

Public-private partnerships for global health

How PATH advances technologies through cross-sector collaboration



INTRODUCTION

For more than 30 years, PATH has been working to advance innovative global health solutions. Our goal is to develop and deliver high-impact, cost-effective technologies, including vaccines, drugs, diagnostics, and devices to improve public health.

Partnering is a core part of PATH's strategy, and is fundamental to how we effectively develop innovations to overcome global health challenges. Our partners come from international health agencies, governments, universities, other nongovernmental organizations (NGOs), and private-sector companies. We work with our partners throughout the product lifecycle—from the early stages of research, all the way through to product introduction and wide-scale adoption—for sustained public health impact.

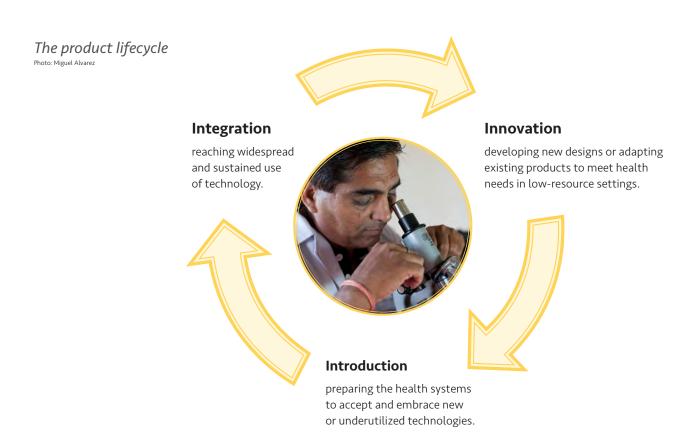
Each of our public-private partnerships is unique. We may partner with a small biotechnology company to adapt their technology design to meet the needs of people living in resource-poor settings, or we may work with a multinational pharmaceutical company to prove the feasibility of a product and introduce it through the public

health system. Other PATH partnerships address late-stage activities, such as manufacturing and distribution, to improve access to technologies. We also work with local NGOs, public health programs and private health providers to enhance adoption and demand by ensuring technologies are introduced as part of a package of services. No matter who the partner is, the collaboration must be mutually beneficial and must fulfill our mission to improve the health of people around the world.

Given the divergent goals and business models of these various entities, catalytic investments are often needed to lay the foundation from which public-private partnerships can grow. Therefore, to ensure that the products we develop and adapt with our partners are available, accessible, and affordable in low-resource settings, investments by all stakeholders in public-private partnerships are critical throughout the product lifecycle.

THE PRODUCT LIFECYCLE

The lifecycle of a product is a complex and iterative process that starts with the identification of unsolved





Leading the field in safe injection technology

In many low-income countries, where budget resources are stretched thin, health systems may not be able to ensure the safety of health tools and products. This leads to situations where the very injections meant to prevent or treat disease can end up causing it instead. For instance, many underresourced, overburdened health care programs reuse or fail to properly sterilize contaminated injection equipment because of poor training and weak infrastructure.

Recognizing the tremendous negative impact that unsafe injection practices can cause, PATH researched how to improve injection practices to reduce the risk of transmitting bloodborne diseases such as HIV and hepatitis B in low-resource settings. The US government, through the US Agency for International Development, provided funding to PATH, enabling us to develop and patent a design for an auto disable (AD) syringe that automatically locks after a single injection.

While PATH had the scientific and technical know-how to design the technology, a commercial partner was needed to validate the design, support large-scale production, and enable widespread distribution. PATH licensed the technology to Becton, Dickinson and Company (BD), the world's largest syringe manufacturer. BD brought product development expertise to advance the technology beyond proof of concept, manufacturing capabilities to produce a global supply, and distribution channels to ensure the availability of the technology in the public and private sectors. The US government's

investment in the product's development—leveraged many times over by BD's own investment in the device—enabled PATH and BD to pursue an aggressive distribution program that led to SoloShot™, the world's first commercially available AD syringe.

