

Maximizing the benefits of public-private partnerships

An overview of PATH's approach to maximizing the availability, accessibility, and affordability of global health technologies through private-sector collaboration

Recent increases in global health resources have prompted new models for solving global health problems. Creative partnerships between the public and private sectors have been one successful approach. Because many of these partnerships receive support from public or philanthropic sources, it is important to ensure that the resulting products are available as “global public health goods”—that is, goods that are available, accessible, and affordable to everyone as a means to improve health.

Since 1977, PATH has partnered successfully with many organizations, including dozens of commercial firms. We typically collaborate with a company to develop a specific product that will help to overcome a global health challenge, especially for people living in resource-poor settings. This document shares our experience working with our partners—whether commercial, academic, government, research, or nonprofit—to ensure that the products we develop together are best made available to improve public health.

Mutually beneficial partnerships

PATH's goal in any partnership is to fulfill our mission: to improve the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors. PATH looks for alignment between our global health goals and our partner's goals to create a successful partnership that provides mutual benefit. We design the project so the goals of both PATH and our partner can be met. The greater the mutual benefit, the stronger the partnership and the more likely that global health goals will be achieved.

PATH actively engages in developing and commercializing health products with our partners. We work collaboratively, helping to solve problems, make decisions, and track progress. Working closely

with partners is critical when several partnerships must be coordinated to develop a single product. PATH codifies our negotiations with partners in legal agreements. These agreements are essential to protecting our investment and ensuring global health goals will be reached. They establish a framework and are one component of our ongoing, collaborative relationships.

Unique partnerships

PATH develops a unique, strategic approach to each partnership. We carefully consider a number of issues and weigh a range of options. In developing our approach, PATH builds an understanding of the risks and barriers that have prevented a particular global health problem from being solved. For example, what is the status of the research? Has the manufacturing process been developed? Is the market for the product clear? Are there complex partnership or intellectual property networks that must be navigated?

PATH also takes time to understand the constraints that define how potential partners can engage. For example, what market pressures are they facing? Where are they succeeding or being challenged? Are they being considered for acquisition or divestiture? How does this potential partnership relate to other products or intellectual property the partner owns? PATH also considers how to best ensure that the partnership's discoveries can be applied to improve health, even if the partnership doesn't proceed as anticipated.

PATH's specific approach to a partnership is a function of the factors outlined in the “Drivers of partnership diversity” figure. Our tailored approach to each partnership allows us to address the variability in these and other factors.

Drivers of partnership diversity

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More certain	Factor	Less certain
Science is known, minimal risk of technical barrier to development	State of science	Science is speculative or not yet at proof of concept
Intellectual property already controlled and/or ownership structure is simple	Intellectual property	Intellectual property status unclear and/or ownership structure complex
Short time to market	Time to market	Long time to market
Market is clearly defined and procurement funded	Clarity of market	Need may be clear but actual paying market may not yet exist
Introduction straightforward and success is highly likely	Distribution system readiness	Introduction complex and unsure, infrastructure not fully in place
Single partner, simple product components and supply, single product focus	Partnership complexity	Multiple partners, complex product components and supply, product one of many in complex portfolio

When a partnership falls further to the left on the continuum for a given driver, there is more certainty so we can be more specific as we discuss the key terms of the partnership.

When a partnership falls further to the right, there is less certainty so our discussions focus on partnership alignment to enable progress and identify specific terms to be negotiated in the future, as we learn more.

Three key areas of focus and agreement

To ensure global access to health products, PATH works with our partners to come to agreement in three key areas: ensuring product supply, making products affordable, and managing intellectual property. We uniquely tailor these three key areas for each partnership. Other areas—such as ensuring a consistent, high-quality product; complying with applicable laws and regulations; and structuring risk management—do not change significantly across partnerships.

Ensuring product supply

PATH seeks to ensure that new products will be available in sufficient volume to have the intended global health impact. The following approaches help ensure product supply will meet global needs:

Supply an agreed-upon volume or proportion of capacity. If there is enough information to forecast

the need and available funding for a given product for the foreseeable future, PATH and our partner can agree to a specific volume that must be supplied. In some cases, rather than stipulating volume, PATH agrees with our partner on the proportion of manufacturing capacity that our partner will dedicate to the product.

Ensure sufficient supply to meet demand for agreed-upon markets and geographic areas. In some cases, the partner agrees to meet the purchase demands of public-sector providers with sufficient lead-time and long-term purchase agreements. In these cases, the public-sector purchasers bear the burden of forecasting product demand.

