Global Health
Technologies Coalition

Briefing Paper, Volume 5: Working with partners to strengthen local research and manufacturing capacity

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

Financing and Coordination of Health Research
May 2014

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About the Global Health Technologies Coalition

The Global Health Technologies Coalition 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, as well as the most effective policies and programs needed to develop and deliver new health tools. These tools include new vaccines, drugs, microbicides, diagnostics, insecticides, and devices. Housed at PATH and funded in part by the Bill & Melinda Gates Foundation, the coalition advocates for increased and effective use of public resources, incentives to encourage private investment, and streamlined regulatory systems.

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

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Acknowledgments

This paper was authored by Claire Wingfield from PATH in consultation with Kaitlin Christenson from the Global Health Technologies Coalition (GHTC) and with support from Tricia Aung (GHTC) and John Ballenot (PATH). We would like to thank our paper series advisory committee members: Rachel Cohen (Drugs for Neglected Diseases *initiative*), Mary Moran (Policy Cures), Eileen Quinn (PATH), Judit Rius (Médecins Sans Frontières), John-Arne Rottingen (Harvard University), Jane Rowley, Katharina Scheffler (Deutsche Stiftung Weltbevoelkerung), and Rachel Wilson (PATH). The views expressed in this paper are not attributed to any one individual or organization represented on the committee. We would also like to thank the nonprofit product development organizations that participated in this analysis: Aeras, Drugs for Neglected Diseases i*nitiative*, European Vaccine Initiative, Foundation for Innovative New Diagnostics, Infectious Disease Research Institute, International AIDS Vaccine Initiative, International Partnership for Microbicides, International Vaccine Institute, Jhpiego, Medicines for Malaria Venture, PATH, Sabin Vaccine Institute, TB Alliance, and TuBerculosis Vaccine Initiative.

Suggested citation: Global Health Technologies Coalition (GHTC): *Working with Partners to Strengthen Local Research and Manufacturing Capacity: Perspectives from Nonprofits on Accelerating Product Development and Improving Access for Low- and Middle-Income Countries Vol. 5*. Washington, DC: Global Health Technologies Coalition; 2014. Available at http://ghtcoalition.org/NPPD-briefing-paper-series.php.

Working with partners to strengthen local research and manufacturing capacity

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

BACKGROUND

Purpose and aims

The Global Health Technologies Coalition's briefing papers on financing and coordination of health research provide examples and perspectives from nonprofit product development organizations (NPPDs). NPPDs are 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 of papers is meant to inform discussions aimed at improving the financing and coordination of health research and development (R&D) addressing the needs of LMICs. These papers may also inform implementation of activities as called for in a resolution passed at the 66th World Health Assembly in May 2013.[1] The actions outlined in the World Health Assembly resolution are based on recommendations in a 2012 report from the World Health Organization (WHO) Consultative Expert Working Group (CEWG) on R&D. The CEWG identified major challenges to advancing R&D to meet the health needs of LMICs and made recommendations to improve the coordination of priorities and activities, increase financing of all phases of research, and enhance monitoring of R&D investments.[2]

The World Health Assembly resolution called for:

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

The first paper in this series set the stage by providing examples of how NPPDs approach product development and describing the key challenges that NPPDs and their partners face in developing and introducing technologies that address the health needs of LMICs. The second paper provided the perspectives of NPPDs on the most significant funding challenges and the types of financing mechanisms that support their work. The third paper described how NPPDs and their partners try to ensure access in LMICs to the knowledge and technologies they develop. The fourth paper outlined the most significant regulatory challenges faced by NPPDs and their partners throughout the product development process and described how these challenges affect their work. This fifth and

[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.

final paper in the series describes NPPDs' efforts to strengthen the research and manufacturing capacity of academic, nongovernmental, and commercial partners in LMICs, and provides examples of the criteria that NPPDs consider when determining investment in capacity strengthening.