A major boost to the introduction and use of AD syringes occurred when the United Nations Children's Fund and the GAVI Alliance began purchasing and distributing AD syringes for their programs. The US government also accelerated the adoption of the technology by **aggregating demand** through the US President's Emergency Plan for AIDS Relief (PEPFAR) program. Because injection safety was one of PEPFAR's top priorities, the US government procured more than 250 million AD syringes for 11 countries through the Making Medical Injections Safer project over the five-year life of the program. Since 1992, more than six billion vaccinations have been delivered using SoloShot™ in more than 40 countries.¹

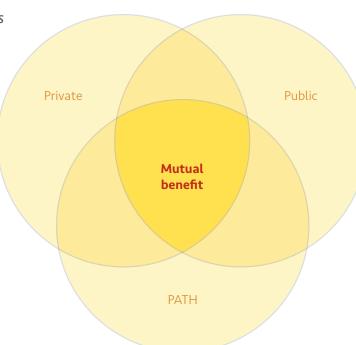
Since the launch of SoloShot™, the use of AD syringes and other safe injection technologies has led to **improved health outcomes**. Studies have shown that transmission of bloodborne diseases caused by dirty needles has been reduced by 90 percent in programs using some form of AD syringe.¹ Public investment in AD syringes helped to catalyze the creation of safe injection as a new technology category. It also launched a global policy shift in safe injection and improved health care delivery by enabling health care workers regardless of experience or training to safely administer injections.

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Key partner contributions

Private sector brings

- Scientific & technical know-how
- Intellectual property
- Product development expertise
- Manufacturing capabilities
- Distribution channels



Public sector brings

- Funding for R&D
- Ability to strengthen capacity
- · Aggregated demand
- Distribution channels
- Incentives for product development & uptake

PATH brings

- Expertise in developing country health systems
- Technical & field evaluation capabilities
- Partnerships with global & local policymakers
- · Ability to strengthen capacity
- · Scientific & technical know-how
- Experience forging new cross-sector partnerships

health challenges and potential solutions, and continues through widespread adoption and sustained use of technologies. PATH's approach begins with the end in mind. Our goal throughout a product's lifecycle is to ensure that the technology being developed is appropriate, available, accessible, and affordable to those who need it most. From the start, we consider the public health need, technical feasibility of potential solutions, economic rationale, market sustainability, and policy environment. We continue to evaluate these factors in more depth as a product moves through the development process. These analyses inform and clarify the value of a technology and determine whether further investment is warranted by PATH and our partners.

PARTNERING THROUGHOUT THE PRODUCT LIFECYCLE

PATH's model is to collaborate with partners at each phase of the product lifecycle. Creating partnerships

that leverage the assets of the private sector and the public sector together is a powerful means to ensure impact, scale, and sustainability for the world's most vulnerable populations. PATH is recognized for our ability to bridge the public and private sectors, and to facilitate public-private partnerships that bring some of the world's most influential players to the table. To advance solutions that are appropriate and culturally relevant, we also work closely with communities—composed of the targeted product users—at every phase. We help align the strengths and requirements of each of our partners to ensure that appropriate technologies and innovations reach communities and individuals with the greatest need.

The private sector's role in public-private partnerships

Commercial partners often bring significant scientific and technical know-how as well as intellectual property to a public-private partnership. This know-how,

Saving lives with the world's smartest sticker

The journey of a vaccine from a manufacturer in Europe to a rural health center in Southeast Asia may take weeks, during which the vaccine is constantly at risk of being spoiled. Too often these vital vaccines are damaged but still used, or they are tossed out too soon because health workers have to assume they have gone bad. To meet this challenge, PATH launched a search for suitable technologies that could be used to monitor heat exposure to let health workers know whether to use or discard vaccine.

PATH identified heat exposure indicator technology—originally designed to help the food industry monitor perishable products—developed by Temptime (formerly known as Lifelines Technology) and recognized its potential for vaccines. Temptime had the scientific and technical know-how and the intellectual property, but lacked understanding of how the technology could be used for global health purposes. PATH partnered with the company to adapt its technology for use with vaccines by contributing an understanding of developing-country health systems and the technical and field evaluation capabilities necessary to appropriately design the product to meet enduser needs and assess its acceptability and impact.

To help supplement upfront investments by Temptime—a small start-up company with limited capital—the US

Agency for International Development provided **funding** to PATH that enabled the development and validation of the technology that would eventually be known as the vaccine vial monitor (VVM).

Throughout the product development process, PATH worked with the World Health Organization (WHO) to test the VVM technology in collaboration with ministries of health throughout the world, and to engage the United Nations Children's Fund (UNICEF), the GAVI Alliance (GAVI), and vaccine manufacturers to facilitate supply of the technology on vaccines for developing-country markets.

