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Perspectives from nonprofits on accelerating product development and improving access for low- and middle-income countries

Financing and Coordination of Health Research
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About the Global Health Technologies Coalition

The Global Health Technologies Coalition (GHTC) is a group of more than 25 nonprofit organizations working to increase awareness of the urgent need for tools that save lives in the developing world. These tools include new vaccines, drugs, microbicides, diagnostics, insecticides, and other devices. The coalition advocates for increased and effective use of public resources, incentives to encourage private investment, and streamlined regulatory systems. The GHTC is housed at PATH.

The Global Health Technologies Coalition can be found online at **www.ghtcoalition.org**.

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Financing and coordination of health research

Perspectives from nonprofits on accelerating product development and improving access for low- and middle-income countries

Purpose and aims

The Global Health Technologies Coalition's "financing and coordination of health research" briefing papers provide examples and perspectives from nonprofit product development organizations (NPPDs) —nongovernmental organizations that partner with the public, philanthropic/not-for-profit, and private sectors to develop technologies targeted at neglected diseases and conditions of high morbidity and mortality in low- and middle-income countries (LMICs).[a]

This series is meant to inform discussions aimed at improving the coordination and financing of research and development (R&D) addressing the health needs of LMICs, and the implementation of activities as called for in a resolution passed at the 66th World Health Assembly (WHA) in May 2013.

The actions outlined in the WHA resolution are based on the recommendations included in the 2012 report from the World Health Organization (WHO) Consultative Expert Working Group (CEWG) on R&D.[1] The main functions of the CEWG were to identify major challenges to advancing R&D for health needs of LMICs and make recommendations to improve the coordination of priorities and activities, financing of all phases, and monitoring of R&D investments. The resolution called for:

- Establishment of a global R&D observatory at the WHO that would act as a central coordinating mechanism to monitor and analyze relevant information on health R&D. The observatory would contribute to the identification of gaps and opportunities for R&D and define priorities in consultation with relevant stakeholders, as appropriate.
- Implementation of several health R&D demonstration projects to address identified gaps that disproportionately affect LMICs.
- Establishment of long-term, sustainable coordination and financing mechanisms, including pooling resources and voluntary contributions, to be assessed and considered at a later date.

The first paper in this series sets the stage by providing examples of how NPPDs approach product development and the key challenges that NPPDs and their partners face in developing and introducing technologies that address the health needs of LMICs. This second paper provides the perspectives of NPPDs on the most significant funding challenges and the types of financing mechanisms that support their work.

Subsequent papers will detail the identified gaps, challenges, and solutions, and will explore how NPPDs:

- Ensure access in LMICs to the knowledge and technologies they develop.
- Address regulatory challenges throughout the product development process.
- Work with local partners in LMICs to strengthen their research and manufacturing capacity.

a The list of diseases is based on the list referenced in Policy Cures's *Neglected Disease Research and Development: A Five-Year Review* (available at: http://www.policycures.org/downloads/GF2012_Report.pdf) and is not an exhaustive list of neglected diseases. Those covered by surveyed NPPDs include bacterial pneumonia and meningitis, dengue fever, diarrheal diseases, helminth infections, HIV, kinetoplastids, leprosy, malaria, trachoma, tuberculosis, and typhoid. We also included technologies that address maternal, newborn, and child health, and sexual and reproductive health conditions.

Methodology

This analysis relies on publicly available data and information collected through interviews conducted with representatives from 15 NPPDs (see Appendix 1 for list of interviewees). Interviews were conducted with each NPPD to capture their perspectives on the most significant funding challenges they encounter and the implications for their organizations. During interviews, NPPDs also provided input on the financing and incentive mechanisms that have impacted—or may impact—the ability of NPPDs and their partners to accelerate the development and improve the accessibility of technologies targeting the health needs of LMICs.