Methodology

This analysis relies on publicly available data and information collected from representatives of 11 NPPDs (see appendix for list of NPPD contributors). Contributors were asked to describe how their NPPDs determine when and how to engage in capacity strengthening with local research and manufacturing partners and to identify the most significant related challenges and benefits.

INTRODUCTION

Research and manufacturing capacity in disease-endemic countries is one of the biggest keys to accelerating the development and dissemination of high-impact, cost-effective health technologies for use in LMICs. Although good R&D infrastructure is needed in endemic countries for locally driven solutions, research and manufacturing infrastructure in these countries remains weak. Many researchers in LMICs have limited experience conducting laboratory and clinical research in accordance with international quality standards of Good Laboratory Practices (GLP) and Good Clinical Practices (GCP); few local manufacturers are producing health products in line with Good Manufacturing Practices (GMP); and infrastructure is inadequate to support high-quality product development. It is estimated that only 25 percent of research on neglected diseases takes place in LMICs,[3] and only 13 percent of manufacturers of medical devices are located in LMICs.[4]

This is not because the potential capacity does not exist in these settings. It is because there has been insufficient investment, particularly from governments in LMICs, in strengthening the science and technology ecosystem—which includes universities, ministries of science and technology, health systems, and the commercial sector. For example, in 2008 in the Bamako Communique and Algiers Declaration on Health, governments committed to invest at least 2 percent of their national health budgets in health R&D (including capacity strengthening),[5,6] but these commitments are not being met. As of 2012, for instance, South Africa was investing approximately 0.8 percent of its annual health spending on health R&D, and Kenya was spending only 0.2 percent.[7]

It is important to note that the mission of NPPDs is to develop new and improved health products targeting poverty-related and neglected diseases and conditions—not to develop capacity in LMICs. The principles of GCP, GLP, and GMP

Defining international safety and quality standards

Principles for conducting high-quality clinical research and laboratory studies and for manufacturing health products have been set forth in internationally recognized documents, such as the Declaration of Helsinki, and in more technical documents, including the Guideline for Good Clinical Practice of the International Conference on Harmonization, the OECD Principles of Good Laboratory Practice, and World Health Organization's Good Manufacturing Practices for Pharmaceutical Products. The principles of Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and Good Manufacturing Practices (GMP) outlined in these documents and similar reference standards provide guidance to ensure the safety and quality of research and manufacturing. Ideally, these standards are translated into laws and regulations enforced by national regulatory authorities.

GCP defines the safety and ethical standards by which all clinical trials and human studies are designed, conducted, implemented, and monitored. Similarly, GLP standards provide a framework within which high-quality laboratory studies are planned, performed, monitored, recorded, and reported. GMP guidelines provide a minimum set of requirements that manufacturers must meet while manufacturing health or food products to ensure that the products are of high quality and do not pose any significant risk to the consumer or public.

apply to all research and manufacturing conducted by NPPDs and their partners. The rigor and safety of these activities must meet international standards consistently across all geographies and populations in order to ensure equitable health impact. However, these standards are not enforced in many LMICs, and many local partners of NPPDs have limited or no experience conducting research and manufacturing in line with these safety and quality standards. Therefore, NPPDs have had to be active in investing in improving the capacity and infrastructure of local product development partners.

At a very high level, this work includes upgrading research and manufacturing facilities, providing training across a spectrum of skills (e.g., laboratory practices, clinical care, financial management, communications, and advocacy), and transferring technological know-how. NPPDs are just one of many institutions conducting capacity-strengthening activities to improve R&D and manufacturing infrastructure in endemic countries. Other examples include:

- The European and Developing Countries Clinical Trials Partnership Programme—a multisectoral partnership between the public, private, and nonprofits sectors to enable clinical trials and development of health technologies targeting poverty-related and neglected diseases—has established centers of excellence throughout Africa to address the challenge of inadequate research infrastructure and the lack of critical mass of researchers in the region.
- GlaxoSmithKline, one of the world's largest pharmaceutical companies, has committed to investing in increasing African manufacturing capacity and establishing 25 academic chairs at African universities to support development of health research skills and capabilities.
- The US National Institutes of Health is collaborating with universities in the United States and India to support research training activities in diarrheal disease and establishing a center of excellence for infectious disease research training in India.

