

# Initial lessons from public–private partnerships in drug and vaccine development

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**Abstract** In recent years, venture capital approaches have delivered impressive results in identifying and funding promising health discoveries and bringing them to market. This success has inspired public sector experiments with “social venture capital” approaches to address the dearth of affordable treatment and prevention for diseases of the developing world. Employing the same focus on well-defined and measurable objectives, and the same type of connections to pool and deploy resources as their for-profit counterparts, social venture capitalists seek to use the tools and incentives of capitalism to solve one of its biggest failures: the lack of drugs and vaccines for diseases endemic to low-income populations. As part of a larger trend of partnerships emerging in health product donation and distribution, public–private partnerships for pharmaceutical development have led research and development (R&D) efforts to generate more accessible and efficacious products for diseases such as malaria, tuberculosis, and AIDS. In this article, three R&D-focused partnerships are explored: the International AIDS Vaccine Initiative; the Medicines for Malaria Venture; and the newly formed Global Alliance for TB Drug Development. The article highlights key elements essential to the success of these ventures.

**Keywords** Orphan drug production; Research; Intersectoral cooperation; Investments; Social responsibility; Drug industry; Organizations, Nonprofit/organization and administration; International agencies; Patents; AIDS vaccines/supply and distribution; Antimalarials/supply and distribution; Antitubercular agents/supply and distribution; Developing countries (*source: MeSH*).

**Mots clés** Médicament orphelin; Recherche; Coopération intersectorielle; Investissement; Responsabilité sociale; Industrie pharmaceutique; Organisation sans but lucratif/organisation et administration; Organisation internationale; Brevet; Vaccin anti-SIDA/ressources et distribution; Antipaludique/ressources et distribution; Antituberculeux/ressources et distribution; Pays en développement (*source: INSERM*).

**Palabras clave** Producción de medicamentos sin interés comercial; Investigación; Cooperación intersectorial; Inversiones; Responsabilidad social; Industria farmacéutica; Organizaciones sin fines de lucro/organización y administración; Organización internacional; Patentes; Vacunas contra SIDA/provisión y distribución; Antimaláricos/provisión y distribución; Agentes antituberculosos/provisión y distribución; Países en desarrollo (*fuentes: BIREME*).

*Bulletin of the World Health Organization, 2001, 79: 728–734.*

*Voir page 733 le résumé en français. En la página 733 figura un resumen en español.*

## Introduction

Today’s technology boom presents a paradox. Armed with an understanding of genomics and increasingly sophisticated research tools made possible by the Internet, science now has the potential to attack human disease as never before. Yet the health gap between industrialized and developing countries continues to widen. Although the private sector has exploited new technological capabilities for creating new drugs and vaccines directed primarily at chronic diseases common in industrialized countries, inno-

vative pharmaceuticals have not been developed to treat infectious diseases plaguing the developing world. Several factors make it difficult to attract the necessary investment in commercial research and development (R&D) for these diseases, including perceived and actual low market returns for these investments, distribution challenges in countries with poor health care infrastructure, and lack of awareness about these diseases in more developed nations. Practices such as parallel importing and compulsory licensing have created further disincentives for companies to invest in products that primarily serve developing-world markets.

At the turn of the millennium, when diseases such as malaria, tuberculosis (TB), and acquired immunodeficiency syndrome (AIDS) are killing millions and threatening the economic stability of nations, there are thus a limited number of drugs and vaccines available to treat the diseases of developing countries (1). Without a significant investment in new

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Ref. No. 00-1088

product R&D, this situation is in danger of worsening. Today, R&D activity in the private sector is the domain of multinationals, venture capitalists, and entrepreneurs. Some in the public and philanthropic sectors, however, now argue that the costs and risks of product R&D for developing-world diseases must be shared with industry to ensure a public health dividend, and the term “social venture capital” has been coined to describe these activities. As a result, a number of public–private partnerships for drug and vaccine development have begun to apply social venture capital approaches to bridge the investment and product gap. The emergence of these R&D partnerships is part of a larger trend that includes partnerships with industry dedicated to the donation and delivery of existing products, as well as partnerships to enhance community outreach or strengthen the infrastructure for delivering treatment and prevention (2, 3).