Introduction

Significant investments from governments and philanthropic organizations over the past decade have led to more robust product portfolios addressing poverty-related and neglected diseases and conditions, even if there are still major gaps and needs not fulfilled. But in the current financial climate, increasing budget constraints are threatening this progress. As a result, traditional funders are scaling back their investments and wanting to see more impact in a shorter period of time. Just as many technologies are about to enter into more expensive, late-stage clinical development and prepare for product registration where increased investments are needed, competition has increased for shrinking available funds.

In 2010–2011, just 12 funders (including aggregated private pharmaceutical investments) accounted for almost 90 percent of all investments in R&D targeting technologies addressing the health needs of LMICs.[2] Much of this investment comes in the form of grants from governments in high-income countries and private philanthropies. Government spending accounted for two-thirds of this overall investment, with 95 percent coming from high-income countries.[2] The Bill & Melinda Gates Foundation and the Wellcome Trust represented 95 percent of philanthropic funding in 2011.[2] This type of grant funding acts as a "push" mechanism to accelerate R&D by reducing the cost or risk to developers by paying upfront for the costs of R&D.[3]

Other types of financing and incentive mechanisms act as "pull" mechanisms for investment in R&D by increasing the reward for success.[4] For example, prizes pay for incremental success along the product development lifecycle. Similarly, the US Food and Drug Administration's Priority Review Voucher, which grants an expedited regulatory review to the developer of a newly approved drug or biologic that targets a neglected tropical disease, rewards the outputs of research.

Regardless of the model used, both types of mechanisms are meant to stimulate and accelerate R&D targeting the health needs of LMICs. Because neither type can overcome the lack of a commercial market in LMICs, a mixture is needed to incentivize new investment and distribute risk across the product development lifecycle.

Findings

NPPD funding landscape

The funding landscape for NPPDs has changed significantly over the past few years, pushing NPPDs to reconsider their business models and funding structures. Traditional donors from the public and philanthropic sectors have scaled back their overall investments, and some have become more restrictive in how their monies are spent. As a result, NPPDs are diversifying their funding base, both to fill the funding gap and to increase the flexibility of the funding they have through pursuing innovative funding models. This paper outlines significant funding challenges, as well as how NPPDs are adapting to the evolving funding environment.

Traditional R&D funding mechanisms

In 2011, NPPDs received approximately 14.8 percent of the total funding and 23 percent of global grant funding for R&D targeting the health needs of LMICs.[2,b] The Bill & Melinda Gates Foundation accounted for more than half of funding invested in NPPDs. The Bill & Melinda Gates Foundation along with the US Agency for International Development (USAID), the UK Department for International Development (DFID), and the Dutch Ministry of Foreign Affairs provided more than three-quarters of investment in NPPDs over the period 2007–2011.[2] Traditionally, the majority of government support to NPPDs has come from international development agencies like USAID and DFID as compared to research agencies like the US National Institutes of Health (NIH), which is the largest overall funder of neglected disease R&D of all entities. In fact, NPPDs received only 1.5 percent of NIH research funding in 2011.[2]

Funding for NPPDs has seen an overall decrease in recent years, with US$451.4 million provided in 2011 as compared to the $469.4 million invested in 2007.[2] Fluctuations in funding during that time may be attributed to reductions in funding commitments as well as completion of funding disbursement cycles. At any rate, since 2009, NPPDs have seen their funding drop by $50 million per year.[2] New public-sector funders, such as the governments of Australia, Germany, and Japan, have launched funding initiatives targeting NPPDs in the past two years. While NPPDs welcome these new players, they note that funding needs have grown as more products move into the later, more expensive phases of development, and these new investments are not sufficient to compensate for the overall reduction in funding levels. NPPDs are continuing to seek out new funding opportunities in regions, such as the Middle East, that have not traditionally funded R&D targeting LMICs, as well as in economies with growing domestic research and manufacturing capacity, such as China and India. High-net-worth individuals, smaller foundations, and companies outside the health sector are additional potential sources.

Government and philanthropic funders: The Bill & Melinda Gates Foundation accounts for between 50 and 90 percent of the funding for some of the NPPDs interviewed. Many of the interviewees noted that public-sector funding from development agencies is often more flexible than monies from government research funding institutions. The latter type of funding is often allocated to specific projects or products, and focuses on supporting local researchers and priorities. In general, government funding for poverty-related and neglected disease R&D from research agencies has been increasing while development agency funding has been going down. This is likely due to the fact that because of the global financial climate, domestic spending—which is the primary focus of research agencies—is being prioritized.