Limited local capacity has been rate limiting for accelerating product development in LMICs. Therefore, investing in capacity strengthening is of increasing importance for NPPDs and their partners and has become a critical part of their product development strategies. Although approaches vary across institutions, there is general agreement that it is mission critical for research and manufacturing partners to conduct clinical trials and manufacture products that comply with stringent safety and quality standards.

FINDINGS

Factors influencing investment in capacity strengthening

Respondents generally agreed that capacity strengthening is integral to most projects but is not an end in itself. NPPDs and their partners invest in strengthening capacity when it is critical to meet the goal of the project to ensure the quality and safety of research, product development, and manufacturing (see Table 1 for criteria). Because NPPDs were created to speed the development and adoption of new technologies to address public health needs in LMICs, in some instances, capacity-strengthening efforts are of lessor importance for achieving the overall mission. Respondents noted that strengthening the capacity of partners based in LMICs is important and, often, necessary to ensure the quality of clinical trials and health technologies but is not a major driver. NPPDs typically do not embark on these efforts alone and collaborate with commercial entities, academic institutions, and governments with years of experience to conduct capacity strengthening with partners in LMICs.

Capacity strengthening can require substantial investments in training and technical assistance and can consequently lead to lengthier timelines. This can create a tension—and a potential trade-off—between accelerating the availability of a new technology and requiring a longer timeline to increase capacity. NPPDs must consider product development timelines and determine whether building capacity will delay delivery of a new

Table 1. Criteria considered by nonprofit product development organizations (NPPDs) when determining investment in capacity strengthening.

Is existing capacity sufficient to meet the needs of the project or product? Capacity strengthening is a priority if it is necessary to achieve the overall mission of ensuring the quality and safety of clinical trials and health technologies.
Are there local partners willing to invest in developing and sustaining capacities? There should be good potential for local partners to leverage the improved capacity for their continued growth and, ideally, for long-term collaboration and partnering with NPPDs.
Will capacity strengthening significantly delay achieving the goal of the project? Capacity development can require substantial investments and lengthier timelines. A balance needs to be struck between accelerating the availability of products and the longer timelines needed for strengthening capacity.
Is there sufficient funding to support capacity strengthening? Funding—especially long-term, sustainable funding—is crucial to strengthening and maintaining improved capabilities and infrastructure.
Is there political commitment to develop and sustain capacity? Governments should be willing and able to enforce compliance with international standards to incentivize investment by local partners and sustain capacity.

tool, and whether the delay will have meaningful long-term benefits that will outweigh the short-term impact on product availability.

Capacity strengthening can be a time-consuming, resource-intense endeavor. When determining investment in capacity strengthening, NPPDs must consider whether potential partners are aligned with the overall NPPD mission to advance affordable and accessible health technologies as well as how these efforts will address future needs of LMICs. There must be potential for the partners and countries to leverage the increased capacity for continued growth. Therefore, some capacity (e.g., infrastructure and technical capacity) must exist to build upon. There must be commitment from all stakeholders, including national governments (e.g., ministries of health, ministries of science and technology, and national regulatory authorities), to enforce international technical and ethical standards and guarantee access to local markets to ensure sustainability of these efforts to develop domestic capacity to innovate.

A weak regulatory environment can undermine capacity-strengthening investments. GMP standards have not been adopted by many small manufacturers in LMICs because they are not enforced by national regulators. In countries where manufacturers are not required to meet international standards (as in many LMICs), smaller manufacturers that do meet these standards risk becoming less competitive in the local market because the financial burden of compliance with GMP requirements increases production costs (for upgrading facilities, training, hiring more staff, etc.). The risk, particularly in the short term, is that manufacturers will have to charge more than other local manufacturers that have lower overhead costs and product pricing because they are not meeting GMP standards. PATH—an NPPD that develops vaccines, drugs, and medical devices—had difficulty finding a manufacturing partner in South America that was willing to make the investment required to produce a supply of devices for use in international markets in line with international standards because these standards were not required by law to reach local markets. If national regulatory authorities required compliance with international standards, manufacturers would have an incentive to invest in ensuring the quality of their products.

