NORTH-SOUTH COLLABORATIONS TO PROMOTE HEALTH INNOVATION IN AFRICA

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ABSTRACT

The significant interest in and reference to regional innovation networks for health capacity building within international and regional public health and development strategies has not been matched with the operational support they need. There is little guidance about how to create and sustain such networks and about how north-south collaborations can contribute to their success. This Article describes a model for building African health capacity through regional health innovation networks that focuses on the complete pathway from idea to commercialization of health technologies, and it suggests guidelines for effective north-south collaborations to support this approach. In doing so, the Article highlights the importance of local legal and business capacity building as part of a product-focused, network-based health innovation strategy.

INTRODUCTION

Developing the health products needed, in the form and at the price needed, to combat diseases that disproportionately impact African countries, requires the strengthening of African capacity to discover, develop, and commercialize health technologies.1 Strengthening African capacity in an effective and sustainable way requires African-led identification of promising technologies, leveraging of existing capacity at all stages of the research and product development pipeline, and building new capacity where gaps exist.2 A major

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1 Health technologies include medical devices, diagnostics, drugs, and vaccines.
2 See, e.g., COUNCIL ON HEALTH RESEARCH FOR DEV. & NEW P’SHIP FOR AFR.’S DEV., STRENGTHENING PHARMACEUTICAL INNOVATION IN AFRICA: DESIGNING STRATEGIES FOR NATIONAL PHARMACEUTICAL INNOVATION (2010); Michel Sidibé et al., Editorial, Commodities for Better Health in Africa—Time to Invest Locally, 92 BULL. WORLD HEALTH ORG. 387 (2014).
gap in developing African health technologies occurs at the point of moving early-stage technologies into development and commercialization. Fostering regional networks that connect existing capacities within and across African countries in ways that support the development and commercialization of African health products is critical to the success of capacity-building efforts.

This regional network-based capacity-building approach informs the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (“Global Strategy”), a global health initiative adopted by the World Health Assembly in 2008. The Global Strategy marks a shift in international thinking about how to address diseases, especially neglected diseases, in developing countries. It reflects an international consensus on the need to build research and development (R&D) capacity in developing countries to enable them to address those diseases that disproportionately impact them. The Global Strategy’s plan incorporates regional innovation networks as proposed mechanisms for building health capacity. At roughly the same time as negotiations over the Global Strategy, the Summit of the African Union adopted the Pharmaceutical Manufacturing Plan for Africa as part of its effort to establish a coordinated regional approach to local production of health products. This plan promotes a vision of a competitive, integrated, and sustainable pharmaceutical manufacturing industry in Africa capable of responding to the continent’s needs for medical therapies. It, too, emphasizes the importance of network building and collaboration at the regional level. A subsequent initiative spearheaded by the New Partnership for Africa’s Development (NEPAD) in 2010, Strengthening Pharmaceutical Innovation in Africa, has provided an assessment both of existing pharmaceutical capacities

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3 See, e.g., Peter A. Singer et al., Commercializing African Health Research: Building Life Science Convergence Platforms, 5 GLOBAL F. UPDATE ON RESEARCH FOR HEALTH 143 (2008); see also Ken Simiyu et al., Stagnant Health Technologies in Africa, 330 SCI. 1483 (2010).
5 WORLD HEALTH ORG., GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY 1 (2011).
6 See, e.g., COUNCIL ON HEALTH RESEARCH FOR DEV. & NEW P’SHIP FOR AFR.’S DEV., supra note 2, at 11.
7 See Regional Network for Drugs and Diagnostics Innovation Exemplified by ANDI: Background Paper for Executive Board, supra note 4.
8 See AFRICAN UNION COMM’N & UNITED NATIONS INDUS. DEV. ORG., PHARMACEUTICAL MANUFACTURING PLAN FOR AFRICA: BUSINESS PLAN 1 (2012).
9 See id.
10 See id. (outlining a business plan designed to accelerate implementation of Pharmaceutical Manufacturing Plan for Africa).
and of the potential for engaging in local research and production of health technologies through regional innovation networks.\textsuperscript{11} A network-based approach to developing health capacity similarly resonates with the United Nations’ Sustainable Development Goals,\textsuperscript{12} the objectives in the African Union’s Agenda 2063 development plan,\textsuperscript{13} and the Science, Technology and Innovation Strategy for Africa 2024.\textsuperscript{14}

While regional networks for building health innovation capacity feature prominently in these international and regional strategies for addressing African health and development challenges, there is little guidance as to what these networks should look like, how to create and sustain them, and how north-south collaborations can best contribute to their success.\textsuperscript{15} As NEPAD notes in its \textit{Strengthening Pharmaceutical Innovation in Africa} report, initiatives like the Global Strategy and the Pharmaceutical Manufacturing Plan “are aspirational statements that need to be translated into work plans and approaches to implementation.”\textsuperscript{16} This Article responds to that implementation gap by drawing from the experiences of the African Network for Drug and Diagnostics Innovation (ANDI), an organization that deploys a network-based model for developing African health technologies, to identify concrete new roles for north-south collaborations as part of these African health innovation networks.\textsuperscript{17} This Article describes the role that such collaborations can play in addressing gaps in capacity for management and transfer of technology and knowledge from one stage of product development to another, thus supporting commercialization strategies for locally developed health technologies. In doing so, this Article helps to focus much needed attention on the importance of local legal and business capacity building tailored specifically to the commercialization of local health technologies as a critical part of a network-based health innovation strategy.\textsuperscript{18}

\textsuperscript{11} See, e.g., \textsc{Council on Health Research for Dev. & New P’ship for Afr.’s Dev.}, supra note 2.


\textsuperscript{13} See \textsc{African Union Comm’N, Agenda 2063: The Africa We Want} (2015).

\textsuperscript{14} \textsc{African Union Comm’N, Science, Technology and Innovation Strategy for Africa 2024}.

\textsuperscript{15} See generally \textsc{BMC Int’l Health and Hum. Rts. Supp.} 2010 (series of twelve articles that discuss African health innovation systems).

\textsuperscript{16} \textsc{Council on Health Research for Dev. & New P’ship for Afr.’s Dev.}, supra note 2, at 66.

\textsuperscript{17} See \textsc{African Network for Drugs and Diagnostics Innovation, Facilitating Health Innovation in Africa: Strategic Plan: 2016–2020} 35 (2016).

\textsuperscript{18} See, e.g., Carlos M. Morel et al., \textit{Health Innovation Networks to Help Developing Countries Address Neglected Diseases}, 309 Sci. 401 (2005) (highlighting the growing ability of some developing countries to undertake health innovations and the importance of innovation health networks as a mechanism for addressing neglected diseases).
Part I of this Article reviews the past performance of north-south collaborations focused on diseases prevalent in Africa and identifies three key limitations of traditional approaches to north-south collaborations. Part II examines the shift in focus of development strategies toward regional capacity building and networks and the corresponding changes in the collaboration landscape. Part III uses past experience with collaboration efforts in African biotechnology and ANDI’s current experiments, including a collaboration between ANDI and Emory University, to generate guidelines for the design of collaborations that focus on the support of regional innovation networks.

I. NORTH-SOUTH COLLABORATIONS AS MECHANISMS TO ADDRESS DISEASES PREVALENT IN AFRICA

North-south collaborations have long played a dominant role in global health strategies intended to address particular diseases endemic in the south. Here “the south” refers to low- and middle-income (developing) countries and “the north” to high-income (developed) countries as classified by the World Bank. Africa, which is home to thirty-four of the world’s forty-eight least developed economies as defined by the United Nations, has been the primary focus of many such collaborations for decades. Until recently, these north-south collaborations have been largely designed, financed, and controlled by the northern partners with a concentration of R&D and decision making in the north, a focus on disease rather than capacity to respond to disease, and a reliance on public and philanthropic funds to finance the work.

