Investing in Health: The Key to Economic Development in Africa Case Studies in Public-Private Partnership

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Global Health Policy Center Health and Global Policy Institute



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Table of Contents

INTRODU	JCTION	3
1.DSM-G	GAIN PARTNERSHIP: DAIRY FORTIFICATION IN KENYA	4
1-1.	DSM	4
1-2.	GLOBAL ALLIANCE FOR IMPROVED NUTRITION (GAIN)	4
1-3.	THE PARTNERSHIP	6
1-3	-1. Framework	6
1-3	-2. Players	6
1-3	-3. Process	7
1-4.	LESSONS AND CHALLENGES	10
2.IAVI-D	NAVEC PARTNERSHIP FOR AIDS VACCINE DEVELOPMENT	11
2-1.	THE INTERNATIONAL AIDS VACCINE INITIATIVE (IAVI)	11
2-1	-2. R&D partnerships leveraging internal and external capabilities	12
2-1	-3. Network of regional partnerships	13
2-1	-4. Regional and global advocacy and outreach	13
2-2.	DNAVEC	13
2-2	-1. Origins	13
2-2	-2. Sendai virus vector	14
2-2	-3. Application to AIDS vaccine	14
2-3.	THE PARTNERSHIP	15
2-3-1. Framework		15
2-3	-2. Process	16
2-4.	LESSONS AND CHALLENGES	16
CONCLU	SION	17
RFFFRFN	ICFS	19

Investing in Health: The Key to Economic Development in Africa¹

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Introduction

Africa is developing rapidly in many ways, with the IMF projecting annual GDP growth in Sub-Saharan nations to be above 5 per cent in 2013-14. In the expanding economy, business is booming and the middle-class population is growing. Societies are changing and social issues such as health and education have started to be addressed. Despite the economic growth and social change, however, economic disparities are still pronounced in many African countries, preventing the basic needs of people with lower economic status from being fulfilled.

Against the backdrop of a developing business environment in many African nations, public-private partnerships (PPPs) have drawn much attention as an effective and efficient method of delivering goods and services to people in need, which has traditionally been the responsibility of the public sector alone. There is extensive evidence that PPPs have brought about favorable change on many social issues, including development and global health. However, the art of partnering has yet to be perfected, and differences between sectors in working culture and objectives and varying expectations of partnerships often complicate PPPs and hamper their performance.

This paper presents case studies of two PPPs that have been successful in their efforts to bring about change on health issues in African countries. While both are partnerships between public or nonprofit organizations and private enterprises, there are distinctive differences in their mechanisms: one is a market-oriented endeavor that bases the product on the corporate partner's core competencies, and the other is a product development partnership that centers on extensive research and development (R&D) activity based on cutting edge technologies possessed by both partners. These two cases - nutrition intervention by DSM and the Global Alliance for Improved Nutrition (GAIN), and AIDS vaccine development by DNAVEC and the International AIDS Vaccine Initiative (IAVI) - were originally presented by the partners themselves in a panel discussion at a partnership event of the Fifth Tokyo International Conference on

¹ This paper is based on the panel discussion "Investing in Health: The Key to Economic Development in Africa", a partnership event of TICAD V (Tokyo, Japan), co-organized by HGPI, Friends of Global Fund Japan, and JCIE on May 31, 2013. HGPI has obtained permission from DSM, GAIN, IAVI, and DNAVEC for the use of presentation figures and diagrams in this paper.

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African Development (TICAD V), "Investing in Health: The Key to Economic Development in Africa", held in Tokyo, Japan, in 2013. The aim of this paper is to record and discuss the valuable insights offered by the practitioners of these PPPs, and to learn from them for future partnerships of this kind.

1. DSM-GAIN partnership: Dairy Fortification in Kenya

One third of the world's population, the majority in developing countries, is estimated to suffer from "hidden hunger." Unlike the hunger that comes from lack of food, hidden hunger is caused by a poor diet chronically lacking in vitamins and minerals. It often presents no visible warning signs, yet its consequences can be severe, leading to mental impairment, poor health and productivity, and even death. Women and children from lower income groups in developing countries are among the most frequently affected.

This section presents a review of a PPP between an international foundation, GAIN, and a private company, DSM, that tries to address the issue of hidden hunger in Kenya by developing and promoting nutritionally fortified dairy product. Among the various forms a PPP can take, this particular partnership represents a type that has a clear aim for the commercial success of a product built on a core competency of the private company involved while also addressing a public health issue.