NPPDs may also consider local cultural norms and their previous experiences working in a particular country or with a partner. Cultural differences can play an important role in capacity-strengthening

efforts. Different norms and business or research practices can create tensions between partners and require patience and transparency. Likewise, different communication styles can lead to misinterpretation and confusion. All parties need to be mindful of potential conflicts.

Challenges to sustainability

The challenge most commonly cited by respondents was ensuring sustainability of strengthened capacity following the conclusion of a specific study or project. Capital investment, consistent revenue or funding, continued scientific and manufacturing opportunities, retention of skilled staff, and maintenance of upgraded facilities are critical to ensuring that the improved capacity is maintained (see Table 2 for challenges). As previously mentioned, the resources required to provide and maintain equipment, training, and technical assistance to achieve the appropriate quality standards are significant. If sustainable investment (through funding, fee-for-service, and/or sales) cannot be secured, it is difficult to ensure the further employment of trained staff and maintenance of upgraded facilities.

Because of the complexity and long-term nature of this work, capacity strengthening is often not prioritized by policymakers in LMICs. Competing priorities limit funding opportunities from governments in endemic countries to co-finance these efforts. And the funding that NPPDs and their partners bring is typically tied to specific projects and is time limited. In many cases, only a relatively small number of organizations and individuals can take advantage of capacity-strengthening opportunities. As a result, only a limited number of researchers and research sites and manufacturers have the experience and facilities to meet NPPD commitments to safety and quality. The limited number of partners equipped to meet international standards can create a vacuum by concentrating capabilities in a small number of individuals, institutions, and countries. At times, NPPDs find themselves competing to use the same set of qualified partners.

When capacity is concentrated, any setbacks can delay or derail product development timelines. For instance, the issue of "brain drain" is an ongoing challenge in many endemic countries—skilled staff leaving for more lucrative employment opportunities in the private sector or with organizations in high-income countries (often working on diseases or products that are of lesser domestic importance). The inability of domestic academic and research institutions to provide competitive compensation and professional development can weaken capacity-strengthening efforts.

Market shifts may compel commercial partners to shift priorities as the business or competitive landscape changes to products with more financially lucrative markets. Because NPPDs were created to develop technologies with little perceived commercial market, this is always a potential risk. If manufacturing efforts are focused on one specific product, the company may be at risk if the technology that has been transferred is surpassed by new technologies making their product less

Table 2. Significant challenges in sustaining improved capacities.

Limited funding opportunities upon completion of the project. When project funding ends, it may be difficult to ensure the further employment of trained staff and the maintenance of upgraded facilities and equipment.
Improved capacity concentrated among a small number of institutions and persons. Because capacity strengthening can be resource intensive, in many cases, only a relatively small number of organizations and individuals are able to benefit.
Shifting priorities of commercial partners. Pharmaceutical, biotechnology, or manufacturing partners may shift priorities as the business or competitive landscape changes, making private market interests more important.

desirable. Respondents noted that capacity-strengthening efforts are sustainable when they support systemic improvements to enable country ownership and domestic investment.

Because of shifts in disease patterns (e.g., changing rates of infectious disease due to immigration), infrastructures previously developed for specific projects could end up in areas with lower incidence and prevalence of the diseases of initial interest. This may limit the use of infrastructures to the diseases for which they were initially conceived. Rather than concentrate on a specific project, technology, or disease, improving the overall research and manufacturing ecosystem would help to ensure that upgraded facilities, production capacities, and increased expertise could be redeployed to respond to existing and emerging domestic health needs.