Private-sector investments: NPPDs noted that investments from their commercial partners, including in-kind contributions (e.g., regulatory expertise, trial site and/or manufacturing capacity building), are becoming more significant, particularly as products advance through the pipeline and enter into larger, more complex research trials. As commercial interest and investment increases in LMICs with growing economies, such as South Africa, NPPDs are seeking partnership opportunities with nontraditional private partners from outside the health sector. For instance, the International Vaccine Institute has partnered with an automotive company and an electronics company for both financial support and to use their in-country networks.

The goal for private-sector collaboration by NPPDs is to improve public health through engaging commercial partners to leverage their expertise and resources to develop technologies that, in the absence of NPPD involvement, would not be a private-sector priority. As NPPDs are engaging more with private-sector partners with commercial interests in LMICs, and using innovative financing models, it is vital that the organizations ensure that their mission to create sustainable, culturally relevant products that are affordable, accessible, and available to address the health needs of LMICs is not compromised.

b The Population Council and Jhpiego are not included in the Policy Cures R&D financing analysis and therefore their funding sources are not factored into these figures. However, both organizations receive the majority of their funding from the US government and foundations.

Innovative R&D funding models

The current funding environment necessitates that NPPDs pursue innovative financing to sustain progress and attract new investment. As a result, NPPDs are exploring different models to diversify their funding base, such as establishing new partnerships with the private sector and cultivating high-net-worth donors, which have been used in other sectors. Some NPPDs noted that mechanisms like social impact investments—which aim to provide both social returns, as part of a philanthropic portfolio, and financial returns like traditional investment funds (see Box 1 on impact investing)—were of interest. But they found it difficult to operationalize this model to attract new investment in R&D for poverty-related and neglected diseases because financial returns are relatively low, and because NPPDs need to reconfigure their expertise to manage these finance mechanisms.

Aeras and the TuBerculosis Vaccine Initiative (TBVI)—two NPPDs developing new vaccines against tuberculosis (TB)—have developed a business case that includes an analysis of the potential market for a new TB vaccine, and how potential equity and debt models could be used to stimulate investment in TB vaccine development, particularly in late-stage clinical trials, which require more capital and are longer-term investments. The proposed financing would be a blend of traditional (e.g., grants) and innovative (e.g., impact investments) funding from the public, private, and philanthropic sectors that could support the entire portfolio of vaccine candidates from preclinical research through Phase III clinical trials.

Box 1: Impact investing: equity and debt financing models for R&D for LMICs

Impact investments have shown success in generating new financial support for global health but not yet in increasing funding for research and development (R&D) addressing the health needs of low- and middle-income countries (LMICs). The International Finance Facility for Immunization uses pledges from donor governments to sell "vaccine bonds." The resulting funds are made available exclusively for the GAVI Alliance—an international vaccine procurement program—to support health and immunization programs.[5]

Impact investing is generally separated into two types of financial models—equity and debt financing—that use a blend of investments from the public, philanthropic, and private sectors.

Equity funds aim to reduce risk for investors by providing a profit guarantee yet still enabling an environment where moderate returns are possible. Because financial returns are not expected to be as high as with traditional investment funds, a public- or private-sector organization makes the initial investment in order to secure additional funders. One example is the Global Health Investment Fund (GHIF), established in 2011 by JP Morgan Chase and the Bill & Melinda Gates Foundation. The fund—managed by Lion's Head Global Partners—was created to increase investment in late-stage development of technologies targeting the health needs of LMICs. The Bill & Melinda Gates Foundation and other funders would cover any initial losses, thereby reducing risk and attracting additional investment. The projected return on investment is 4 to 6 percent over five years.[6] At the time of print, the GHIF had not yet gone public.

