local R&D and production capacity; regulatory harmonization; commitment to common goods for health; investment in health systems strengthening and UHC; introduction, appropriate and responsible use, and sustainable supply of the most impactful health technologies; anti-fragile infrastructure to support manufacturing, storage, and delivery; environmentally conscious
Patients and communities	Top-down approach where communities and patients from LMICs are rarely involved	Greater involvement of patients and communities in product development and communication processes (e.g. Product Patient Access Profiles, human-centred design); advocacy and collective pressure on governments; access to PDP products and improved health

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ABBREVIATIONS

TABLE 7: List of abbreviations used in this report and their definitions

AMR	Antimicrobial resistance
CEA	Cost-effectiveness analysis
CEWG	WHO Consultative Expert Working Group on R&D: Financing and Coordination
CGH	Common goods for health
DALY	Disability-adjusted life-year
DFID	Department for International Development
FCDO	Foreign, Commonwealth & Development Office
HIC	High-income country
HTA	Health Technology Assessment
IP	Intellectual property
IPR	Intellectual property rights
LMIC	Low- and middle-income country
NGO	Non-governmental organization
NTD	Neglected tropical disease
PDP	Product development partnership
PFG	PDP funding group
PPP	Public-private partnership
PRND	Poverty-related neglected disease
R&D	Research and development
SDG	Sustainable Development Goal
SWOT	Strengths, weaknesses, opportunities and threats
TB	Tuberculosis
TPP	Target product profile
UHC	Universal health coverage
WHO	World Health Organization

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ABOUT THE AUTHORS

Barbara Bulc is the Founder and Principal of Global Development (GD), a new kind of consulting enterprise, specialized in research, design and co-creation of an emerging collaborative economy for health and wellbeing of people and planet. She has over 25 years of leadership experience in pharmaceutical industry, multisectoral diplomacy and international development. She has been a driving force in building pioneering global partnerships across private, public and civic sectors, including creating novel access solutions with the Clinton Health Access Initiative (CHAI), leading the Global Business Coalition (GBCHealth) in Geneva and serving as the founding CEO of KRKA Pharmaceuticals in the USA.

bbulc@gd-impact.org
Global Development - gd-impact.org
@barbarabulc

Rohit Ramchandani is CEO of Antara Global Health Advisors and an Adjunct Professor of Global Health Innovation at the University of Waterloo, Canada. He has more than 15 years of experience working in global health and development, including designing, implementing, evaluating and scaling complex programmes. His work on transforming access to ORS and zinc for childhood diarrhoea has been recognized with a Transformational Business Award in Health from the International Finance Corporation and Financial Times. He completed his Doctorate of Public Health at Johns Hopkins and is a Fellow of the Balsillie School for International Affairs. He is currently serving as consultant to the Secretariat of the Independent Panel for Pandemic Preparedness and Response.

rohit@antaraglobal.com
Antara Global Health Advisors - antaraglobal.com
@drRramchandani