Developing research capacity through trainings and partnerships

Nonprofit product development organizations (NPPDs) participate in numerous partnerships and collaborations to leverage resources and strengthen capacity to conduct health research in low- and middle-income countries (LMICs). The International Partnership for Microbicides (IPM) has partnered with 17 research centers to train more than 600 staff and community advisors on microbicides and clinical trial implementation in communities with high HIV prevalence in Africa. This network is a platform for providing training and networking opportunities for local researchers and enables IPM to conduct multicenter studies to advance its portfolio.

International Vaccine Institute (IVI) has partnered with the World Health Organization Special Program for Research and Training in Tropical Diseases (better known as TDR), which trains researchers from LMICs on Good Laboratory Practices. IVI also holds an annual advanced vaccinology course for researchers and policymakers. This enables IVI to support both on-the-ground research and help influence the policy environment to advocate for vaccine research.

The TuBerculosis Vaccine Initiative (TBVI) and the European Vaccine Initiative (EVI) have received funding from the European and Developing Countries Clinical Trials Partnership to coordinate platforms to strengthen collaboration and capacity to conduct clinical trials in Africa. TBVI coordinated the "Collaboration and integration of tuberculosis vaccine trials in Europe and Africa" (better known as TBTEA) which enhanced TB vaccine clinical trial capacity through collaborative workshops and training programs and by providing training fellowships for postdoctoral researchers in Africa. Similarly, EVI coordinates the Malaria Vectored Vaccines Consortium (MVVC), a mulitsectoral network that strengthens the capacity of researchers in Africa to conduct clinical trials on malaria vaccine candidates. The MVVC sponsors training of local scientists, conducts workshops on a variety of topics such as clinical trial protocol development, and data and financial management, and supports infrastructure upgrades at research institutions.

Drugs for Neglected Diseases *initiative* convenes several regional R&D platforms to improve clinical capacity to develop treatments for neglected diseases. These platforms include the Leishmaniasis East Africa Platform, the Human African Trypanosomiasis (sleeping sickness) Platform, and the Chagas Clinical Research Platform. These platforms are regionally focused, and their members include NPPDs and academic institutions. Each platform increases local R&D capacity by addressing gaps in infrastructure and providing clinical research training.

The Malaria Vaccine Advocacy Fellowship, managed by the PATH Malaria Vaccine Initiative, provides malaria vaccine researchers and scientists in Africa skills to advocate for malaria vaccine research. This program trains researchers to communicate their research to less technical audiences, influence African policymakers on malaria vaccines, and advocate for increased and sustained funding for malaria vaccine research and development. Improving researchers' nonclinical skills (e.g., proposal writing, communications, advocacy) is just as critical as increasing their clinical expertise.

Formal training opportunities through collaborations with local academic institutions and fellowships help further encourage growth and retention of local research capacity. NPPDs have contributed to improving local capacity and ensuring that the necessary infrastructure exists to support locally driven health research.

Improving laboratory and site infrastructure

By investing in research infrastructure in endemic countries, nonprofit product development organizations (NPPDs) have helped to improve laboratory and clinical facilities that can support high-quality product development. Strengthening infrastructure includes construction of new facilities, renovation of existing sites, and upgrading of laboratory equipment. These activities are supplemented by training to familiarize researchers with new equipment, techniques, and administrative procedures.

During the past 13 years, Aeras—an NPPD developing tuberculosis (TB) vaccines—has collaborated with the South African Tuberculosis Vaccine Initiative (SATVI) to strengthen the research infrastructure and technical capacity to make SATVI the largest dedicated TB vaccine research group in Africa. Aeras has also collaborated with Wuhan University in China to develop an animal and immunology center of excellence for TB research. This will expand on Wuhan University's existing Animal Biosafety Level 3 Laboratory, making it the largest in China. Aeras, along with Chinese vaccine developers, will use the site to conduct non-human primate studies to evaluate potential TB vaccines.