1-1. DSM

DSM is a global, science-based company active in the fields of health, nutrition, and materials. One of its core businesses is food additives, including nutritional supplements for use in the food, pharmaceutical care, and animal feed industries. The company has been active in collaborating with various government and non-governmental organizations to provide its knowledge and expertise in nutritional food additives. It is a founding member of Partners in Food Solutions, a non-profit organization assisting small food processors in African countries by sharing facilities and the expertise of its volunteer employees.

1-2. Global Alliance for Improved Nutrition (GAIN)

GAIN, the Global Alliance for Improved Nutrition, is a foundation created at a Special Session of the UN General Assembly on Children with the specific aim of supporting public-private partnerships in increasing access to missing dietary nutrients. Itself an alliance of governments, international organizations, the private sector, and civil society, it funds and advises projects that are implemented in partnership with government, business, and civil society organizations. With a worldwide presence, its projects now involve more than 600 companies and civil society organizations in 30 countries,

reaching an estimated 667 million people with nutritionally enhanced food products. The organization aims at reaching one billion people by 2015 with food that has a sustainable nutritional impact.

In GAIN's regular PPP project model, private companies take up product development and transportation, while governments and NGOs are responsible for demand creation and distribution. GAIN provides expertise in nutrition and food fortification, project management capacity, and mobilization of its network with local stakeholders. GAIN projects are characterized by their prioritization of sustainability, primarily through market-based approaches involving local manufacturers and retailers. The fact that GAIN is the only organization focusing on malnutrition with an emphasis on market-based solutions places it in an advantageous position. It has been able to accumulate knowledge and expertise, and is now recognized as a locus of information with regard to projects addressing malnutrition. **Figure 1** provides a summary of the areas where GAIN has an established strength.

Why Partners Work with GAIN



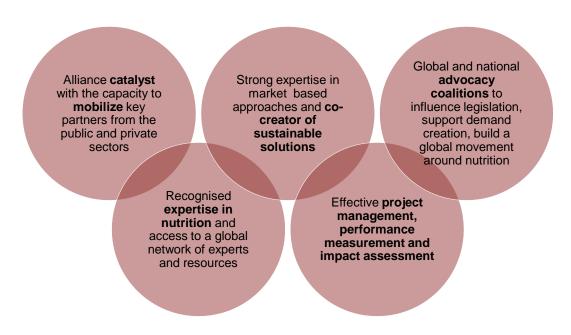


Figure 1.

1-3. The Partnership

1-3-1. Framework

DSM and GAIN initiated their collaboration through the Amsterdam Initiative against Malnutrition (AIM), a joint public-private partnership founded by the Ministry of Foreign Affairs of the Government of the Netherlands, GAIN, Unilever, DSM, AkzoNobel, Wageningen University, and the Interchurch Organization for Development Cooperation (ICCO). AIM represents a Dutch alliance of businesses, government, academic and non-governmental organizations initiated in 2010 during the GAIN Business Alliance Global Forum. Its goal is to eliminate malnutrition for 100 million people in Africa by 2015. Five Dutch companies whose businesses are at different points along the food value chain develop projects to address malnutrition in African countries by building on their own competencies in collaboration with local partners. GAIN and other non-profit partners provide know-how and links to local networks, Wageningen University provides monitoring and evaluation, while the Dutch government provides funding.

1-3-2. Players

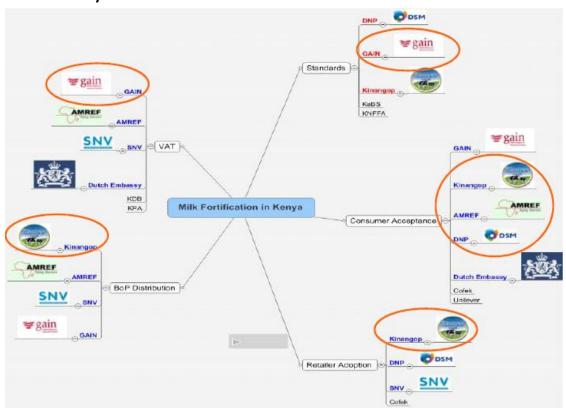


Figure 2

Dairy fortification is one of the projects conducted under the AIM framework. In addition to GAIN and DSM, the project involves multiple stakeholders in each dimension of the project: SNV, a Dutch NGO specializing in development, Kinangop, a Kenyan dairy producers' cooperative, AMREF, a Kenya-based international medical NGO, and the Dutch Embassy. **Figure 2** shows how each player relates to the project.