Debt financing uses assets—such as a portfolio of technologies—to attract public, philanthropic, and private investments. This model has not yet been used to stimulate investment in R&D targeting LMICs, but is of growing interest among some governments, investors, and nonprofit product development organizations (NPPDs). The idea is that a portfolio of products could be used to secure debt financing, and the revenue from any successful products coming out of a portfolio would be used to repay the debt. Because the return on investment would be based on revenue from successful product development, the payout would be based on the longer timelines associated with R&D, as compared to traditional investment funds that may provide a faster return. The debt bond could be used to incentivize additional public and private funders to invest. A significant challenge of using this model for R&D targeting LMICs is that neglected tropical diseases do not have strong commercial profit potential and therefore may not be able to adequately reduce risk to attract investment.

The two organizations have signed a memorandum of understanding outlining how their combined portfolio could be used to secure financing for TB vaccine R&D and ensure that the most promising candidates advance through the pipeline. The business case modeling showed the potential market value of a new TB vaccine to be between $13–14 billion over 10 years. Based on this market potential, Aeras and TBVI are in the process of presenting their business case to funders for consideration.

Another model using commercial business practices to stimulate investment, which some NPPDs have employed, is reinvesting revenue from products they have developed back into their portfolios. The revenue comes from royalties guaranteed in licensing agreements and from for-profit companies that have been established to bring these newly developed technologies to the commercial market (see Box 2 on reinvesting revenue).

The Bayh-Dole Act of 1980 permits universities, small businesses, and nonprofit institutions based in the United States to own inventions stemming from federally funded research.[7] The act allows organizations to patent and license technologies that have been developed using funding from the US government. Following the lead of universities—which have used this practice for years—the Infectious Disease Research Institute (IDRI) and the Population Council have licensed some of their technologies and generated resulting revenue to support their mission-centric technology portfolios.

This model allows organizations like IDRI and the Population Council to create a flexible funding source that is used to sustain a portfolio of projects targeting poverty-related and neglected diseases and conditions. Any profit generated is reinvested into the mission-centric programs, allowing them to leverage investments from other funders and partners.

However, critics note that the notion of using profits made in wealthy markets to subsidize R&D addressing health needs in LMICs is the opposite of de-linkage, which is a core principle of the CEWG

Box 2: Reinvesting revenue: The Infectious Disease Research Institute

The Infectious Disease Research Institute (IDRI)—which develops diagnostics, drugs, and vaccines for infectious diseases with high burden in low- and middle-income countries (LMICs)—has licensed new technologies developed in-house to both established and newly-created biotechnology companies. The goal is to facilitate the further development of IDRI's technologies, as well as to generate revenue to complement grant funds used by IDRI to support its mission of developing technologies targeting infectious diseases of global importance.

IDRI has licensed certain diagnostic and vaccine technology applications that may have utility in health areas, such as cancer, that are not within IDRI's mission, to start-up biotechnology companies while reserving the rights to continue the development of products targeting neglected diseases. These biotechnology companies are separate legal entities from IDRI. However, IDRI maintains a financial stake and receives royalty payments, which are then reinvested into the IDRI portfolio of products targeting infectious diseases without a commercial market, such as leishmaniasis and leprosy.

The rights that IDRI has licensed are for health concerns such as cancer and allergies, which attract private capital to support product development from the new biotechnology companies, but are not a part of IDRI's mission. The benefits to IDRI are twofold. First, IDRI receives licensing revenues that it uses to support its programs in neglected infectious diseases. Second, the scientific studies conducted by the new biotechnology companies, and funded by private-sector investment, have provided critically important data and information used by IDRI to strengthen its own infectious disease research.

For example, IDRI granted license rights to some of its vaccine adjuvants—chemicals that improve the long-term immune response to vaccines—to Immune Design Corporation (IDC), which was established in Seattle in 2008 with a focus on cancer, allergies, and certain infectious diseases. The royalties and other funds from IDC have helped support IDRI's programs, and IDC's clinical safety data relating to the adjuvants have been vital in IDRI's ability to accelerate the development of vaccines for tuberculosis and leishmaniasis, two diseases with an immense burden in LMICs.

recommendations. De-linkage creates "competitive intermediaries" between developers and the commercial market, ensuring that the costs of R&D are de-linked from the price level of the final product. There is not common agreement across the NPPDs in how de-linkage is operationalized. This topic will be explored in more detail in a subsequent briefing paper on how NPPDs ensure access to the products they develop.