PATH's Malaria Vaccine Initiative (MVI) has contributed to the strengthening of overall clinical and laboratory practices at 11 sites participating in a phase 3 malaria vaccine trial. The research centers have been equipped and staff trained to conduct microscopy to detect malaria parasites. Similar work was done around digital X-ray technology, which is used in identifying the cause of respiratory distress and thus helps to avoid over-diagnosis of malaria. As part of these efforts, MVI also worked with the sites to strengthen communication capabilities through crisis communications training, the establishment of a network of communications officers, and the provision of media/presentation training for site spokespersons.

Medicines for Malaria Venture (MMV) has been working closely with regional partners to upgrade site facilities to meet international quality standards. This includes constructing new buildings, upgrading laboratory equipment, building facilities for inpatient care, and purchasing computers for data management. These efforts have helped to develop local research capacity and provided professional opportunities for local scientists. In 2013, MMV partnered with the Centre Suisse de Recherche Scientifique to set up a laboratory in Côte d'Ivoire to conduct robust disease surveillance and assess the response to new malaria medicines. Built from the ground up, the new laboratory contributes to global resistance monitoring through the Antimalarial Resistance Network and provides training opportunities to local graduate students.

PATH provided technical assistance and technology transfer to the Christian Medical College at Vellore in India to help establish a rotavirus reference laboratory. This laboratory is performing clinical assays to support development of new rotavirus vaccines by multiple Indian vaccine manufacturers. The rotavirus reference laboratory also invited and trained technical staff from the Wuhan Institute of Biological Products and Instituto Butantan in Brazil and provided standardized critical reagents so that they could establish assays in their own organizations to support new rotavirus vaccine development. The rotavirus reference laboratory was designed as a sustainable facility to support rotavirus vaccine development in India indefinitely.

Strengthening facilities is critical to increasing domestic capacity to conduct research in line with rigorous standards and to enabling locally driven research and development to address local needs.

Benefits from local engagement in and ownership of projects

One of the most significant benefits of capacity-strengthening efforts is encouraging local engagement in and ownership of projects and facilities in endemic countries (see Table 3 for advantages of local ownership). Capacity strengthening enables studies to be conducted and products to be manufactured directly in the affected regions. The ability to conduct high-quality clinical research and the availability of high-quality manufacturing capacity (potentially at lower cost) in LMICs can help to accelerate the development and delivery of new health technologies and drive local economic growth.

Table 3. Advantages of local ownership.

Improved quality and safety of research and manufacturing. Capacity strengthening improves understanding of and capabilities to conduct research and manufacturing in line with stringent international safety and quality standards; it also protects the rights of participants and consumers.
Increased capacity for locally driven solutions. Strengthened domestic capacity enables studies to be conducted and products to be manufactured directly in the affected regions; this enables local response to new and emerging health issues.
Increased competition among manufacturers. More competitive markets help to lower prices, reduce supply constraints, and disperse manufacturing capacity.

Respondents noted that investing in strengthening the capacity of research institutions in LMICs is helpful to ensuring that the products are technically relevant and effective in endemic settings. By increasing the ability of local researchers and institutions to conduct laboratory and clinical studies in accordance with GLP and GCP standards, the overall quality of research has improved. Capacity strengthening also helps to generate more rigorous results and data to inform regulatory reviews and product registrations. It also improves attention to study participants' rights, safety, and needs by increasing site staff understanding of international clinical and ethical standards. If capacities can be maintained beyond initial projects, they can be redeployed to address new and emerging health issues, potentially increase understanding of disease (i.e., local incidence and prevalence patterns), improve timelines for the development and uptake of new health products, and enable locally driven product development.

Technology transfers and upgrading of manufacturing facilities have helped to build competitive markets that include endemic-country manufacturers. The availability of high-quality, local manufacturing capacity at lower cost is critical to affordable prices and improving access by increasing competition among producers. This alleviates supply constraints created when only one or two global manufacturers can make a product. This dispersed capacity also enables a more robust response to critical situations (e.g., outbreak of pandemic flu) by increasing the accessibility of high-quality products, and it may allow manufacturers the flexibility to tailor products (e.g., single dose versus multiple doses) to local needs. Finally, improved local manufacturing capacity can increase employment opportunities and help to improve local economic conditions.