These new partnerships are unique in several aspects. They focus on funding high-risk and high-cost projects to convert basic scientific discoveries into usable products. Also, rather than linking with a single company, they interact competitively with many companies. Finally, driven by a defined goal and mandate, they have established themselves as independent legal entities outside existing international and philanthropic organizations.

Examples of recently established partnerships are shown in Box 1. Three early partnerships to emerge were the International AIDS Vaccine Initiative (IAVI), formed in 1996; the Medicines for Malaria Venture (MMV), formed in November 1999; and the newly formed Global Alliance for TB Drug Development (Global Alliance), which was launched in October 2000. This article explores operational aspects that are critical to the success of these organizations in developing affordable new drugs and vaccines for diseases endemic to low-income populations and providing access to the target populations.

All three of the above partnerships have adopted a business model that lies at the core of today’s technology revolution and exploits the venture-capital approach to investing (4). Operating as social venture capitalists, these new public–private partnerships seek to pool the skills and efforts of partner organizations around specific projects, including corporations, industry groups, academic institutions, non-profit community efforts, and government agencies from industrialized and developing countries. By focusing funding towards a common objective, the partnerships are mobilizing the development of drugs and vaccines necessary to deal with neglected diseases.

## Operational aspects of social venture capital

Like venture capitalists, these partnerships screen potential projects for feasibility and channel funds into selected projects, structuring deals to ensure that

### Box 1. Public–private partnerships for product development

#### Alliance for Microbicide Development

(<http://www.microbicide.org/>)

#### Cooperative Research Centre for Vaccine Technology

(<http://www.crc-vt.qimr.edu.au/>)

#### Concept Foundation (injectable contraceptives)

(<http://www.conceptfoundation.org>)

#### Epidemic Meningitis Vaccines for Africa (proposed)

#### Global Alliance for TB Drug Development

(<http://www.tb Alliance.org>)

#### Hookworm Vaccine Initiative (at Albert B. Sabin

Vaccine Institute) (<http://www.sabin.org/hookworm.htm>)

#### International AIDS Vaccine Initiative

(<http://www.iavi.org>)

#### Leishmania Vaccine Initiative (at Infectious Diseases Research Institute (IDRI))

(<http://www.cwru.edu/CWRU/Med/medicine/research.htm>)

#### Malaria Vaccine Initiative

(<http://www.malaria vaccine.org>)

#### Medicines for Malaria Venture

(<http://www.malaria medicines.org>)

#### Sequella Global Tuberculosis Foundation

(<http://www.sequella foundation.org>)

Source: Global Forum for Health Research, Initiative on Public–Private Partnerships for Health, 2000.

the goals and assets of the investing organizations match the goals and needs of the projects. By maintaining a small, effective management team that coordinates project selection and portfolio management, overhead costs are minimized, a limited number of staff are employed, and a flexible, responsive operation is maintained.

There are key operational similarities among the three organizations mentioned above, as well as those listed in Box 1: all three organizations focus on disease-specific indications (i.e. antimalarial drugs, anti-TB drugs, and HIV vaccines); receive the bulk of their funding from the public and philanthropic sectors; primarily seek in-kind contributions from the industry through project partnership; and fund projects that involve for-profit partners. In addition, all three rigorously evaluate projects and are proactive in their establishment and operation, and register and license products for production and commercialization. Finally, all three seek contractual arrangements that develop products at “affordable” prices, in return for their R&D investment, and all three recognize intellectual property rights (IPRs).

The social venture capital approach is well suited to the changing landscape of drug and vaccine discovery and development, which increasingly relies on biotechnology firms and academics to harness new information and technologies (5). These players then collaborate as partners with larger, traditional pharmaceutical companies to best realize the technical and commercial potential of their findings. Large

pharmaceutical companies or venture capitalists provide “risk” funding for commercially attractive activities identified by the biotechnology companies and academics, but have little interest in funding projects that target diseases which have minimal commercial return. This niche need is increasingly met by social venture capital organizations.