1-3-3. Process

Milk is one of the staple foods in Kenya, making dairy products an ideal choice to deliver vitamins and minerals lacking in the regular diet of low-income families. The goal of the project is twofold: introducing fortified dairy to low-income families in Kenya, thereby improving their nutritional status, and building a sustainable business model for local dairy companies that produce or sell fortified dairy.

As of summer 2013, the project had secured a grant from the Dutch government to cover costs until it attains profitability, and started product development and marketing. From a preliminary survey of targeted BOP customers, the partners found that, given how popular dairy products are in Kenya, the very perception that milk is already a highly nutritious food actually works against the introduction of fortified milk. This led to the choice of yogurt rather than milk as the commodity with which to start the pilot project. The market for yogurt is smaller than that for milk and therefore easier to control in terms of production and distribution, as well as measuring marketing impact. The strategy is to build brand recognition of their dairy product as being desirable and nutritious in a small market first, and then building on this when they expand production to fortified milk. This strategy prompted the choice of Kinangop, a local milk cooperative, as a partner to bring fortified dairy to the market. The cooperative represents only a relatively small fraction of the total market, but the basic goal of the pilot is for the cooperative to obtain both a first mover advantage and to set an example when it comes to safety, quality, and additional benefits. The plan is for other cooperatives to follow the new standards of dairy production once demand for dairy products increases. Figure 3 illustrates the planned market dynamics.

Market Dynamics of DSM

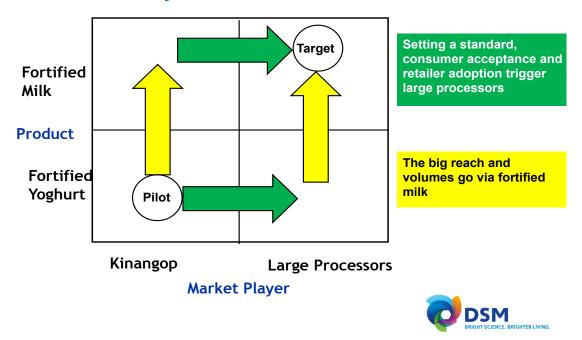


Figure 3

The partners anticipate their fortified dairy project having a ripple effect on surrounding countries in East Africa. Kenya already has a relatively well developed business environment and is recognized as a hub for business and ideas in the region, and success in Kenya is likely to lead neighboring countries to replicate the business model. In addition, the fact that Kenya has a large milk market (25% of the entire Sub-Saharan milk market) makes the country an ideal testing ground for the product.

Based on their experience in developing a product targeting the BOP market, GAIN and DSM identified key steps that need to be cleared over the course of developing and distributing a product of this nature, as illustrated in **Figure 4**. The first key step is to obtain government approval. Food in general, and fortified food in particular, is normally subject to government regulation and approval. Setting clear standards for production methods and nutritional values based on scientific data is vital for a smooth approval process, and DSM is creating a proposal for the standard composition of the micro nutrient premix while at the same time providing technical support to Kinangop. GAIN has supported the standard setting process through their experience and network with the Kenyan government and local dairy processing cooperatives.

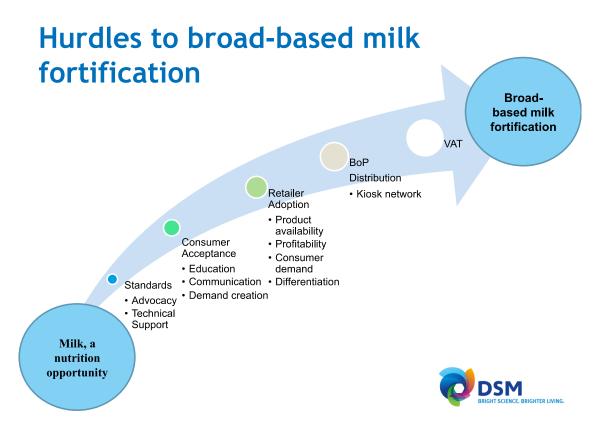


Figure 4

Education to create demand and secure consumer acceptance is a second key step. Since fortified dairy is a concept new to Kenyan consumers, effective dissemination of facts about micro-nutrients and the role of fortified dairy is critical to cultivate a market for the product. DSM and GAIN have collaborated with the African Medical and Research Foundation (AMREF), an NGO working on health education in African countries, to conduct educational activities including e-learning on nutritional facts. Establishing a distribution system to reach the BOP target is another vital step, and Kinangop will tap into its existing distribution network once the product is ready for retail sales.