CONCLUSION

Although capacity strengthening is not an end in itself, it is integral to conducting high-quality research, product development, and manufacturing and to improving access in challenging environments. The growth in the pipeline of health products targeting the health needs of LMICs requires increased research and manufacturing capacities in endemic settings. Commons themes outlined by respondents include:

- There must be a shared commitment among partners to comply with international technical and ethical standards to ensure volunteers' safety and rights as well as to facilitate access to high-quality products among those in need.
- Capacity-strengthening investments must weigh accelerating the near-term availability of much-needed products against the potential of lengthier timelines to increase capacity. At times, the need to accelerate access to a product may take precedence over local capacity strengthening.
- Capacity strengthening should enable home-grown solutions and local product development to be responsive to existing needs and emerging challenges. These efforts should enable local

Strengthening manufacturing capacity through technology transfer

Nonprofit product development organizations (NPPDs) were established to develop, not deliver, health technologies. Therefore, they must work with manufacturers to ensure a sustainable supply of high-quality products. This includes facilitating the transfer of health technologies, upgrading facilities, and expanding the skills of local manufacturers to comply with international standards.

To improve manufacturing capacity and increase supply of MenAfriVac® (a vaccine against meningitis A), the Meningitis Vaccine Project, a partnership between PATH and the World Health Organization, helped to facilitate the transfer of a conjugation technology developed by the US Food and Drug Administration to the Serum Institute of India Ltd (SIIL). This technology transfer strengthened SIIL's capacity to produce a quality-assured vaccine for less than US$0.50 a dose. It not only enabled SIIL to produce large quantities of MenAfriVac® but also capacitated the company to produce additional conjugate vaccines in bulk to meet global need.

To facilitate access to an antimalarial medication, artesunate-mefloquine fixed-dose combination (ASMQ), the Drugs for Neglected Diseases *initiative* (DND*i*) facilitated a technology transfer between the Brazilian government and Cipla Ltd. in India. This technology transfer was the first of its kind in that it involved a transfer from a public entity in Brazil, Farmanguinhos, to a private company in India. The technology transfer facilitated the alignment of procedures to Good Manufacturing Practices to produce similar and comparable products from both producers that meet international requirements. As a result of the transfer, ASMQ was registered in India in 2011 and in Malaysia and Myanmar in 2012, expanding access to the drug in Asia.

In another example, PATH transferred a rapid point-of-care diagnostic platform and the know-how to develop new test applications (across a spectrum of infectious diseases) to multiple manufacturers in India. This approach included training of manufacturing staff and providing post-transfer trouble-shooting and quality monitoring. The collaboration with Indian diagnostic manufacturers helped to build local capacity for product development, created a competitive local market, and accelerated the growth of the diagnostic manufacturing industry in India.

Technology transfer can increase the reliability of supply, decrease reliance on foreign manufacturers, lower prices, and encourage locally driven solutions for domestic health needs. Thus, local production can contribute to a sustainable, long-term solution to the most pressing health needs in endemic countries.

engagement and country ownership of health research, related product development, and manufacturing in endemic countries.

- Capacity-strengthening investment needs to be sustainable and enable LMICs to leverage the value of this increased capacity for their continued future growth. Because capacity strengthening can be a time-consuming and complex endeavor, donors and governments in endemic countries must commit to financing and enforcing international research and manufacturing standards to ensure an even playing field for the long-term sustainability of these efforts.

NPPDs and their partners have made significant investments to increase the capacity of researchers and manufacturers in LMICs to innovate and ensure the accessibility of the final products. Strengthening local capacity enhances engagement and ownership of product development and manufacturing in the affected countries; ensures that high-quality studies can be performed directly in the populations and settings where the final products will be rolled out; and helps to build competitive markets that include endemic-country manufacturers—which lowers prices and accelerates the availability of new products.

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