A. Traditional Models of North-South Collaboration

Traditional north-south collaborations to combat diseases prevalent in Africa have generally taken one of the following forms: (1) nonprofit product development partnerships (PDPs), (2) funding mechanisms to supply and procure drugs and vaccines, (3) research institutes and platforms devoted to research on neglected diseases, (4) pharmaceutical philanthropy, and (5)

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19 See, e.g., Fred Binka, Editorial, North-South Research Collaborations: A Move Towards a True Partnership, 10 TROPICAL MED. & INT’L HEALTH 207 (2005) (commenting on the evolving role of north-south partnerships and the need to move away from historical models of scientific colonialism).


22 See, e.g., Binka, supra note 19; see also COUNCIL ON HEALTH RESEARCH FOR DEV. & NEW P’SHIP FOR AFR.’S DEV., supra note 2, at 10–12, 16–17.
overseas scientific training and technical assistance. Each of these categories is described further below, and a summary of these models and their key strengths and weaknesses is attached as the Appendix.

The first category, PDPs, has emerged as one of the most popular and effective strategies for trying to bridge the gap between the growing scientific and technological capabilities of mature economies and the needs of developing economies. PDPs focus on the challenge of creating health products and processes that meet the health needs of developing economies where market incentives are lacking. They are typically nonprofit organizations created as mechanisms for pooling funds from public and philanthropic entities to support R&D in a particular disease or disease area. While each PDP has a slightly different structure, the majority of PDPs focus on managing disease-specific projects rather than on conducting their own R&D, forming partnerships with academic institutions and pharmaceutical companies to implement their projects. Some of the most active and successful PDPs in diseases endemic to African countries include the Medicines for Malaria Venture (MMV), the Drugs for Neglected Diseases Initiative (DNDi), the Global Alliance for TB Drug Development (TB Alliance), the International AIDS Vaccine Initiative (IAVI), PATH, and the Foundation for Innovative New Diagnostics (FIND). These PDPs, and others like them, have successfully increased the amount of R&D in diagnostics and drugs that target neglected diseases and have produced viable portfolios of products in key disease areas.

While the PDP model is one of the most successful approaches to date in producing new medical therapies for neglected diseases, it has several
limitations that prevent it from being sufficient, on its own, to serve as a comprehensive strategy for addressing neglected diseases. The PDP approach is heavily reliant on public and philanthropic funding, which creates challenges in achieving long-term financial sustainability of existing projects and limits the number of new projects that can be undertaken. As a result of the nature and limits of the funding, the range of diseases that receive the bulk of PDP funds and effort is fairly narrow, with most of the funds going to research on malaria, TB, and HIV/AIDS. While there are a number of early-stage research projects underway in PDPs, the PDP model has had limited success in implementing affordable innovation strategies and only a relatively modest number of drugs and vaccines have reached the marketplace. Finally, this model does little to build local and regional R&D capacity, focusing instead on R&D efforts located largely in the north.

The second category includes a range of alternative funding mechanisms to support drug, vaccine, and diagnostics R&D, as well as the purchase of the resulting health products. Some financial mechanisms provide support for R&D, either in the form of grants, such as those provided by the Bill & Melinda Gates Foundation, or prizes, such as the Global Grand Challenges initiatives of the Bill & Melinda Gates Foundation and the United States Agency for International Development (USAID). Other financial mechanisms are used to finance purchases of health products. The four

30 See, e.g., Sarah E. Frew et al., A Business Plan to Help the ‘Global South’ in Its Fight Against Neglected Diseases, 28 HEALTH AFF. 1760 (2009) (showing the important role of local private-sector initiatives in addressing the local health problems in developing economies); Nick Chapman et al., Policy Cures Research, G-FINDER, Neglected Disease Research and Development: A Pivotal Moment for Global Health 76 (2016), (stating that 72% of total global investment in R&D for new products for neglected disease went to HIV, malaria, and TB; 15% of the total came from private firms and the rest from philanthropy and governments).


32 See, e.g., Topal, supra note 26, (describing PDP structures). But see Binka, supra note 19, at 207; Morel et al., supra note 18, at 402 (documenting examples of recent partnerships between PDPs and companies in developing economies).


largest multilateral health financing mechanisms that account for the majority of health product purchases are the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), the Global Alliance for Vaccines and Immunization (Gavi), the World Bank’s Global Financing Facility in Support of Every Woman Every Child (GFF), and Unitaid. These organizations have developed a range of innovative financing mechanisms to support purchases of essential medicines and vaccines, including, for example, the Advanced Market Commitment, in which donors promise to purchase developing country disease-focused drugs. These organizations have also developed a variety of funding strategies, including transaction taxes such as airline ticket levies, disease bonds, and public-private matching funds. While providing needed resources and incentives for R&D, this approach is reliant on public and philanthropic funds, research efforts take place primarily in the north, funds support purchases of drugs and vaccines produced largely outside of Africa, and the bulk of the funds target only a limited range of diseases. In addition, evaluations of the major funds in particular have emphasized the need for improved strategies for increasing the involvement of the private sector in health financing.

The third category includes research institutes and research platforms focused on neglected diseases. Research institutes engage in early stage R&D for neglected diseases, either as part of a university, a nonprofit, or a pharmaceutical company. Examples include the Tres Cantos Open Lab Foundation created by GlaxoSmithKline to support research on neglected diseases, nonprofit institutes, such as the Infectious Disease Research Institute (IDRI) (now perhaps better characterized as a PDP with its emphasis on internal product development), and a large number of institutes and centers within research universities. Research platforms can take the form of collaborations designed to create mechanisms for sharing knowledge and research for use in neglected diseases areas or mechanisms for collecting and pooling research and coordinating research partnerships around a particular

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36 See id.
37 See, e.g., Advanced Market Commitments (AMC), LENDING GROUP ON INNOVATIVE FINANCING FOR DEV. (Feb. 27, 2009), http://www.leadinggroup.org/rubrique178.html.
39 See, e.g., id.
40 See, e.g., id. at 54–55 (evaluating performance of alternative financing mechanisms).
41 See, e.g., About the Open Lab, TRES CANTOS OPEN LAB FOUND., http://www.openlabfoundation.org/about.html (last visited Jan. 20, 2018).
A good example of this platform strategy is WIPO Re:Search, which provides a public research platform to support knowledge sharing in the area of neglected tropical diseases. While this approach promotes knowledge sharing and research capabilities, it again remains heavily reliant on public and philanthropic funding, and most of the R&D activity continues to take place in the north. In addition, the focus is largely if not exclusively on early-stage research, while many of the challenges in addressing neglected disease occur at the later stages of identifying promising potential products and moving them through development and commercialization.

The fourth category is pharmaceutical philanthropy. This includes philanthropic product donations from pharmaceutical companies, often provided to non-governmental organizations for distribution. One of the earliest and most successful drug donation programs was a program initiated by Merck & Co., Inc. in 1987 for the donation of Mectizan, a human formulation of the veterinarian drug ivermectin, to treat river blindness in Sub-Saharan Africa. Since then, a number of other pharmaceutical companies have followed suit with their own drug donation programs. Pharmaceutical philanthropy also takes the form of cash donations, technology transfers, and internal research programs focused on neglected diseases. While providing much needed resources and expertise, pharmaceutical philanthropy is limited in magnitude and in scope. It is subject to the discretion and interests of the pharmaceutical company donors (as is all corporate philanthropy), targets a very limited range of diseases, and does little to securely address long-term health needs.