In the case of fortified dairy, lobbying for a reduced rate of value-added tax (VAT) is also critical for successful introduction of the product to the market. Given the additional resources and processing steps necessary for production, fortified dairy is likely to be more costly to produce and thus more expensive to purchase than regular dairy products. Aggressive cost cutting and pricing efforts alone will not bring down the price to an adequate level, and since affordability is a critical element of success in BOP markets, the partners will lobby for reduction of the VAT rate for their fortified dairy on the basis of the health benefit it provides to consumers. GAIN's accumulated

experience with this type of issue and established relationship with the Kenyan authorities will be a great asset in these lobbying efforts.

1-4. Lessons and challenges

- ◆ As this review of the project shows, it is a large-scale, multi-dimensional endeavor involving multiple stakeholders. The participation and cooperation of stakeholders at each phase of the project is imperative to ensure successful implementation. Expertise and experience with the local culture and market, or with marketing for BOP in general, as accumulated in organizations such as GAIN, SNV, and AMREF, are essential for securing such participation.
- ◆ Distribution of roles among the partners was clear from the outset of the project: GAIN looks after overall strategy, DSM is in charge of product development, and local enterprises look after distribution and communication. The partners acknowledge that harnessing expertise from different sectors and clear division of roles have been two key points in facilitating smooth progress of their project.
- ◆ Another distinctive characteristic of the project is its emphasis on demand creation through education and communication. As the issue of hidden hunger is still unrecognized among target consumers, raising awareness is a core component of the project. Matching the product with local preferences by presenting it as an aspirational good through an effective marketing campaign is also a must.
- ◆ It should also be noted that nutritional interventions offer great potential for a market-based approach. According to GAIN, more than 90 percent of people in the world, including BOP populations, purchase food as opposed to receiving it free of charge. This means the food and nutrition sector is full of commercial opportunities. With the involvement of an organization such as GAIN that can pave the way for a balanced approach that benefits both the population in need as well as private companies, PPP seems to be a desirable option. Not only can such a partnership leverage the resources of private companies for the benefit of the population at risk, but also its economic viability can secure the sustainability of the intervention.
- Negotiation with regulators and other stakeholders on nutritional standards for the planned product appears to be the most challenging hurdle in the course of the project. In this respect, the project benefits both from the experience of GAIN in such processes and from the participation of local stakeholders such as Kinangop. Expertise in regulatory procedures among the partners is thus recommendable.
- ◆ Although this is a market-oriented project, funding from the bilateral donor for the initial phase of the project was crucial. It alleviated the short-term pressure on the corporate partner until their brand was established in the target market.

2. IAVI-DNAVEC partnership for AIDS vaccine development

Product Development Partnerships (PDPs) are public-private partnerships that focus on pharmaceutical product development for neglected diseases and epidemics prevalent in developing countries. The mission of such partnerships is product development, as opposed to focusing exclusively on delivery of existing technologies or services. A number of PDPs first emerged in the late 1990s as an innovative approach for research and development on global health issues, and thereafter played an important role by knitting together the expertise, knowledge, and financial resources of both private and public sectors for development of critically needed medical technologies. This section reviews the case of a joint project to develop an AIDS vaccine between the International AIDS Vaccine Initiative (IAIV), a global PDP, and DNAVEC, a Japanese biotech company, and discusses lessons learned from their experience.

2-1. The International AIDS Vaccine Initiative (IAVI)

Founded in 1996, The International AIDS Vaccine Initiative (IAVI) is a PDP pioneer. It is a global non-profit organization whose mission is to ensure the development of safe, effective, accessible, preventive AIDS vaccines for use throughout the world. **Figure 5** illustrates the three areas IAVI's activities center around: R&D partnerships, regional partnerships, and advocacy and outreach.