It is important to note that each licensing agreement is different (depending on the type of technology or product). For those products that have applicability for diseases in LMICs, the licensor inherits the NPPDs' global access commitments to ensure provision and distribution of the product at little or no cost. For instance, the Population Council—an NPPD that develops products to improve the family planning and reproductive health options of people throughout the world—reinvests all royalty payments earned from Population Council–developed contraceptive products back into its technology portfolio. As part of the licensing agreements, the Population Council's commercial partners must ensure that these products are offered at a public-sector price to people living in LMICs.

Some other innovative funding mechanisms that have been accessed by NPPDs come from NIH and UNITAID. For instance, PATH has received subgrants from private-sector partners who have received Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants from the NIH to develop device and diagnostic technologies. The SBIR and STTR programs allow domestic small businesses to apply for federal funding to support R&D that has the potential for public benefit; also, they support the collaboration of US research institutions with small businesses for the commercialization of new technologies.

UNITAID is a funding mechanism that is financed primarily by a levy on airline tickets and gives grants to address inefficiencies in markets for medicines, diagnostics, and prevention for HIV/AIDS, malaria, and TB in LMICs. Drugs for Neglected Diseases *initiative* (DND*i*), Medicines for Malaria Venture, and TB Alliance have received grants from UNITAID to develop new pediatric formulations of existing drugs for HIV/AIDS, malaria, and TB, respectively. Likewise, UNITAID has provided funding to the Foundation for Innovative New Diagnostics to support the roll-out of new diagnostics for TB and multidrug-resistant TB and to establish a model for sustainable quality control for point-of-care diagnostics in low-resource settings for malaria. In general, UNITAID is focused on supporting market development rather than developing new technologies.

Challenges and implications

In most cases, product development spans many years (sometimes decades) and may require significant amounts and multiple sources of funding. NPPDs outlined the most significant challenges and the implications on their organizations. Some of these challenges—such as funders shifting from portfolio funding to more narrowly restricted project-specific funding, and the need to reconfigure skills and expertise to pursue and sustain funding—are emerging. Other challenges, like an overreliance on a small number of funders willing to significantly invest in poverty-related and neglected disease R&D, and the misalignment of funding cycles and requirements, have consistently hampered NPPDs. It is important to note that NPPDs have made progress despite these challenges and the inability of current funding mechanisms to accommodate the limited (or in many cases, the lack of) commercial incentive to invest in developing new technologies to address the health needs of LMICs.

Table 1:
Funding challenges and implications for nonprofit product development organizations (NPPDs)

Challenge	Impact on NPPDs
Donor shifts from unrestricted funding for a portfolio to more narrowly restricted project- or product-specific funding	NPPDs have less flexibility to shift funds to more promising projects. Funding—not science—may drive decision making. Product developers find it difficult to maintain a portfolio of products at different stages of development. Activities are scaled back as overhead funds shrink.
Small number of major funders	Competition for smaller amounts of money increases as R&D costs rise and donor funds decrease. NPPD's vulnerability to shifting funder priorities increases.
Misalignment of funder requirements	Varying length and timing of donor cycles create significant funding gaps and jeopardize ongoing projects. Discordant donor requirements increase burden on and need for specialization of grants management.
Limited NPPD capacity to identify, cultivate and sustain funding	Increased staff time (including additional staff, both scientific and non-scientific) and resources must be dedicated to resource mobilization and grants management. NPPDs require different business infrastructure and staffing configurations to pursue and manage new funding sources.