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47 See, e.g., ACCESS TO MED. FOUND., ACCESS TO MEDICINE INDEX 2016 76–77 (2016).

48 See, e.g., John LaMattina, Even Pharma’s Good Deeds Are Criticized, FORBES (May 6, 2013, 8:40 AM), https://www.forbes.com/sites/johnlammattina/2013/05/06/even-pharmas-good-deeds-are-criticized (examining some of the global health initiatives undertaken by pharmaceutical companies).

49 See, e.g., Cristina P. Pinheiro, Editorial, Drug Donations: What Lies Beneath, 86 BULL. WORLD HEALTH ORG. 580 (2008) (describing problems that arise from lack of good procurement practices in drug donation programs); Adam Robert Green, Drug Donations Are Great, but Should Big Pharma Be Setting the
The fifth category encompasses overseas technology transfer and training programs.50 The technology and knowledge transfer model typically involves a flow of educational programs, training, and technical assistance from the north to the south. While some of these programs begin to address the deficit in legal and business capacity, their primary focus seems to remain largely on supporting education and institutional collaboration in the sciences. Most programs have not been product-development focused and do not adequately address the translation of technologies from lab to clinics to market.51 When they are product focused, the programs tend to export models of drug discovery and development that are better suited to well-developed markets and typically lack mechanisms for long-term financing and sustainability.52

In summary, while making great strides in the study of neglected diseases, these traditional collaboration models have not produced and sustained the robust and comprehensive product development pipelines needed to respond comprehensively and sustainably to the many Type II and Type III diseases endemic to different regions within Africa.53 Although they vary in form, these five approaches remain tied to a developed economy model of health product discovery and development, relying primarily on public and philanthropic funds, northern capacity for the development of new medical therapies, and donor decision making about where to focus drug discovery and development efforts.54 As a result, there has been a neglect of region-specific R&D needs imposed by Africa’s growing chronic disease burden and emergent infections55 as well as a failure to adequately invest in the potential of local resources, traditional knowledge, and local markets.56 These approaches have generally

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50 See, e.g., Luis A. Salicrup, Opinion, NIH Forges R&D Partnerships in Developing Countries, 25 NATURE BIOTECHNOLOGY 976 (2007) (describing the role of United States National Institutes of Health Office of Technology Transfer in north-south partnerships involving training in multidisciplinary skills needed in technology transfer).


53 See, e.g., Moran, supra note 51. For a definition of Type I, II and III diseases, see, for example, Mary Moran, Debating the Scope of a Health Research and Development Convention, 91 BULL. WORLD HEALTH ORG. 618 (2013).

54 See, e.g., Al-Bader et al., supra note 52.

55 See, e.g., Ama de-Graft Aikins et al., Commentary, Tackling Africa’s Chronic Disease Burden: From the Local to the Global, GLOBALIZATION & HEALTH, Apr. 19, 2010, at 1.

56 See, e.g., Simiyu, supra note 3.
not addressed the enabling elements of local product development, such as management of intellectual property, licensing and technology transfer, market analysis, business plan development, and business plan implementation. But perhaps the most significant and pervasive limitation of these collaboration models is the lack of mechanisms for ensuring financially sustainable approaches to the development and commercialization of health products and services targeted at meeting African health needs. 57

Even the most successful, product-focused collaborative efforts, such as the PDPs described above, have struggled to attract the investment, business and regulatory support, and human capital needed to move essential health products like drugs and vaccines beyond early stages of R&D into the market. Most of the funding for developing new treatments for neglected diseases comes from foreign government and philanthropic sources. 58 These funding sources have been uncertain, limited in amount and duration, directed largely to support research and early stage development rather than downstream efforts at commercialization, and highly concentrated in three major disease areas (HIV/AIDS, TB, and malaria). 59 In addition, public and philanthropic funding tends to be directed largely toward public and nonprofit institutions, with only limited investment in the private for-profit sector. 60 Private sector funding, especially the sources of risk capital that support early stage ventures, has been extremely limited or non-existent for technologies that target diseases

57 See, e.g., CHAPMAN, supra note 30, at 7 (stating that 40% of all neglected disease R&D funding goes to organizations that rely on the U.S. government for more than 80% of their funding and that PDPs continue to rely on the Bill & Melinda Gates Foundation, with nearly half of them receiving the majority of their funding from the foundation); MARY MORAN ET AL., GEORGE INST. FOR INT’L HEALTH, G-FINDER, NEGLECTED DISEASE RESEARCH & DEVELOPMENT: NEW TIMES, NEW TRENDS 7 (2009) (providing a survey of global funding on neglected diseases and reporting that 87.6% of funding for R&D on neglected diseases came from philanthropic and government sources).

58 See, e.g., CHAPMAN, supra note 30, at 5 (noting an overall decline in neglected disease funding almost continuously since 2009 with 63% coming from the public sector, 21% from philanthropic funders, and 15% from industry—the highest industry funding share ever recorded by G-FINDER); MORAN ET AL., supra note 57, at 54 fig.21 (showing a large increase in funding by philanthropic sources); see also David McCoy et al., Global Health Funding: How Much, Where It Comes from and Where It Goes, 24 HEALTH POL’Y & PLAN. 407, 409–10 (2009).

59 See, e.g., WORLD HEALTH ORG., STATE OF HEALTH FINANCING IN THE AFRICAN REGION (2013); see also, CHAPMAN, supra note 30, at 4 (noting that 71% of funds for neglected diseases go to HIV/AIDS, TB, and malaria).

60 See, e.g., COMM’N ON THE PRIVATE SECTOR AND DEV., UNITED NATIONS DEV. PROGRAMME, UNLEASHING ENTREPRENEURSHIP: MAKING BUSINESS WORK FOR THE POOR 35 (2004); Gulifieya Abuduxike & Syed Mohamed Aljunid, Development of Health Biotechnology in Developing Countries: Can Private-Sector Players Be the Prime Movers?, 30 BIOTECHNOLOGY ADVANCES 1589, 1590 (2012).
that disproportionately affect the poor.\(^{61}\) As a result, the number of new drugs, vaccines, and diagnostics and other medical devices developed specifically for African markets has been small, and African biotechnology markets and the institutional and regulatory systems to support them have remained underdeveloped.\(^{62}\)

**B. Limitations of Traditional Collaboration Models as Mechanisms for Capacity Building**

Building on lessons learned from a review of traditional collaboration models, a summary of which is included in the Appendix, and direct past experience with north-south collaborations, this Article suggests that there are three key, interconnected limitations of traditional north-south collaborations as mechanisms for building African health innovation capacity. These limitations, as further discussed below, are: (1) the neglect of local decision making and capacity, (2) the failure to connect research efforts with downstream processes for development and commercialization, and (3) the absence of mechanisms to ensure long-term financial sustainability.\(^{63}\)

1. **Neglect of Local Decision Making and Capacity**

The northern mode of biopharmaceutical discovery and development is capital and technology intensive, highly regulated, and reliant on proprietary intellectual property strategies and data protections. It is supported by well-developed capital markets and driven by market incentives. Underlying the research, discovery, and commercialization process is a network of relationships between stakeholders in the healthcare industry, including scientists, government agencies, research universities and institutes, pharmaceutical and biotechnology companies, medical device suppliers, healthcare providers, investors, regulators, and patient groups. This network

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\(^{61}\) See, e.g., Hassan Masum et al., *Venture Funding for Science-Based African Health Innovation*, in *BMC Int’l Health and Hum. RTS. Supp.*, supra note 15, at S12 (discussing the “health innovation financing gap in Africa” and limited venture capital investment in African life sciences opportunities, and noting lack of infrastructure and experienced human resources as one of the barriers).