Today, all vaccines procured by UNICEF and GAVI must include VVMs to ensure that only potent vaccines are administered in routine immunization programs, improving health outcomes for children worldwide. The VVM provides the global health community an estimated US\$5 million cost savings annually. These benefits have not been limited to the public sector. In fact, the seed funding provided by the US government and the strategic partnerships with global and local policymakers facilitated by PATH have led to new market opportunities for New Jersey-based Temptime, enabling its growth from a small start-up with five employees into a financially stable company that now has more than 60 employees developing global health technologies.



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Ending epidemics through cross-sector cooperation

For more than a century, meningitis swept across sub-Saharan Africa with unstoppable force. With each epidemic, the disease decimated communities, killing one in ten people and leaving one-quarter of survivors severely debilitated. The Meningitis Vaccine Project (MVP)—a partnership between PATH and the World Health Organization—was created to accelerate the development and introduction of MenAfriVac®, a safe and affordable vaccine that would provide long-lasting protection against the strain of meningitis (meningococcal A), which threatens the lives of the 450 million people living in the 26 African countries that comprise the "meningitis belt."

Several US government agencies—including the US Agency for International Development, National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration (FDA)—provided critical investment through **funding**, and **capacity strengthening** through laboratory and field testing, and technology transfer in the development and validation of the vaccine, as well as the manufacturing processes. MVP partnered with an Indian vaccine manufacturer, Serum Institute of India Ltd. (SIIL), to leverage their **manufacturing**

capabilities to bring the vaccine to the global market at an affordable price. MVP facilitated the transfer of a critical technology created by the FDA to SIIL, which strengthened their capacity to scale up the process, and produce and distribute the vaccine for less than US\$0.50 a dose. The transfer of the conjugation technology not only enabled SIIL to produce large quantities of MenAfriVac® but has created new market opportunities for the manufacturer to develop much-awaited additional conjugate vaccines for the global market.

As a result of the commitments made by public -and private-sector partners and the **new cross-sector partnership** forged by MVP, MenAfriVac® was developed for less than one-tenth the cost of a typical new vaccine in just less than ten years, and is expected to provide US\$570 million in **cost savings** to the global health community during the next decade.³ The vaccine's impact on **improving health outcomes** in the region is becoming evident. First introduced in Burkina Faso in December 2010, the vaccine has now been deployed in ten African countries, resulting in a dramatic fall in cases of meningitis A in the region. In Chad, not a single group A meningitis case was identified in the three areas of the country that received the vaccine.

in addition to product development expertise (e.g., experience in navigating complex regulatory processes) helps the private sector rapidly innovate to meet consumer preferences. Private-sector partners also contribute manufacturing capabilities (e.g., ability to produce large quantities of a product), capital investment, market development experience, and wide-scale distribution channels that serve the health system. Partnerships with the private sector not only accelerate product development but are also a key means through which access can be achieved.

Each partnership is unique. In some cases, a commercial partner may be engaged early in the technology development process, creating a new product or adapting an existing technology to be more affordable and appropriate for developing-country settings. In other cases, the commercial partner may be involved in the introduction of a technology, by helping to create demand and produce a sustainable source of supply to meet that demand. Private-sector engagement is critical throughout the product lifecycle.

The public sector's role in public-private partnerships

The public sector is an equally important partner in identifying, creating, and disseminating global health technology innovations. The perceived financial risks are often too high relative to the potential returns to rely solely on private-sector investment. Therefore, governments play a critical role in mitigating risk and providing incentives to the private sector to invest in developing products for low-income countries and individuals.

Experience shows that the public sector is a driver of innovation and growth for the private sector. Basic research conducted and funded by governments lays the foundation for many products that have been further developed and manufactured by commercial entities. Government institutions have also transferred technology to industry to strengthen the capacity of private-sector partners to innovate and produce appropriate and affordable technologies.

The public sector can play a key role in encouraging sustainable commercial investments in product development throughout the product lifecycle by entities that otherwise would not engage in such endeavors. The public sector can provide aggregated demand (through mechanisms like the GAVI Alliance) to increase market attractiveness, distribution channels (through public health programs), and other creative incentives (e.g., tax credits or accelerated regulatory approval timelines for products that serve the poor) to lower costs and accelerate the innovation, introduction, and integration of global health technologies. These

public-sector contributions facilitate the engagement of all stakeholders in global health research.