Donor shifts from unrestricted funding for a portfolio to more narrowly restricted project- or product-specific funding: NPPDs noted that a growing trend among funders is to award project-specific funding—which can only be used for a designated activity—as opposed to unrestricted, core funding that can give NPPDs the ability to work on multiple projects at different phases of development. Each of the NPPDs interviewed identified this donor shift away from more flexible portfolio funding as their most significant challenge. Because of the current global financial climate, funders, particularly those from the public sector, are under increased pressure to demonstrate that government investments are having impact in a time frame that does not lend itself to longer product development timelines.

This shift puts the robust portfolios that have been developed over the past decade in jeopardy. Donors are less eager to fund the technologies in a portfolio that are still in the early phases of research—before proof of concept—making it more difficult for NPPDs to pursue promising science that may hold more risk but have potential for longer-term impact, because they don't have the flexibility to transfer funds to promising projects. Therefore, the funding, not necessarily the science, sometimes guides prioritization, and more emphasis is put on research projects that are "safer." As a result, "riskier" projects that may have promise to develop technologies with larger health impact but longer timelines are not necessarily prioritized.

NPPDs also report that as core funding is decreasing, they have to scale back critical work that is central to advancing technologies through the product pipeline. This includes regulatory activities, intellectual property (IP) management, knowledge management and dissemination, and activities, like grants management and business development, which are essential to running the organization. This work supports day-to-day product development activities, as well as the long-term objectives of developing new and improved products to improve health equity. Those NPPDs with in-house R&D capabilities that support their entire portfolio struggle to cover the costs to maintain their facilities

because it is more difficult to use project-specific funding to cover these expenses. As a result, the burden of paying for these expenses falls on the few donors who are still providing core funding.

Small number of major funders: Because NPPDs have been successful in developing and moving new technologies targeting neglected diseases and poverty-related conditions through the pipeline, a number of products are now entering or are close to entering late-stage clinical trials. However, the small number of funders investing in this space cannot keep pace with the increased costs associated with the large-scale studies needed to demonstrate safety and efficacy in diverse populations. This is compounded by the fact that some funders of NPPDs have scaled back their investments. As a result, the funding available to NPPDs has decreased as R&D costs are increasing when technologies advance through the pipeline.

Many of the NPPDs recognize that the overreliance on just a few donors has made their portfolios more vulnerable to shifts in priorities among funders. For example, some of their larger donors want to have greater control over portfolio management within the NPPD. For donors who must illustrate impact within a time frame that is more aligned with political cycles than with longer product development timelines, often due to political pressure, there may be greater aversion to risk, which could impact a NPPD's ability to maintain a diverse portfolio of products at various stages of development. As a result, there may be less investment in potentially game-changing technologies that are in early stages of development, which may be perceived as high risk, but potentially offer significant impact in the long term, if successful. Some NPPDs felt that the combination of donors' desire for greater control and the pressure to show impact sooner has made it difficult to find consistent investments in more upstream research, which may not yield results for years.

Misalignment of funder requirements: As some funders reduce their financial commitments, the need to have multiple donors increases. Some NPPDs, like DND*i*, have been very intentional about the diversification of funding sources, while others are pursuing new donors out of necessity. DND*i* requires that no single donor can fund more than 25 percent of the organization's activities in one year (see Box 3 on DND*i* fundraising policy). The advantage of diversification is that it can help to provide independence. Multiple funders across a portfolio can ease reliance on donors whose priorities may shift. However, it can also create significant challenges in managing multiple funder requirements and can result in gaps in funding. These gaps can have a substantial impact not only on the final product, but also on when the product becomes available to the populations that need it most.

Box 3: DND*i* fundraising policy

The cornerstone of the Drugs for Neglected Diseases *initiative's* (DND*i*) fundraising policy is maintaining a diversified funding base. A minimum of 50 percent of its budget must be covered by public funds, and no single funder can represent more than 25 percent of the organization's annual budget. DND*i* seeks funding from individuals, governments, public institutions, companies, foundations, and nongovernmental organizations that share a commitment to its vision and mission. Specifically, the policy outlines that:

- All contributions will support the initiative, specific projects for R&D, and all activities pursued to achieve DND*i*'s mission.
- DND*i* will publically release an annual financial audit that will provide activity and financial information on the use of donor contributions.
- DND*i* reserves the independence to pursue its mission and R&D projects based upon patient needs and scientific merit.
- According to the goals of DND*i* to ensure the quality of life of neglected populations and its humanitarian values, DND*i* will not accept contributions from: corporations that derive their income from the production and/or sales of tobacco, alcohol, and arms manufacturing industries, or groups and individuals who encourage racism and intolerance.[c]

c DND*i*'s full fundraising policy can be read at http://www.dndi.org/donors/fundraising-policy.html.