\(^{63}\) See, e.g., Laura Diaz Anadon et al., *Making Technological Innovation Work for Sustainable Development*, 113 Proc. Nat’l Acad. Sci. 9682, 9683 (2015) (providing insights into how to better harness technological innovation for sustainable development: need to align current institutions, i.e. rules, norms, and incentives, toward the goal of sustainable development, need for local decision making, and need to consider all stages and scales of the innovation process).
operates to move promising health technologies into the marketplace. As described above, traditional collaboration models are largely designed around this northern mode of health product innovation. Even when much of the R&D work for neglected diseases takes place in the north, however, this approach still works poorly as a means of satisfying the needs and constraints of markets in developing economies. The products that result are often unaffordable and not designed with local conditions in mind, and local development and commercialization strategies flounder when components of the commercialization network are either missing or inadequate to support continued product development. This northern approach to pharmaceutical innovation is likely to fail completely when the bulk of the research and development work is shifted to developing economies, which face very different regulatory frameworks, R&D infrastructure, and resource constraints.

The continued reliance on traditional northern health product discovery and development approaches, despite their limitations in contexts of scarce resources and neglected diseases, is not surprising given the concentration of both funding and decision making in Western Europe and the United States and the tendency to pursue innovation strategies and fund entities and diseases that are familiar. While previous north-south collaborations to address diseases endemic in Africa have varied in structure and goals over time, the lack of control exerted by southern collaborators has remained largely consistent, with only recent and gradual shifts toward a more balanced partnership model and greater attention given to the divergent contexts of innovation. The comparative lack of financial participation by African

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64 See Al-Bader, supra note 52; Moran, supra note 51.
66 See, e.g., Linda Nordling, Africa Aims for Research Autonomy, 520 NATURE 142 (2015) (stating that the majority of research done in Africa is still predominately financed and directed by global funders from Western Europe and the United States).
67 See, e.g., Binka, supra note 19 (examining the shift of north-south collaborations toward partnership models); see also Linda Nordling, Africa’s Fight for Equality, 521 NATURE 24, 25 (2015) (suggesting that roots of unequal partnerships between north and south lie in how modern research in Africa began and examining some recent measures to address inequality, such as the COHRED Fairness Index, which permits institutions, funders, or other groups involved in research to receive certification if they engage in good partnerships).
governments and funders and the limits of existing African infrastructure and pharmaceutical expertise have contributed to this partnership imbalance.68

Instead of seeking to transplant R&D strategies that have worked well in developed markets for health technologies, north-south collaborations supporting African capacity-building initiatives must find ways to optimize the existing African infrastructure and work around—or address—its limitations. The focus must be on medical therapies aimed at diseases endemic to African countries, many of which are associated with large disease burdens but low economic returns. The strategies must incorporate alternative innovation models, including what have been called “frugal innovation”69 and “affordable innovation” strategies,70 as well as efforts focused on adapting overseas strategies and products to domestic market needs. The strategies must also be designed with local institutional, legal, cultural, and political contexts and relationships in mind. While recognizing the limitations, it is equally important to harness the unique opportunities that the African continent offers, not just in scientific capacity, but also through natural remedies, indigenous knowledge, and biodiversity.71 Perhaps most importantly, the strategies must involve decision making by African stakeholders, building on earlier “blueprint[s] on how to foster collective self-reliance and sustainable development of the continent”72 to further the African Union’s vision of “an Africa driven and managed by its own citizens and representing a dynamic force in the international arena.”73 While one of the key sticking points in expanding local decision making continues to be the lack of investment in health innovation capacity by the governments in many African countries, alternative funding vehicles are being developed to support African-driven health innovation strategies.74 In addition, models of balanced partnerships that emphasize the decision-making roles of local partners are gaining traction.75

68 See, e.g., Nordling, supra note 67.
70 See, e.g., Frew et al., supra note 30, at 1766–67 (emphasizing the importance of affordable innovation models built on local firm capabilities).
71 See, e.g., Solomon Nwaka, Harness Local Knowledge, 484 NATURE OUTLOOK 523 (2012) (noting that “[about 80% of the populations of Africa, Asia and Latin America meet their primary healthcare needs” through reliance on local translational medicines and pointing out the need for coordinated mechanisms and investment to support translation of local knowledge into products).
72 AFRICAN UNION COMM’N, supra note 14, at 12.
73 Id. at 11.
74 See, e.g., Nordling, supra note 66, at 142 (discussing the formation of the Alliance for Accelerating Excellence in Science in Africa (AESA), a regional hub to award grants and develop African research capacity).
2. Failure to Conduct R&D Activities with a Product Focus in Mind

Many existing north-south initiatives have focused only on the training or research aspects of health innovation.\textsuperscript{76} They have not adequately integrated early-stage research efforts with downstream opportunities for product development, nor have they addressed the lack of financial and institutional support available to assist with moving early technologies into the marketplace. Not surprisingly, therefore, researchers in many African research institutions have not been encouraged to think entrepreneurially about how products that could stem from their research efforts can support local health needs. There is thus a need to complement upstream scientific training and expertise with the more applied, product-focused skills, knowledge, and incentives to pursue downstream development activities.\textsuperscript{77}

Even where there is interest in moving promising discoveries into product development, the long, risky, and expensive development and distribution processes are fraught with challenges.\textsuperscript{78} Many African countries lack established institutional, regulatory, and manufacturing capabilities to develop and distribute health products and ensure they pass adequate quality and safety standards. Intellectual property protection and data exclusivities, which play a major role in the U.S. and European models of pharmaceutical innovation, are less developed in many African countries.\textsuperscript{79} The lack of movement on national biosafety frameworks for agricultural biotechnology provides a stark example of the lag in governance capacity for biotechnology.\textsuperscript{80} Less than twenty of the countries included in the African Union have established any laws, regulations, guidelines or policies that relate to modern biotechnology.\textsuperscript{81} “The challenges facing the continent on biotechnology and biosafety include lack of fund[s]; loss of trained technical expertise; slow development of the biotechnology sector; inadequate Intellectual Property Rights infrastructure; government not

\textsuperscript{76} See, e.g., Salicrup, supra note 50.

\textsuperscript{77} See, e.g. Simiyu, supra note 3, at 1483 (summarizing findings from interviews with African researchers about why African health technologies sometimes stagnate instead of reaching the market).

\textsuperscript{78} See, e.g., id.


\textsuperscript{80} See, e.g., Diran Makinde et al., Status of Biotechnology in Africa: Challenges and Opportunities, ASIAN BIOTECHNOLOGY & DEV. REV., July 2009, at 1, 7–8.