R&D partnerships leveraging internal and external capabilities

- · Applied Research to identify leads
- Product Development to advance candidates—multiple industry partnerships
- Clinical Trial Capabilities
- Human Immunology Lab—Imperial College London
- AIDS Vaccine Design and Development Lab—Brooklyn
- Consortium focusing on Neutralizing Antibody vaccines— Scripps
- Replicating Vector programs



Network of regional partnerships

- IAVI-supported network of clinical research centers in Africa
- Community and National outreach in Africa and India
- Joint HIV vaccine program with Uganda Ministry of Health
- Jointly funded IAVI-India laboratory (to be launched in 2012)
- International academic and biotech partner networks



Regional and global advocacy and outreach

- Regional advocacy partner network development
- HIV vaccine advocacy in global devp and HIV policy processes
- Policy work on potential impact, access to HIV vaccines
- Communicating accurate info about HIV vaccine R&D
- Media training on HIV vaccine R&D in partner countries
- HIV vaccine R&D resource tracking
- Resource mobilization to support continued focus on HIV vaccines



2-1-2. R&D partnerships leveraging internal and external capabilities

IAVI maintains an in-house R&D capacity through its three laboratories in New York, California, and London. The research and product development process for an AIDS vaccine is lengthy and involves different players at various stages of development. For example, government research institutions and academic laboratories usually concentrate their effort in the early stages of research while pharmaceutical companies are engaged in the advanced stage of development. Furthermore, there are clinical research centers and contract manufacturing organizations that provide specific services necessary to conduct clinical trials. IAVI's R&D team works with all these players and fills the gaps between their activities by providing critical translational research capabilities that knit together innovative concepts and technologies, expertise in production development and manufacturing, and clinical trial know-how. Since its inception, IAVI has conducted 20 clinical trials with more than 11 vaccine candidates and is able to apply this experience and expertise to advance vaccine development programs into clinical settings. **Figure 6** illustrates IAVI's translational support model.

IAVI accelerates the global efforts in AIDS Vaccine development via partnerships

IAVI has sought to fill gaps and accelerate HIV vaccine R&D by partnering with academia, government and industry to provide critical translational capabilities

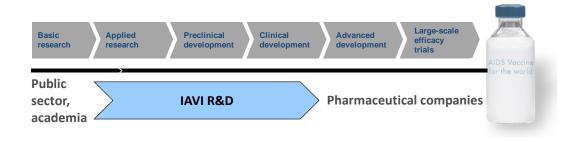




Figure 6

2-1-3. Network of regional partnerships

IAVI and its partners have established a clinical research network to conduct evaluation of vaccine candidates and related epidemiological research in sub-Saharan African countries (Kenya, Rwanda, South Africa, Uganda, and Zambia). The research centers work closely with local communities and have established advisory mechanisms to ensure that communities are fully informed and educated about the clinical trials and that their concerns are taken into account in conducting the studies. IAVI also seeks partnerships with the governments of the developing countries. These partnerships, not only ensure that the candidates under development today will be tested and adopted in the communities that need them most, but also allow IAVI to leverage some of the scientific talent that exists in the emerging market, and to build capacity that lasts in each community. A joint AIDS vaccine program with the Uganda Virus Research Institute, and a laboratory jointly funded by IAVI and the Government of India, are examples of such initiatives.

2-1-4. Regional and global advocacy and outreach

IAVI conducts policy analysis and advocacy to build a supportive environment for AIDS vaccine development, and to promote comprehensive access to AIDS prevention, treatment, and care, including future access to vaccines. Advocacy work caters to all levels of stakeholder, including policy makers, civil society groups, and members of the communities hardest hit by the pandemic. Recent endeavors in this field include development of Impact Modeling with Futures Institute, and advocacy to the HIV Vaccines and Microbicides Resource Tracking Working Group with UNAIDS and other partners.

2-2. DNAVEC

2-2-1. Origins

DNAVEC Corporation is a biotechnology venture company originally incubated in 1995 as a national project supported by Japan's Ministry of Health and Welfare. During its nine-year project period, DNAVEC Research Inc., the predecessor of DNAVEC Corporation, successfully developed innovative vectors including Sendai virus vector, the company is now working on with IAVI as the component of their AIDS vaccine candidate. DNAVEC Research Inc. was converted into DNAVEC Corporation in 2004, funded by the board members and four Japanese pharmaceutical companies, with the purpose of developing business from DNAVEC's core technologies. The company's business is based on gene therapy, gene vaccines, and cell therapy utilizing virus vectors it has developed. It has obtained a number of international patents for the vectors and their use after initial testing predicted a high efficacy and safety profile. As with most biotechnology companies, DNAVEC leverages a relatively small team of

scientists by engaging in multiple joint R&D programs with national and global research institutes and pharmaceutical companies.