While such a hands-on role in drug development is not well suited to broad multilateral agencies, small and targeted social venture capital funds can excel in this realm. Therefore, by emulating the specialized focus and expansive resource network of venture capitalists, public–private partnerships for drug development can contribute effectively to public health objectives.

In addition to sharing managerial focus, all three partnerships are separate not-for-profit entities, subject to standard financial audit controls, although each has its own organization which varies depending on the national location of the partnership. The Global Alliance and IAVI, for example, operate under laws governing USA not-for-profit organizations. MMV, in contrast, is based in Geneva and operates under Swiss laws.

Beyond local legal differences, the partnerships display many common approaches. Directors, for example, are selected on the basis of their expertise, rather than because they represent donor stakeholders. For the Global Alliance and MMV, there is also an annual stakeholder’s meeting, equivalent to a company shareholder meeting, at which the concerns and viewpoints of stakeholders can be voiced.

Since the partnerships are stand-alone and independent organizations, they are accountable for both their finances and their actions. Because they are at the interface between the public sector and industry, they are subject to greater public scrutiny than similarly sized, private, for-profit organizations. As a result, to maximize the transparency of their operations, the partnerships invest more time and effort in explaining their approaches, and commit more resources to communications than their private counterparts.

### The value of focus and commitment to specific goals

Because the social, political, logistic, technological and regulatory hurdles are immense, the partnerships must adopt a laser-like focus if they are to have a meaningful impact on the diseases of the developing world. As a result, they have emulated businesses, by establishing specific R&D objectives and setting criteria for funding activities, which increase the chances of generating products. (See Box 2 for the missions of these partnerships.) For example, MMV’s targeted emphasis on producing affordable drugs prevents resources from being squandered on products which ultimately would be inaccessible to most malaria sufferers.

#### Box 2. Missions of the featured partnerships

##### International AIDS Vaccine Initiative

To ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world.

##### Medicines for Malaria Venture

To discover, develop, and commercialize antimalarial drugs at a rate of one new product every five years and at prices that are affordable to populations worst hit by the disease.

##### Global Alliance for TB Drug Development

To accelerate discovery and/or development of cost-effective new TB drugs that will:

- shorten the duration of TB treatment or otherwise simplify its completion;
- improve the treatment of latent TB infection;
- be effective against multidrug-resistant TB strains.

If partnerships do not focus properly they risk finding themselves at odds with partners that must balance the needs of a broader agenda and with agencies that compete with the partnerships for scarce resources. Partnerships must approach these tensions with honesty and sensitivity if they are to cultivate the trust necessary to reach their goals.

### Carefully selecting and rejecting projects

To be successful and to select projects that are most vital and most likely to succeed, a partnership must possess a thorough understanding of the disease and the status of R&D in its area of focus. To help achieve this goal, IAVI has published its *Scientific blueprint 2000* (6) and the Global Alliance has developed two publications: the *Scientific blueprint for TB drug development* (7) and *The pharmacoeconomics of TB drug development* (8). These publications catalogue knowledge about diseases and medical approaches, as well as about the barriers that prevent the development of new interventions. Using this information, the partnerships have identified gaps in drug and vaccine development and set priorities about which gaps are the most pressing. The pharmacoeconomics report, for example, provides information on the epidemiology of TB, the potential market for new TB drugs, the cost of TB drug development, and the options for funding and conducting drug development. Using this analysis, as well as continuing surveys of TB drug development, the Global Alliance will select and fund projects where it believes its actions will best advance drug candidates towards final products (8).

The Global Alliance and MMV rely on a competitive call for project proposals, providing applicants with detailed information outlining project requirements and the product profiles required by the partnership. In IAVI’s case, staff members seek appropriate projects through meetings, published literature, and expert advice. In some cases, partnerships with industry are already in place; in other cases, industry partnerships must be established once a scientific evaluation assesses a project as feasible. The

partnerships select projects for funding primarily with the assistance of scientific advisory committees that combine basic science and industrial and clinical expertise. However, the core management team, using input from the committee, executes portfolio management decisions as it sees fit. Ultimate responsibility for decisions typically lies with partnership management, who have retroactive accountability to the Board and stakeholders (9, 10).