\textsuperscript{81} See, e.g., id. at 1 (discussing lag in the development of a governance capacity for biotechnology).
taking a more active political role in promoting the technology and the issue of public acceptance brought about by activism.\textsuperscript{82} Financial markets are similarly underdeveloped, with either limited or non-existent sources of risk capital such as those provided by venture capitalists and angel investors.\textsuperscript{83} Thus, while there are promising discoveries coming out of African labs, these discoveries too often remain undeveloped. Suitable intellectual property management, licensing and technology transfer strategies that are based on the realities and opportunities of local and regional markets, along with financing strategies designed to support these efforts, should be an integral part of innovation capacity building in Africa.\textsuperscript{84}

3. Absence of Mechanisms to Ensure Long-Term Financial Sustainability

Finding sustainable, long-term funding remains one of the biggest challenges in moving promising African health products through development and into the marketplace.\textsuperscript{85} Financial support for many of the north-south initiatives directed at neglected diseases are short-term in nature, often with only a few years of guaranteed funding at a time. This limitation is the result of heavy reliance on grant funding from public and philanthropic sources that are limited in both amount and duration. The long time-horizons required to bring a drug or even a medical device to the market do not fit well with the budgeting and reporting needs of these public and philanthropic funders. There is also a disconnect between the types of projects that public and philanthropic funders typically support and the business needs of early stage companies seeking to develop products. While government and philanthropic sources of funding have helped to boost the pipeline for several neglected diseases, they are often limited to research or seed funding for early stage ideas, with a dearth of such funding for commercialization efforts.\textsuperscript{86}

There are both formal and informal barriers that limit the use of public funds to support the profit-making efforts of private companies, making it difficult to fund the small- and medium-sized companies interested in taking products to the market. In some of the developed economies, concerted efforts have been made by government funders to adapt public funding programs to

\textsuperscript{82} Id.
\textsuperscript{83} See, e.g., Masum et al., supra note 61.
\textsuperscript{84} See, e.g., Frew et al., supra note 30, at 1770 (discussing the need for legal and business capacity building, and suggesting the idea of a global health accelerator to provide intellectual property, business, and financial support to grow local networks).
\textsuperscript{85} See, e.g., Masum et al., supra note 61.
\textsuperscript{86} See, e.g., Declan Butler, Neglected Disease Fund Touted, 465 NATURE 277 (2010).
the needs of emerging businesses. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs in the United States and the Innovative Medicines Initiative in the European Union have been designed with this goal in mind. Such efforts are largely absent in developing economies, however.

Overall, public and philanthropic funding on their own—whether through grants, tax credits, loans, and other push mechanisms, prizes and advance purchase commitments, or even public programs to support the research and development efforts of private companies—have not been adequate to support and sustain health product development in African developing economies. Moreover, the public and philanthropic funding come largely from foreign countries, primarily countries in Western Europe and North America, with very limited funding supplied by African governments. While there is great variation in government spending across countries within Africa, the average amount of national budgets devoted to health in 2013 was 9.8%, below the 15% target adopted by the African Union, and as low as 2% in some countries. The African Union target of 1% of health expenditures directed to research, adopted in 2006, has yet to be achieved by most of its members.

Government investment in infrastructure, support for capacity building, development of a cohesive policy framework, and strengthening of national regulatory authorities are all required to encourage investment in local pharmaceutical production.

Private funding of African biotechnologies has also been woefully inadequate in most African countries. The lack of significant domestic funding of biopharmaceutical R&D and infrastructure by most African countries makes

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87 The SBIR and STTR programs are U.S. federal government programs designed to support R&D efforts of promising small businesses in the form of grant- or contract-based funding. See About SBIR, SBIR STTR AM’S SEED FUND, https://www.sbir.gov/about/about-sbir-sbir-program (last visited Nov. 28, 2017); About STTR, SBIR STTR AM’S SEED FUND, https://www.sbir.gov/about/about-sttr-sttr-program (last visited Nov. 28, 2017).


91 See, e.g., Jicui Dong & Zafar Mirza, Supporting the Production of Pharmaceuticals in Africa, 94 BULL. WORLD HEALTH ORG. 71 (2016) (describing the role of Ethiopia as a model country for local investment in pharmaceuticals).
attracting private-sector capital difficult.\textsuperscript{92} In many African countries, capital markets are not mature, venture capital is largely absent, and limits in purchasing power create risks that R&D costs may not be covered by returns on investment.\textsuperscript{93} While in developed economies the private sector is the largest biotechnology investor, in developing economies most of the investment in health research is sponsored by the government or supported by philanthropic organizations and is carried out in public and nonprofit institutions.\textsuperscript{94} Where private-sector investors are present, they often concentrate their investments in sectors where projects have shorter time horizons and are less risky and costly.

II. REGIONAL INNOVATION NETWORKS AS ALTERNATIVE PARADIGM

The Global Strategy encourages a departure from the traditional paradigm of north-south collaboration discussed above, with its focus on donor-led R&D initiatives to satisfy the needs of developing countries. It promotes greater international engagement in the design of strategies for building R&D capacity in developing countries in order to allow these countries to respond to their own health needs. This Part examines the growing shift in focus of global health development strategies toward regional capacity building and networks, and explores corresponding changes in the collaboration landscape.

A. Shifting the Focus of Collaborations to African Health Capacity Building

While the challenges that many African countries face are daunting, its young, growing population and uneven—but in some areas rapid—economic growth, along with the wide and fast uptake of new technologies such as mobile phone technologies, and an expanding middle class, are creating a new view of Africa as a source of economic growth and opportunity.\textsuperscript{95} Change in the collaboration landscape is occurring as international and domestic interest in African biotechnology markets and business opportunities grow.\textsuperscript{96}

The number of entrepreneurial biotechnology collaborations among firms in developed economies and firms in some of the more advanced African


\textsuperscript{93} See, e.g., Masum et al., supra note 61.

\textsuperscript{94} See, e.g., Morel et al., supra note 18, at 401–02.


\textsuperscript{96} See, e.g., Melon et al., supra note 23, at 232; Halla Thorsteinsdottir et al., Health Biotechnology Innovation on a Global Stage, 9 NATURE REVS. MICROBIOLOGY 137, 138 (2011).
markets has increased,\(^97\) as have south-south collaborations at both the firm and government level.\(^98\) Many of the private-sector partnerships have emerged as the result of entrepreneurial efforts by firms in more developed economies in the south to find new business opportunities. Africa is now home to seven of the ten fastest growing economies, a rapidly growing population, an expanding middle class, and largely positive trends in private-sector growth.\(^99\) While Africa’s pharmaceutical industry is one of the fastest growing, the industry faces a shortage of specialists and a need for standardized regulation and strengthened regulatory authorities.\(^100\) Further, most of the R&D and clinical research continues to be performed by international companies, albeit sometimes through local subsidiaries.\(^101\) Although north-south and south-south collaborations among private-sector participants are growing, local investments in infrastructure and human resources are needed to ensure that the collaborative activities build local pharmaceutical capabilities.

At the state level, countries such as India and China have partnered with the governments in some African countries to adopt frameworks for greater regional cooperation that include investment in African science and technology capacity. Recent examples include the China–Africa Science and Technology Partnership Program (CASTEP) and the Africa–India Framework for Cooperation.\(^102\) These government-led efforts focus primarily on either high-level principles for cross-border cooperation or specific programs promoting African research capacity and cross-border research collaborations. They include few, if any, specific measures to build local African health-sector development and commercialization capabilities.