Discordant funder priorities and requirements—such as reporting, data collection, compliance policies, and financial management —require more administration and staff resources. Often these roles are covered by core funds, making it difficult for NPPDs to adequately support these administrative activities. It should be noted that there have been efforts to alleviate this challenge, notably by the Product Development Partnerships (PDP) Funders Group, which developed a standardized reporting form to align information being asked of grantees. However, some of the larger funders of NPPDs have not yet adopted these streamlined forms.

Limited NPPD capacity to identify, cultivate, and sustain funding: As NPPDs seek new funding opportunities, they must invest in new configurations of skills. This may mean strengthening the skills and capacities of current staff, as well as bringing on new staff to complement existing expertise to manage, identify, and cultivate new funding sources such as high-net-worth individuals, new and emerging economies, and private-sector partners outside of the health sector who have not traditionally invested in health R&D, such as the extraction or automotive industries. Not only do NPPDs need to diversify their fundraising capacity, but they must dedicate time (e.g., frequent travel) and even establish additional infrastructure (e.g., set up legal entities in countries to receive funds) to cultivate these relationships.

NPPDs also noted that grants and proposals are becoming more technical and requiring more clinical detail, which requires researchers to invest more time in fundraising, responding to funders, and grants management. Concern was raised that the requests for more detail are not necessarily matched with additional funding to ensure that these activities do not take away time and resources from scientific activities.

Conclusion

The funding landscape for R&D for poverty-related and neglected diseases and conditions is evolving, creating new challenges and opportunities for NPPDs. Some traditional funding sources for NPPDs are scaling back their investments and increasing their involvement in decision-making. This is forcing NPPDs to reconsider their business models and funding structures. As commercial interest in LMICs increases, NPPDs are presented with opportunities for new private-sector partners and sources of support. These new investment and partnership opportunities come with significant challenges. Organizations must do due diligence to ensure that values and objectives are aligned and expectations are agreed-upon with partners. Commercial investment must be tied to conditions that will ensure affordability and access in LMICs. It is critical to ensure that the resulting technologies and research results are available, affordable, and accessible through public-sector and private-sector channels, as appropriate, in LMICs. The goal of creating cost-effective and culturally relevant products that are affordable, accessible, and available to address the health needs of LMICs cannot be compromised by commercial interests.

At the same time, NPPDs must look for new ways to leverage their assets for sustained investment and to better assess the range of innovative financing and incentive mechanisms. To do so, however, they need to strengthen their internal capacity to identify, vet, and pursue these opportunities at a time when traditional funding sources are less willing or able, often due to political pressure, to fund activities that are not able to directly demonstrate health impact. These challenges highlight the need for better coordination among R&D stakeholders—whether public or private sector, funder or recipient, NPPD or academic institution or commercial entity—to improve the efficiency of limited resources and ensure that the entire product development process

is being adequately resourced and funding cycles are aligned to advance R&D to meet the health needs of LMICs.