Another key element of these small organizations is that they can initiate and terminate projects in a timely manner and adjust them without complicated approval mechanisms. MMV, for example, seeks to combine its social venture capital approach with project management operations similar to those of a small R&D company. All discovery and development processes are performed outside the organization, but they are monitored, reviewed, and managed centrally. This management paradigm, which is gaining importance in the pharmaceutical industry overall, allows MMV not only to utilize cutting-edge science, but also to engage in cutting-edge managerial approaches to achieve its goals (11). As the number of projects increases for all three organizations, the issue of portfolio management and the matching of the portfolios to medical need will become of paramount importance.

## Intellectual property rights

The social venture capital model embraced by IAVI, MMV, and the Global Alliance considers patenting and licensing rights a strategic element of project deals. Typically, the partnerships expect that collaborating companies will ultimately manufacture and distribute the final product, providing advantaged access to the developing world through lower pricing or other means. To encourage a private firm to assume this responsibility, the company intending to market and manufacture a product must be granted access to intellectual property rights (IPRs) to the product. Under the social venture capital model, private firms must be able to earn a profit if product production is to be sustainable.

On the other hand, to provide low-income populations with the greatest access to affordable products, social venture capital organizations leverage their investment by negotiating to keep profit margins as low as possible. Companies can be compensated for the expectation of reduced profits in developing countries by being allowed to profit more extensively from the sale of the product in the developed world, or from the application of patented technologies to other products. In addition, large companies can obtain nonfinancial benefits from their collaboration with a venture associated with public health efforts, for example by demonstrating they are good corporate citizens. Small companies, too, can rely on their collaboration with the partnership to showcase their expertise and ability to deliver products.

## IPRs in the Global Alliance

For partnerships, intellectual property remains a tool to achieve their philanthropic objective of equitable access to a drug or vaccine. This is illustrated in the Global Alliance business plan (12) which outlines the options open to organizations for leveraging IPRs for low prices. Depending on the stage of development and the access or affordability issues at stake, the partnerships may require a range of solutions, from retaining all IPRs to forgoing all rights. Typically, IAVI seeks nonexclusive licensing deals for the most restricted of uses and confines its product rights to meeting the needs of the public sectors of developing countries (13). However, IAVI crafts IPR terms to accomplish its goals and negotiates a range of possibilities, including exclusive and nonexclusive rights, pricing agreements, technology transfer arrangements, and royalties (14).

## IPRs in IAVI

Much of IAVI's early experience has been with biotechnology companies, rather than with large pharmaceutical companies. When structuring a project, IAVI will opt for whichever licensing option best suits the individual partners and best advances its mission of delivering an affordable, effective product. IAVI recognized that a US\$ 5–10 million investment in a small biotechnology company could represent as much as 20–40% of the company's capital, and has forgone substantial equity in such firms in exchange for assurances that the product will be affordable in low-income countries.

Under this approach, IAVI has allowed biotechnology companies to retain development rights, as long as they make the product available at a reasonable profit (e.g. cost plus no more than 10%) and in reasonable quantities for the public sector of the developing world. Under the arrangement, the biotechnology company retains the right to offer the product in the industrialized world — and the private sector of the developing world — at any price the market will bear. But IAVI retains march-in rights, i.e. the right to transfer the technology to another manufacturer, if the biotechnology company fails to deliver affordability to the public sector. Because this approach allows the company to keep its valuable assets, it creates a business incentive to work with IAVI, even as IAVI advances its philanthropic mission.

## IPRs in MMV

In contrast, MMV has focused on drug-discovery projects with large companies, for which limited IPRs have been created. In these situations, the level of project investment represents a small percentage of the company's R&D effort and profit has not been the primary motive for the companies to enter into partnerships. In these cases, MMV secured downstream rights to develop compounds, either through patent ownership or through a free licence on drug-development candidates that result from the research. The companies engaged in the discovery

research may enter into a development and commercialization agreement after a candidate has been identified, although the issue of product affordability will need to be addressed. Future agreements will vary depending on the types of partners and the stages of drug development. With biotechnology companies, for example, the IAVI model may be more relevant.