The African Union has also engaged in a number of initiatives aimed at strengthening regional health innovation capacity through collaborative efforts. One such effort to build African regional science and technology capacity in the biosciences is the establishment of Africa’s Science and Technology Consolidated Plan of Action (CPA) in 2006 through the auspices of

\(^97\) See, e.g., Melon et al., supra note 23.
\(^98\) See, e.g., Thorsteinsdóttir, supra note 96, at 409.
\(^101\) See, e.g., id.
\(^102\) See, e.g., Thorsteinsdóttir et al., supra note 96, at 139.
NEPAD, an operational support arm of the African Union. The CPA utilizes a regional network strategy for promoting research and development in the biosciences. Other regional strategies focusing on the development and support of African biopharmaceutical capacity include the Pharmaceutical Manufacturing Plan for Africa, adopted by African Union member states; the African Science, Technology and Innovation Policy Initiative, supported by the United Nations Educational, Scientific and Cultural Organization (UNESCO) along with African Union member states; the ResilientAfrica Network, funded by USAID; and the Africa Technology Policy Studies Network, supported by some of the African Union member states.

As opportunities for collaboration increase in both public and private sectors, and as regional innovation network strategies proliferate, it becomes increasingly important to identify success factors for such strategies, where success is defined in terms of the growth in local health innovation capacity. This requires a more careful understanding of, and research into, what innovation network strategies entail and how they can be used to support the building of African health capacity.

B. The Emerging Strategy of Regional Health Innovation Networks

The theory of innovation networks has its foundations in social network analysis, the study of how people, organizations, or other entities interact and their relationships with each other. In this context, an African “health innovation network” can be understood as a web of connections between and among stakeholders with shared interests in the development of African products and services to meet the health needs of African countries.

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103 See, e.g., Makinde et al., supra note 80, at 2.
Networks create, support, and connect collaborations in a systematic way in the pursuit of shared or complementary health innovation objectives. Strong networks allow participants in the network to build social capital, where social capital can be understood as “the sum of the actual and potential resources embedded within, available through, and derived from the network of relationships possessed by an individual or social unit. Social capital thus comprises both the network and the assets that may be mobilized through that network.”109 The hallmark of the innovation network approach is the centrality of relationships and ties among stakeholders rather than the individual features of the stakeholders themselves.

Innovation, the creation of new, technologically feasible, commercially realizable products, processes and organizational structures, emerges from the ongoing interaction processes of innovative organizations such as universities, research institutes, firms . . . government agencies, venture capitalists and others. These organizations generate and exchange knowledge, financial capital, and other resources in networks of relationships that are embedded in institutional frameworks on the local, regional, national and international level.110

The emphasis in network-based innovation strategies is placed on mapping existing local capacities and fostering relationships to connect these areas of local capacity in ways that support discovery, development, and commercialization of new technologies and products. Where capacities are understood in terms of the ability to make and distribute useful health products, the study naturally encompasses all of the relationships needed to move a product through the development process and into distribution. This includes not only science and technology, but also the financial, business, legal, and regulatory aspects of the process, as well as some understanding of the competitive landscape and potential consumer base. It encompasses very different types of stakeholders, including universities, scientists, entrepreneurs, state and local regulators, public and philanthropic funders, private sector funding sources, healthcare providers, healthcare insurers, and consumers. Legal professionals must also be included, since scientists, entrepreneurs, investors, and end-users must be able to rely upon harmonized regulatory schemes and reliable enforcement of contracts, along with business professionals skilled in product development and market analysis. Of

necessity, networks also encompass and respond to the specific cultural, political, and economic contexts within which these stakeholders operate.

III. BUILDING AND SUPPORTING HEALTH INNOVATION NETWORKS THROUGH COLLABORATION: AN EXAMPLE

While a growing number of global health policymakers have acknowledged the importance of regional health capacity building and recognized the role of regional networks as strategies for capacity building, designing initiatives that are effective in building sustainable health innovation capacity has proven to be challenging. North-south collaborations can play a critical role in these efforts, but only if they are designed with local needs, opportunities, and constraints in mind. This Part draws from past experiences with collaboration efforts in African biotechnology, along with current collaboration strategies employed by ANDI, to generate guidelines for the design of collaborations that support regional innovation networks as a capacity building strategy.

A. ANDI: An Example in the Construction of Health Innovation Networks

It is the challenge of integrating early-stage opportunities into a robust and financially viable product development and commercialization process that continues to be the weak link in many of the most recent regional innovation strategies. ANDI was established in 2008 with the goal of responding to this challenge by developing an African regional innovation network focused specifically on the development and commercialization of African technologies. ANDI is an African led and owned organization formed with the goal of creating a sustainable, organized network for African health innovation by “linking expertise and capacities from across the continent to cost-effectively build common technology platforms and manage pharmaceutical projects.”111 ANDI seeks, through partnerships with other African initiatives and collaborators from the north and the south, to develop sustainable, pan-African innovation networks that move from early-stage research to product development and manufacture of health technologies—including diagnostics, drugs, vaccines, and medical devices—in disease areas that disproportionately impact African countries.112 It employs an innovation-network approach to capacity building that concentrates on identifying, building, and strengthening

111 Regional Network for Drugs and Diagnostics Innovation Exemplified by ANDI: Background Paper for Executive Board, supra note 4, at fig. 1.
112 See AFRICAN NETWORK FOR DRUGS AND DIAGNOSTICS INNOVATION, supra note 17, at 14–16.
relationships between different participants that can contribute to product development processes.  

ANDI’s divergence from traditional approaches to addressing neglected diseases results from the very different orientation of innovation network strategies and the anchoring of such strategies inside the African continent. In line with the innovation-network approach, ANDI’s early efforts involved mapping available African resources to develop health technologies and identifying gaps where additional resources are needed. ANDI has since moved into the design and support of networks that bring together those technologies and actors that are needed to create and implement sustainable business plans and to successfully commercialize health products within African markets. ANDI hopes to use some pilot examples of technologies moving through the network to demonstrate that African markets are ripe for health product innovation even with little financial support from African governments.

Reflecting the central role of relationships among people, organizations, and institutions in network theories of innovation, ANDI’s current strategic plan focuses specifically “on the brokerage of partnerships and fostering of collaborations” to build health-product focused networks. A key part of ANDI’s strategy rests on its ability to identify, select, and broker the kinds of south-south and north-south collaborations needed to facilitate the validation, scale-up, registration, and marketing of promising African health technologies. Partners must be chosen with care since the value of the network lies, in part, in the value of the relationships that are created among network participants—which can be understood as the social capital of the network. North-south collaborations will be most valuable as part of a network strategy if they can increase the social capital of the network, either by filling a gap in the network or by providing tools and resources to support necessary connections among existing participants in the network. Legal and business professionals will play a critical role in filling these gaps. Scientists, entrepreneurs, investors, and end-users must be able to rely on harmonized regulatory schemes and reliable enforcement of contracts, and product development must be informed by a knowledge of market opportunities and constraints and an ability to evaluate and implement successful business plans. ANDI’s strategy includes the design

113 See id.
114 See id.
115 Id. at 11.
116 See Nahapiet & Ghoshal, supra note 109, at 243.
of regional platforms that can provide affordable professional services as the local professional workforce develops.\(^\text{117}\)

**B. Three Guidelines for North-South Collaborations in Innovation Networks**

The three limitations of traditional north-south collaborations discussed above become even more important in this kind of regional network-based strategy. Neglect of local capacity and decision making will not lead to effective capacity building, a failure to connect research with development and commercialization runs contrary to the idea of building an innovation network, and financial sustainability will be essential for the network to flourish and attract new participants.\(^\text{118}\) ANDI employs three guidelines in its design of collaborations to address these limitations and respond to the needs of an innovation network strategy: (1) focus on locally driven product development processes, (2) employ a product-focused approach to health innovation that connects research with development and commercialization, and (3) build strategies for financial sustainability into the design of both the collaboration and the network.\(^\text{119}\) These three guidelines are interconnected, and a successful program design needs to reflect and plan for all three.