2-2-2. Sendai virus vector

Sendai virus vector was first engineered by DNAVEC and Dr. Yoshiyuki Nagai (then at the Institute of Medical Science, University of Tokyo (IMSUT)). It is an RNA virus derived from a weakened form of Sendai virus, a virus related to the measles and canine distemper viruses that replicate in the respiratory system. It ordinarily infects rodents and is not known to cause disease in humans. Sendai virus vector is unique in two aspects. First, it is a cytoplasm RNA vector that replicates its genome exclusively in the cytoplasm and produces protein in large quantity without entering the cell nucleus. Since the cytoplasm RNA vector's genome is made of RNA, a material chemically different from the patient's chromosomal DNA, it does not alter the chromosomes in the cell nucleus as other conventional vectors do. This characteristic means Sendai virus vector is in principle free of risks associated with conventional vectors, such as integration or recombination of vector DNA with patient DNA, which have potentially adverse effects. Secondly, it is a replicating virus that retains the ability to multiply inside the human body, mimicking with greater fidelity the natural course of viral infection. Researchers suspect that these types of replicating vector might be able to elicit immune responses that are broader, longer lasting, and more potent than those elicited by non-replicating vectors bearing antigens. Kyushu University Hospital concluded a Phase I/IIa clinical trial on gene therapy research for severe ischemic limbs using the Sendai virus vector in 2010, confirming the safety and possible effectiveness of this therapy. Vaccines against other infectious diseases are also under development. As Japan's first viral vector for gene therapy, there is a strong focus on the potential of Sendai virus for application in cell engineering, cell therapy, and regenerative medicine in Japan's medical and pharmaceutical fields.

2-2-3. Application to AIDS vaccine

Preclinical studies of the Sendai virus vector carrying genes from simian immunodeficiency virus (SIV, an HIV-like disease in non-human primates) indicated the candidate was able to protect non-human primates against SIV infection. These studies were conducted by DNAVEC and Dr. Tetsuro Matano, chief scientist of the Sendai virus vector vaccine development program at IMSUT and the National Institute of Infectious Diseases. Prior to its partnership with IAVI, DNAVEC had conducted joint projects with the University of Tokyo, as above, and the Government of China to develop an AIDS vaccine using Sendai virus vector vaccine.

2-3. The Partnership

2-3-1. Framework

Figure 7 illustrates the framework of the partnership. IAVI supports the project through provision of funding as well as technical expertise with product development and clinical trials in multiple countries, while DNAVEC provides its unique vector technology. The Japanese government pledged US\$10 million through the World Bank in 2010 as a grant to support the project.

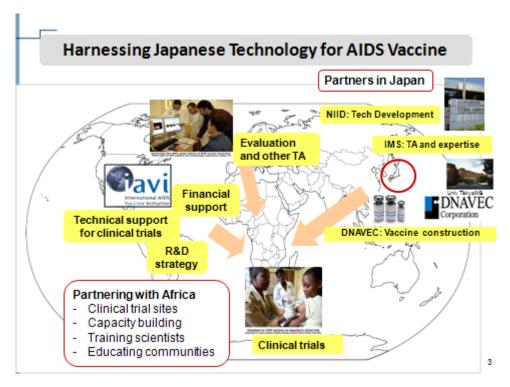


Figure 7

Arrangement of intellectual property (IP) rights is of special importance in PDPs. IAVI works with development partners to ensure that the final products are accessible in the countries that need them most. The IP arrangement ranges from the partner having exclusive rights to IAVI having exclusive rights, as shown in **Figure 8**. In the partnership between IAVI and DNAVEC, the arrangement is one of "shared rights". DNAVEC will receive royalties for any vaccine developed for use in developed countries, while both partners have agreed to make any successful vaccine available as quickly as possible, and to not profit from distribution, in countries hardest hit by the epidemic.