Although the mechanisms discussed above differ, two requirements are common to both approaches. First, both place a strong emphasis on the affordability of the end product in developing countries. Second, both organizations retain the right to take over development should the commercial partner withdraw.

### **Orchestrating networks is necessary for success**

Public–private partnerships exist at the nexus of several diverse organizations necessary to achieve equitable, improved treatment. Like a successful venture capital firm, partnerships must effectively orchestrate the resources within and across these organizations if they are to enhance drug access and affordability. To engage all relevant players successfully, partnerships must demonstrate that private, public, and academic organizations alike will derive as much value as they deliver.

### **Reducing risks and adding value**

There is an obvious need for partnerships to reduce the costs and risks that otherwise prevent companies from engaging in R&D for the low-margin products needed by the developing world. If they are to funnel resources from profitable activities to neglected diseases, companies must feel that doing so affords them access to knowledge, technology, competitive advantage, or markets that they might not otherwise gain. IAVI, for example, seeks to fund an array of potential products, allowing large companies to cherry-pick the most promising ones and reduce their risk of failure. Partnership alliances can also help private companies gain brand-enhancing public relations, as well as platform technology that can be applied in developing other more profitable drugs. Finally, companies can use the products resulting from partnerships to meet the needs of profitable niches in both the industrialized and developing worlds. An HIV vaccine, for example, could be sold profitably to high-risk groups and health care workers in the industrialized world; similarly, the military and frequent travellers might pay dearly for a malaria vaccine first developed for low-income populations.

### **Value for money**

In the same vein, the public and philanthropic sectors must be convinced that their investment will yield a public health return. To demonstrate this value,

partnership models must compete with other calls on public/philanthropic resources, even while complementing existing efforts. MMV, for example, was incubated within the Special Programme for Research and Training in Tropical Diseases (TDR), a global collaboration cosponsored by the United Nations Development Programme (UNDP), the World Bank, and WHO. MMV was spun off when WHO recognized that a partnership focused on product development best complemented existing efforts by operating outside the main organization.

### **Working together**

Public–private partnerships do not replace any organization in the fight against disease. Instead, they are assets that help to create new tools more quickly and flexibly. In working closely with traditional organizations, however, public–private partnerships will by design strain the traditional system. The partnerships cannot succeed without the strong participation of WHO and nongovernmental organizations, and they must define relationships that utilize the broad experience of these organizations.

Many links have been established to cement the interactive partnerships required for success. For example, IAVI has strong links with UNAIDS ([www.unaids.org](http://www.unaids.org)) and the World Bank ([www.worldbank.org](http://www.worldbank.org)); the Global Alliance has strong links with the WHO Stop TB programme ([www.stoptb.org/home.html](http://www.stoptb.org/home.html)); and MMV operates closely with the Roll Back Malaria Partnership ([www.rbm.who.int](http://www.rbm.who.int)). The Global Alliance has also established a strong working relationship with several nongovernmental organizations, notably Médecins sans Frontières ([www.msf.org](http://www.msf.org)), in part through its Drugs for Neglected Diseases Initiative.

Because the Global Alliance and MMV maintain a strong focus on drug discovery and development, both organizations are developing close links with scientific agencies such as the United States National Institutes of Health, the United States Centers for Disease Control and Prevention (CDC), and the Wellcome Trust, as well as the European Union. Furthermore, by locating Global Alliance and MMV offices respectively in Cape Town, South Africa, and New Delhi, India, links to scientific and industrial efforts in the southern hemisphere have been strengthened. The academic and scientific organizations are drawn to the partnerships not only by the opportunity to advance public health, but also by connections to public funding, private know-how, and vehicles for applying basic research. In some cases, experience and relationships are further consolidated when academic and government leaders hold membership positions on key advisory committees to the partnerships. This is the case with the Global Alliance, for which the chairman of the Scientific Advisory Committee is also the CDC's chief of research on TB elimination and one of the Board members is the President of the South Africa Medical Research Council.

## Conclusions

The public–private R&D partnerships discussed in this article are still nascent and experimental. Indeed, the realities of product R&D dictate that the true value of these initiatives will not be known for some years. It is also evident that far greater resources must be invested in health care infrastructure and capabilities if affordable treatments and accessible health care are to be provided to developing countries.