1. **Focus on Locally Driven and Designed Capacity Building to Advance Local Technologies**

The starting point for an ANDI collaboration is a local need or opportunity that an African entity or individual can pursue primarily within an African market. In some cases, this will be a new or underdeveloped market, and the participants in the collaboration will be navigating its development. ANDI has selected over forty public and private institutions from across the African continent with expertise and capacity in a variety of different health R&D areas to function as Centers of Excellence, providing focal points where promising new technologies are likely to emerge, with the expectation of growing this number over time.\(^\text{120}\) These Centers of Excellence serve as sources of promising new African technologies.

\(^\text{117}\) See AFRICAN NETWORK FOR DRUGS AND DIAGNOSTICS INNOVATION, supra note 17, at 20.


\(^\text{119}\) See, e.g., id.

\(^\text{120}\) See, e.g., AFRICAN NETWORK FOR DRUGS AND DIAGNOSTICS INNOVATION, supra note 17, at 15.
ANDI begins with a rigorous process for selecting those technologies likely to succeed as products and then tackles the problem of building pathways to move these technologies through the long, risky, and expensive development, commercialization, and distribution processes. ANDI’s focus is on building the networks that will encompass and connect the various participants needed to move health technologies through all the stages of product development and commercialization. ANDI’s collaborations are designed to be opportunistic, supporting promising technologies as they emerge from the Centers of Excellence and seeking to train the local innovators in the areas that they need to progress their technologies down a product development and commercialization pathway. As these projects advance, participants in the process form relationships with each other and gain an understanding of the process and their role in that process, strengthening the network. Since the institutional and technological contexts may shift over time or across regions, and the relationships between participants and organizations have value as part of the network, collaborations that continue over time with the ability to review and learn from past performance and adapt to new circumstances will be most effective, reinforcing the need to invest in social capital.

2. Employ a Product-Focused Approach to Health Innovations

ANDI takes an intentional approach to the design of the network that is based on existing resources and product development goals. The network must be capable of moving promising health technologies through commercialization and into the marketplace at prices and in forms that will meet local health needs. A product’s successful move from lab to market requires careful selection of early-stage technologies focusing not just on scientific merit, but also on the requirements of these technologies at later stages of development and the likelihood of finding resources for their further development. Moving technologies beyond the early stages of development requires a viable business plan, attention to the intellectual property and regulatory strategies needed to turn the technology into a financially sustainable product, and financial and business strategies for getting products to market. In nascent domestic markets these strategies will often serve as prototypes for future product development efforts, evolving over time as local market conditions change.

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121 See, e.g., id.
122 See, e.g., id. at 28–31.
ANDI’s network-based approach includes the development of regional platforms to support local health technologies at critical junctures in the product development process. These regional platforms will provide African scientists with the tools and knowledge they need to move promising technologies into the product development process. They will provide African entrepreneurs with the skills and support needed to develop and implement business plans. This platform-based approach provides a way of economizing on the legal and business expertise required to support product development while domestic capacity grows, as well as a training ground for new legal and business professionals. North-south collaborations such as the partnership between ANDI and Emory University, described below, are being used to help in the design and implementation of these platforms.

3. Incorporate New Financial Mechanisms for Long-Run Sustainability

ANDI is currently exploring ways of combining public, philanthropic, and private funds to support a portfolio of health projects with mechanisms for providing reasonable returns to stakeholders or investors, while at the same time protecting the public interest in ensuring accessible and affordable health products. While there are significant differences in the financial markets facing African product developers, organizational experiments with alternative funding models for the “valley of death” confronting many new biotechnologies being developed in the United States can nonetheless usefully inform African experiments with alternative funding models. One such organizational innovation in funding models for neglected diseases is underway at Emory. Emory has formed a special drug-development vehicle designed to confront the challenges of financing drugs that may not be associated with large economic markets through a product portfolio and hybrid financing strategy. This model is called the Drug Innovation Ventures at Emory, LLC (DRIVE).
C. The ANDI–Emory Collaboration

ANDI’s collaboration with Emory provides an example of a program design that reflects all three guidelines. ANDI collaborated with Emory in 2015 with two main goals.\(^\text{127}\) The first goal is to equip African scientists and entrepreneurs with the multidisciplinary skill set needed to move African health technologies from early-stage ideas to product commercialization. The second goal is to design new strategies to support selected technologies through the valley of death—the costly and risky phases of later-stage product development—in African markets.

The collaboration has developed a two-phase program (the “Program”) to support these goals.\(^\text{128}\) Phase I currently (1) identifies talented African scientists with technological innovations; (2) provides the scientists with a focused, experiential learning curriculum in the legal, business, technical, and translational skills and knowledge needed to advance local health technologies through product development; and (3) for selected technologies, provides assistance in developing the business case for further investment and support. The Program is designed to be opportunistic. It responds to local promising technologies and seeks to train the local innovators in what they need to know to move their technologies down a product-development and commercialization path. The Program is also adaptive, absorbing lessons learned from each year to alter program design for the following year. Repeat relationships between the north and south partners are a critical part of this adaptive process.

Phase II of the Program will focus on the design of regional innovation platforms to provide the financial, legal, and entrepreneurial support and services needed to translate early-stage technologies into products. Finding ways of achieving financial sustainability both for technologies and for the regional networks is a critical part of Phase II. As the networks mature, they will hopefully provide product-development support not only to health technologies coming out of ANDI’s Centers of Excellence, but also to technologies from other interested African institutions. Mature innovation platforms will be equipped to provide advice and support on business and legal


aspects of technology progressions, including, but not limited to, the management of intellectual property, technology transfer, licensing, feasibility and market analysis, business plan development, and marketing. Separate hybrid public-private funding mechanisms will be used to support the development of the technologies, as further discussed below.

The Program adheres to the three guidelines discussed in this Article. First, the selection of technologies and scientific collaborators is done locally, coordinated by ANDI. Second, all activities are product focused, with an emphasis on building and supporting product-development pipelines. Third, the scientists of selected technologies work with advisors to develop a sustainable financial model.

In working on innovative financial models, ANDI and Emory are exploring ways of adapting a unique approach to the financing of R&D for neglected diseases developed at Emory to support African R&D projects. Using proceeds from a royalty monetization of Emtriva, a leading HIV therapy, Emory has been experimenting with ways of overcoming what is often referred to in the biopharmaceutical industry as the valley of death. It has developed a model designed to address two key challenges in the translation of promising drug candidates into products: (1) coordinating upstream discovery activities with downstream development and commercialization; and (2) finding sustainable funding for the drug development process, particularly for drugs that treat neglected diseases.