PATH's role in public-private partnerships

PATH and other nonprofit product development organizations serve as important bridging agents between the public and private sectors. Fundamental to PATH's approach to innovation is a deep understanding of health challenges and identification of potential solutions based on user, country, and market needs. Our approach is analogous to being a skilled translator because we recognize the language, models, and needs of our commercial partners. We also understand developing-country health systems and have strong networks within countries, as well as technical and field evaluation capabilities, to ensure that the resulting products truly meet the needs of end users. We can translate these needs into opportunities for mutual benefit by leveraging our strategic partnerships with both sectors to maximize resources and expertise and impact. We also bring scientific and technical know-how that can strengthen capacity, given our three decades of hands-on experience designing, developing, adapting, and testing products for global health.

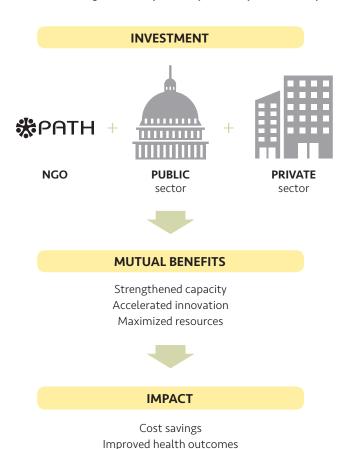
PATH's longstanding relationships with global bodies like the World Health Organization and developing-country governments, as well as our extensive collaborator networks, enable us to add value to our commercial partners to ensure the technologies being developed are aligned with global and national policies and regulations, and meet the needs of end users. PATH and other nonprofit product developers create linkages between developing countries' public health needs and private-sector capabilities.

MUTUAL BENEFITS

Public-private partnerships provide a forum for maximizing complementary areas of expertise. They improve knowledge of the most pressing global health needs and lead to solutions that improve health equity. By strengthening the capacity of different sectors, these partnerships accelerate the development and introduction of the most promising technologies for those most in need. Finally, forging new cross-sector partnerships with public institutions and commercial entities enable PATH to maximize the limited global health resources of both sectors—financial, technical, and structural—to reduce costs and avoid redundancy in our efforts to ensure the affordability of much-needed global health technologies.

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Outcomes of PATH's public-private partnerships



RECOMMENDATIONS

Adequately fund public-private partnerships to maximize global health impact

New market opportunities

Public-private partnerships are an efficient and sustainable model for conducting global health research and development throughout the product lifecycle. They leverage the resources and expertise of different stakeholders to accelerate the development and delivery of high-impact, cost-effective products to improve public health. As the lead funder of global health research and development, the public sector should ensure that its investments support the critical work of public-private

partnerships in accelerating the availability, accessibility, and affordability of global health technologies.

Provide support throughout the product lifecycle to accelerate innovation, introduction, and integration of global health technologies

To maximize impact, the public and private sectors and NGOs must begin with the end in mind. Support by the public sector for technology development alone does not guarantee that a product will reach those most in need. To ensure that innovative ideas become products that efficiently advance from development through widescale adoption for sustained public health impact, the public sector must support the products throughout their lifecycle. Thus, investment in market development from the very beginning is essential to build the foundation for supply, create demand, and provide an incentive for private-sector partners to sustain their investments.

Create incentives for private-sector engagement to advance health products for low-resource settings

Public-sector investment—through funding, capacity strengthening, or providing incentives—helps to create an enabling environment that encourages commercial investment in global health. Incentives such as accelerated regulatory reviews and pooled funding mechanisms enable commercial partners to meet the needs of the public and the private sectors. Such incentives need to be offered in combination with other innovative mechanisms—such as milestone prizes that provide rewards for incremental achievements along the product lifecycle—to ensure mutual benefits for the public and private sectors, as well as for the global health missions of NGOs like PATH.

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PATH is an international nonprofit organization that transforms global health through innovation. We take an entrepreneurial approach to developing and delivering high-impact, low-cost solutions, from lifesaving vaccines and devices to collaborative programs with communities. Through our work in more than 70 countries, PATH and our partners empower people to achieve their full potential.

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