Nevertheless, the partnerships provide a real opportunity for success. They offer a new and effective response to the medical needs associated with low commercial returns, needs that are not being addressed through competitive industrial R&D. Early

successes of these partnerships include highlighting the lack of product R&D in neglected diseases and attracting new resources to tackle these issues. The projects supported by these partnerships also represent new industrial activity in R&D that would not otherwise take place, and the scientists have new opportunities to exploit discoveries, a trend that will lead to more directed research for new products. The goals of the partnerships, although ambitious, now appear within reach and it is clear that the partnerships can help bring more affordable and efficacious health care products to the developing world. ■

**Conflicts of interest:** none declared.

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## Résumé

### Les premières leçons des partenariats public-privé concernant la mise au point de médicaments et de vaccins

Ces dernières années, les méthodes du capital-risque ont donné des résultats spectaculaires dans l'identification et le financement de recherches prometteuses pour la santé ainsi que dans le développement des découvertes jusqu'à leur commercialisation. Un tel succès a inspiré au secteur public des expériences recourant aux techniques du capital-risque social pour faire face à l'absence de moyens financièrement abordables pour le traitement et la prévention des maladies des pays en développement. Accordant la même importance aux objectifs bien définis et mesurables et utilisant le même type de relations pour réunir et déployer les ressources que leurs homologues à but lucratif, les capital-risqueurs sociaux s'efforcent d'appliquer les outils et les incitations du capitalisme pour trouver une solution à l'un de ses plus grands échecs : l'absence de médicaments et de

vaccins pour traiter les maladies endémiques dans les populations à faible revenu. Dans le cadre d'une tendance plus large des nouveaux partenariats concernant les dons et la distribution des produits de santé, les partenariats public-privé pour le développement pharmaceutique ont conduit les actions de recherche et développement (R & D) à la fabrication de produits plus accessibles et plus efficaces pour le traitement de maladies comme le paludisme, la tuberculose et le SIDA. Dans le présent article, trois partenariats centrés sur la recherche et développement sont examinés : l'Initiative internationale pour le vaccin contre le SIDA, l'Opération médicaments antipaludiques et l'Alliance mondiale pour la mise au point d'antituberculeux récemment créée. L'article met en lumière les éléments essentiels au succès de ces entreprises.

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## Resumen

### Lecciones iniciales extraídas de las alianzas de los sectores público y privado en el campo del desarrollo de vacunas

En los últimos años, las iniciativas emprendidas con capital de riesgo han dado formidables resultados en lo que respecta a identificar y financiar descubrimientos prometedores en el campo de la salud e introducirlos en el mercado. Esos éxitos han inspirado al sector público la idea de experimentar con una suerte de «capital social de riesgo» para intentar remediar la escasez de medios de tratamiento y prevención asequibles contra enfermedades del mundo en desarrollo. Aplicando la misma perspectiva a objetivos bien definidos y cuantificables, y el mismo tipo de conexiones para allegar y desplegar recursos, que sus homólogos con fines lucrativos, los responsables de ese capital social de riesgo pretenden usar los instrumentos e incentivos del capitalismo para resolver uno de sus mayores fracasos, a saber, la falta de medicamentos y vacunas para enfermedades endémicas

en poblaciones de bajos ingresos. Como parte de una tendencia más amplia a la formación de alianzas en el campo de la donación y distribución de productos sanitarios, las alianzas de los sectores público y privado para el desarrollo de productos farmacéuticos han orientado las actividades de investigación y desarrollo (I+D) hacia la generación de productos más accesibles y eficaces para enfermedades como el paludismo, la tuberculosis y el SIDA. En este artículo se examinan tres alianzas centradas en la I+D: la Iniciativa Internacional para una Vacuna contra el SIDA; la operación «Medicamentos antipalúdicos», y la recientemente creada Alianza Mundial para el Desarrollo de Medicamentos Antituberculosos. En el artículo se destacan los elementos clave de los que depende el éxito de esas iniciativas.

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