The model involves creating platforms of expertise at particular levels of the drug discovery and development process that can support a portfolio of drug candidates as they move through lead optimization and pre-clinical testing and into proof of concept clinical trials. This platform approach allows for cost and risk sharing both in the drug-development process and for the funders of this process. The first part of the model was implemented in 2008, when Emory established the Emory Institute for Drug Development (EIDD), an institute that has an applied drug development agenda and drug development capabilities. EIDD has equipment and laboratory facilities necessary to transition drug-discovery efforts into early drug development projects. The second part of the model was implemented in 2012, when Emory


130 For a basic overview of the U.S. drug discovery and development process, see, for example, The Drug Development Process, U.S. FOOD & DRUG ADMIN. (June 24, 2015), https://www.fda.gov/ForPatients/Approvals/Drugs/default.htm.
created a new kind of drug-development company, a not-for-profit company wholly owned by Emory called DRIVE. DRIVE is EIDD’s industrial partner, providing the financial, business, project management, and regulatory expertise to move drug candidates through lead optimization and pre-clinical testing into proof of concept clinical trials. Successful drug candidates are out-licensed to pharmaceutical companies, spun out into venture-backed companies, or partnered with philanthropic or government initiatives. DRIVE focuses on an area of expertise rather than a specific drug, seeking to exploit Emory’s human capital and research capabilities in the area of infectious diseases to identify, develop, and commercialize drugs. It focuses on the development of small-molecule drugs that address viruses that have significant global health impact, including RSV (respiratory syncytial virus), HCV (the hepatitis C virus), influenza viruses, Zika, and dengue fever virus. DRIVE provides a platform that offers drug development and business expertise and sustainable financing to support the translation of promising discoveries into drugs that will treat viral diseases of global importance.

The basic idea behind this approach is to create an organizational structure that can combine both public and private financing to support a portfolio of drug-development projects that include both commercially viable drugs and drugs for neglected diseases endemic in financially constrained economies. It takes a portfolio approach to drug development in which both costs and revenues are pooled across alternative drug projects. This approach economizes on costs by sharing facilities and pooling resources. It also provides a way of attracting financing by allowing for a mix of public and private investments in a portfolio of drug projects, some of which may generate substantial licensing revenues and some of which may need financial support. DRIVE seeks to attract and combine a mix of funding, including donor, government, venture, and industry funding to address unmet needs for treatments for viral diseases. A key aspect of this organizational structure is the modularity of the research, early-stage development, and later-stage financing and project management functions within a single not-for-profit university system. Different incentive structures are used within each entity or unit, but they all share a common organizational home and not-for-profit status. This preserves room for the public-interest aspects of project choice and broadens the types of funders that may be interested in supporting drug-development processes.

Innovative financing approaches such as this offer ideas for structuring public and private sector participation in supporting promising technologies as they emerge from ANDI’s Centers of Excellence. The idea of using platform
approaches to allow diversification of risk and to support combinations of public and private support may provide a way of securing the financial support needed to reach financial self-sustainability.

CONCLUSION

While promising technologies designed to meet local and regional health needs are emerging in increasing numbers from public and private research labs and workshops in many African economies, these technologies are unlikely to progress without the type of integrated capacity-building work that is explored in this Article. The health-innovation network approach that we have described provides a concrete strategy for implementing the regional innovation networks that are at the heart of Agenda 2030 for Sustainable Development, the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, as well as the African Union’s Agenda 2063. While north-south collaborations form an important part of this network strategy, they must be responsive to the unique needs and opportunities of an African regional innovation network. Drawing from ANDI’s experience in designing an African health innovation network, as well as lessons learned from past and current collaboration efforts, we have provided three guidelines for the design of effective north-south collaborations to support African health innovation networks. Network strategies rely on scale and, if successful, this collaboration model can be adopted by other partners seeking to work together to build African health innovation capacity.
**APPENDIX**

Table: Categorizing Traditional North-South Collaboration Strategies

<table>
<thead>
<tr>
<th>Type of Collaboration</th>
<th>Examples</th>
<th>Description</th>
<th>Key Strengths and Limitations</th>
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<tr>
<td>Product Development Partnerships</td>
<td>MMV, DNDi, TB Alliance, International AIDS Vaccine Initiative, Global Antibiotic Research and Development (GARD), PATH, FIND.¹³¹</td>
<td>PDPs are typically nonprofit organizations that use funds from public and philanthropic entities and form partnerships with public and private institutions to implement projects. They focus on one or a specified group of diseases, with R&amp;D based primarily in the North. MMV and DNDi focus on drugs for malaria and neglected diseases respectively, FIND focuses on diagnostic tests for neglected diseases, and PATH spans work on vaccines, drugs, diagnostics, devices, and system and service innovations.</td>
<td>Strengths: (1) Increases R&amp;D of diagnostics and drugs that target neglected diseases; (2) has resulted in a viable portfolio of products; and (3) has helped to develop and put a number of products (largely based on reformulation of existing products) on the market. Limitations: (1) Heavy reliance on public funding and philanthropy; (2) limited mechanisms for achieving long term</td>
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¹³¹ For a review of PDPs see, for example, Muñoz et al., *supra* note 23, at 324.
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| Pharmaceutical Philanthropy/ Drug Donation Programs | Drug Donation Programs e.g., Merck Mectizan Drug Donation Program, Pfizer’s Diflucan Partnership Program, Novartis distribution of Imatinib to eighty- | Philanthropic product donations from pharmaceutical companies, often provided to non-governmental organizations for distribution. | Strengths: (1) Provides life-saving treatments; and (2) bridges immediate needs until other options |

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<table>
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<tr>
<th>Funding Mechanisms:</th>
<th>Global Fund, GAVI, UNITAID.</th>
<th>(a) Financial mechanisms to procure and supply needed drugs for developing economies.</th>
<th>Strengths: (1) Provides funds for life saving treatments; (2) bridges immediate needs until other options can be found; and (3) catalyzes</th>
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</thead>
<tbody>
<tr>
<td>(a) Purchasing Drugs and Vaccines</td>
<td>Grants and Prizes: Bill &amp; Melinda Gates Foundation (BMGAF), Global Grand Challenges initiatives of BMGF, USAID, DFID, Canada.</td>
<td>(b) Financial mechanisms to support product R&amp;D and/or technology development.</td>
<td></td>
</tr>
<tr>
<td>(b) Grants and Prizes</td>
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Limitations: (1) Depends on availability of approved treatment; (2) does not always reflect domestic health priorities and needs; (3) lacks mechanisms to ensure sustainability; (4) lack of sustained quality control systems in Africa; and (5) may negatively impact local production.133

See, e.g., Bero et al., supra note 45.
| Research Institutes, Research Platforms, and Programs for Research Coordination | Research Institutes: Pharmaceutical: Novartis Institute for Neglected Disease, GlaxoSmithKline Tres Cantos Research Institute. R&D initiatives within universities and national R&D centers. | Research Institutes: R&D institutes focused on early stage product discovery for neglected diseases, either as part of a university, a nonprofit, or as part of a pharmaceutical company. | Strengths: (1) Helping to generate a critical mass of new product leads; (2) promoting knowledge sharing, including pooling patents; and Limitations: (1) Limited number of diseases as targets; (2) does not address local innovation capacity; (3) does not address sustainable supply chain issues in developing countries; (4) limited financial capacity; and (5) sustainable financing for the critical next steps of going to market with products or access not addressed. |

| Technology transfer and training programs | USAID HESN initiatives, Wellcome Trust H3Africa initiative focusing on genomics, DELTAS program now run through African Academy of Sciences. | Technology and knowledge transfer model involving educational programs and technical assistance flowing from north to south. Includes a number of basic research, education and institutional capacity-building initiatives. | Strengths: (1) Supporting education and institutional collaboration; and (2) supporting basic research and knowledge generation. Limitations: (1) No product focused initiatives and (3) providing education and capacity building through university education or targeted capacity building. Limitation: (1) Largely located outside of Africa with limited impact on local capacity building; and (2) focus on early stage research and discovery with no product development. |
do not address translation of technologies from lab to clinics to market; (2) export of northern models and questions to the south; and (3) lack of mechanisms for long term financing and sustainability.