IAVI Vaccine Development Program: Intellectual property (IP) License Rights -No 'one size fits all' solution -Flexible modeldepending on partner's capabilities and contributions IAVI Partner Shared controlled rights controlled -Exclusive rights -Non-exclusive Exclusive rights rights -Worldwide or -Worldwide or -Segregation of developed countries developing territories or sectors countries -Access of markets (public commitments for -March-in vs. private sector) developing countries provisions for developing countries Pavi

Figure 8

2-3-2. Process

The partnership between IAVI and DNAVEC to jointly develop an AIDS vaccine using DNAVEC's Sendai virus vector technology started in 2007. The aim of the project is to develop an AIDS vaccine that elicits mucosal and cell mediated immunity. The collaboration agreement includes pre-clinical testing for safety and immunogenicity data, process development for manufacturing, and a Phase I clinical trial. The first two stages and licensing out process were successfully completed in 2010 and the partners started a Phase I clinical trial in April 2013. The trial is multi-centered, and will be conducted in IAVI and its partners' research locations in Rwanda, Kenya, and the United Kingdom to evaluate the safety and immunogenicity of the candidate. The results of the trials are expected in the second half of 2014.

2-4. Lessons and Challenges

- ◆ The IAVI-DNAVEC partnership exemplifies how a global PDP such as IAVI and an innovative firm can forge a successful partnership. The partners acknowledge the following two factors as crucial elements of their success:
 - ➤ Both partners possess unique expertise to make complementary contributions to the partnership. The partnership is based on the fact that DNAVEC's vector technology and IAVI's accumulated product development experience are both indispensable for the success of the project.
 - > The partners have focused on moving the partnership forward despite

organizational differences by prioritizing three key areas: building trust, sharing goals, and ensuring clear communication. It is not uncommon for partnerships to be complicated by differences between sectors with regard to working culture, timelines, objectives, and the like. Prioritizing these three points is essential for a productive partnership.

- ◆ The framework of the partnership presents a strong case for an effective donor contribution in innovative technology development. Sendai vector technology is originally a product of a national project that combined Japanese biotechnological expertise. By funding the IAVI-DNAVEC partnership to bring this technology to practical application, the Japanese government is able to seamlessly support the development of Japanese technology while leveraging its investment with IAVI's capacity and simultaneously promoting its commitment to the global fight against AIDS.
- ◆ As shown in the case of the IAVI-DNAVEC partnership, bringing innovative technology to practical application requires considerable time, resources, and expertise. Such resources are often hard to come by through regular commercial channels when it comes to African health issues, including that of neglected diseases. PDPs are capable of offering the necessary expertise in situations where technology matches their mission. When such matching occurs, the resulting collaboration can create favorable synergy that boosts the return on investment. Given the potential of such collaboration, approaching a PDP should be considered as an option when a firm explores practical applications for its innovative health-related technologies.
- Matching between the technology and the needs of a PDP is the first hurdle in formulating a productive partnership with a PDP. The public sector has a role to play in facilitating the matching process to reduce the cost of searching for a potential partner. Such facilitation would be especially important and effective when groundbreaking technology is developed by a small firm with little global visibility.

Conclusion

The two cases described here demonstrate the potential of public-private partnerships (PPP) as tools with which to address health issues in Africa. Improving health often presents complex challenges that call for multi-dimensional approaches. PPPs have proved to be an effective framework to create the desired approach by bringing together a diversity of expertise from across multiple sectors.

There are four essential conditions for a successful partnership. First, each partner needs to understand its own strengths and the areas in which it can provide the

highest value-added contribution before exploring any potential partnership. Understanding its own strong points leads to a better understanding of the capacities required in potential partners in order to create a self-sufficient partnership. Secondly, the division of roles among the partners should be made clear from the start of any partnership. This can occur naturally when a partnership is formed between entities with complementary expertise, yet it is an important point to be considered in any functional partnership. Thirdly, all the partners must share the goal of the project. Goal sharing and commitment are the foundation of trust, which is the very basis of a partnership. Finally, local entities or experts on the local environment must be included in the partnership so that the local context and culture are fully taken into account throughout the project.

It has been more than a decade since PPPs emerged as an effective instrument in international development, including global health, and experiences in Africa and other emerging economies have been accumulated. The PPP mechanism is ever more relevant as a vehicle to deliver much needed health innovations to populations in need in today's resource-constrained environment. Building on the lessons learned from the experiences of PPP practitioners, including those recorded in this paper, will serve to further refine PPP methodology and enhance its capacity to bring about much desired changes.

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