The NPPDs outlined some criteria that could be used to design and evaluate financing. Funders should consider these issues when identifying research priorities and designing their funding schemes. Likewise, NPPDs can use these criteria when vetting funding opportunities. Finally, institutions charged with monitoring and evaluating funding for health R&D can use these standards to assess whether financing mechanisms are sufficiently accelerating product development and uptake. Specifically, funding mechanisms and donor support must:

- **Support a portfolio of products at different stages of development.** This allows costs to be more equitably shared and risk spread across a portfolio of technologies and ensures that the entire product development lifecycle—from preclinical through introduction and wide-scale adoption—is funded. The portfolio approach ensures that only the most promising products advance through the pipeline and allows organizations to shift funds from a failing project to more promising products within their portfolio.
- **Provide sustainable funding commitments.** The duration of investment should be guided by the scientific need. In order to ensure that promising technologies are sustainably funded throughout the product development process, and are able to make long-term impact on the health of LMICs, consistent funding levels are needed. This will require multi-year commitments from funders that align with the timelines of the product development process.
- **Support core activities.** These are activities that are critical to the day-to-day success of any organization, public or private. This type of support helps organizations to cover administrative and facility costs as well as support activities that bring attention to the health needs of LMICs, advance products through the pipeline, improve uptake of new technologies, and cultivate new funding sources. In too many instances, much of this work is minimally covered by restricted grants. Therefore, all funding—whether restricted or unrestricted—must include a minimum or proportionate level of support for the overall costs of running the business and/or specific programs.
- **Incentivize new investment.** Financing mechanisms are most effective when they can be leveraged to attract new financial and in-kind investments. The more flexible the funding, the better able the recipient is to provide opportunities to complement existing investment. Funding needs to be tied to agreed-upon measures of success to ensure that resources are being used to maximize efficiency and impact.

The examples and perspectives cited in this paper provide a high-level overview of the most significant funding gaps and challenges faced by NPPDs, but are not intended to serve as a comprehensive list of challenges or financing and incentive mechanisms used by NPPDs to advance the development of products targeting the health needs of LMICs.

As illustrated, NPPDs have and must continue to adapt their financing models and explore new opportunities to respond to an evolving funding environment. Better collaboration among stakeholders—including NPPDs, governments, academia, foundations, and the private sector—is critical to improving financing of R&D to address the health needs of LMICs.

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Appendix 1 : List of interviewees

Aeras: Kari Stoever, Vice President, External Relations

Drugs for Neglected Diseases *initiative* (DNDi): Rachel Cohen, Regional Executive Director, North America; Pascale Boulet, Head of Policy Affairs and IP Advisor

European Vaccine Initiative (EVI): Stefan Jungbluth, Business Manager

Foundation for Innovative New Diagnostics (FIND): Jérôme St-Denis, Senior Advocacy and Resource Mobilization Officer

Infectious Disease Research Institute (IDRI): Stewart Parker, Chief Executive Officer; Erik Iverson, Executive Vice President, Business Development & External Affairs; Curt Malloy, Senior Vice President, Operations & General Counsel

International AIDS Vaccine Initiative (IAVI): Tom Harmon, Senior Policy Analyst; Margaret Lidstone, Senior Director, Global Public Giving

International Partnership for Microbicides (IPM): Sharyn Tenn, Senior Advisor, External Affairs

International Vaccine Institute (IVI): Christian Loucq, Director-General; Deborah Hong, Head of Communications and Advocacy

Jhpiego: Brinnon Mandel, Team Leader, Innovations Development Program

Medicines for Malaria Venture (MMV): Andrea Lucard, Executive Vice President, External Relations; Matthew Doherty, Manager, Donor and Stakeholder Relations; Christina do Paço, External Relations Officer

PATH*: Tim Elliot, Senior Business Officer, Technology Solutions; Sally Ethelston, Director, Communications and Advocacy, Malaria Vaccine Initiative; Neeti Nundy, Commercialization Officer, Technology Solutions; Eileen Quinn, Director, Communications and Advocacy, Vaccine Development; Gretchen Shively, Associate Leader, Technology Solutions

Population Council: Jim Sailer, Vice President, Corporate Affairs

Sabin Vaccine Institute: Tara Hayward, Director, Resource Development

TB Alliance: Ben Alsdurf, Senior Analyst, External Affairs; Kari Frame, Senior Manager, Resource Mobilization

TuBerculosis Vaccine Institute (TBVI): Rene Coppens, Director, Resource Mobilization

* Four NPPDs sit within PATH, including Drug Development, the Malaria Vaccine Initiative, Technology Solutions, and Vaccine Development

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