Donate agreed-upon product volume for select use. In select circumstances, PATH works with a partner to determine an appropriate product donation. This decision often occurs in the later stages of product development, when the donated product is used to pilot introduction within the health system as a way to accelerate uptake and use.

Making products affordable

In successful product-development partnerships, contributions from the public sector (e.g., financial incentives, political will, and knowledge of lower-income countries) are combined with contributions from the private sector (e.g., intellectual property, development capabilities, manufacturing capacity, distribution systems) to create solutions that are

affordable to target populations. Several factors determine the affordability of the product.

Defining the value proposition. In the global health environment, those who need a product are often not those who will purchase it. For example, governments may purchase commodities for distribution to their citizens. PATH works to ensure that buyers have a good understanding of the unique value the product will bring and then determines what price various purchasers are willing to pay.

Cost structure/cost of goods sold. PATH also seeks to understand how much the product will cost to produce. We consider information that is already known about the product itself, the manufacturing process, and the required materials. Often, limited information requires creative approaches to understanding costs. For example, we may consider the costs of other comparable products.

Available financing. Given the variety of stakeholders who may be involved in purchasing a product, it is important to consider who will actually finance the product and whether any subsidies have been committed. Will countries purchase the product directly? Will nongovernmental organizations or multilateral groups be responsible for purchasing? Is a specific funding mechanism (e.g., advance market commitments) available to finance purchase of this product? Are other commercially valuable rewards (e.g., priority review vouchers) available?

Product demand. PATH often works with multiple partners to advance several products that address a health need. By diversifying our portfolio, we are at less risk from normal product failures and business challenges. Diversification also ensures that if multiple products are successful, market pressures and competition will put downward pressure on pricing.

The timing of pricing discussions is critical. Some of PATH's partnerships are working on science and technology that is in a very early stage of development. In such cases, it may not be feasible to determine an eventual price because so little is known about the final product formulation and manufacturing process. We may choose not to negotiate for specific guarantees around price or supply until a particular phase of product development, or we may estimate a price but come to a final agreement at a later stage. In other cases, we may elect not to agree on price at all, relying instead on the market to set a competitive price and simply focusing on developing a low-cost product.

Throughout these discussions, however, we highlight the importance of the product's affordability.

PATH has often pursued the following approaches to reach agreements around affordability:

Agree to a price ceiling. In many of our agreements, PATH works with our partner to establish a price ceiling for a product. Often, that price applies within specific geographic areas (e.g., low- and middle-income countries as defined by the World Bank) or markets (e.g., for public-sector purchase and use). As appropriate, we agree to allowances for inflationary increases in costs, especially for long-term contracts.

Offer preferential pricing. In some cases, PATH agrees with a partner that they will offer preferential pricing to select geographic areas or markets. Such tiered pricing allows our partner to set a competitive market price for more established markets and simultaneously offer a preferred price to advance global health.

Sell at cost plus margin. In some situations, PATH works with our partner to establish a limited margin above their cost of goods sold for select geographic areas or markets. For example, the partner may agree to only charge a certain margin above their cost of goods sold for public-sector purchase and use in low- and middle-income countries.

Sell at cost for select markets. In very select circumstances, PATH and our partner agree that products will be sold to select regions and markets (typically, the public sector in low-income countries) at cost. This solution may be mutually acceptable in situations where the product has dual uses (e.g., the product can be sold in both high-income and low-resource settings).

Managing intellectual property

Managing intellectual property is an important means of advancing PATH's mission. We do not manage intellectual property primarily as a revenue source. Although receiving royalty income is sometimes an option, we can typically achieve a greater social impact by foregoing modest financial revenue in return for more robust supply and pricing commitments from commercial partners.

Because we recognize the importance of intellectual property to our partners, we seek to determine an approach that will ensure global health goals are

met while protecting critical intellectual property rights. For example, will health goals be met if we license the intellectual property for use in the public sector in lower- and middle-income countries—leaving our partner unconstrained to sell in the private sector? Do we need to own or license the intellectual property, or can we simply secure residual rights that could be claimed if a partner abandons the intellectual property?

PATH may generate needed intellectual property, license it from an outside entity, or co-generate it with a partner. When entering a partnership, PATH carefully develops a strategy for managing any resulting intellectual property. By ensuring that we have access to knowledge developed during a partnership, we protect the public sector's investment in improving global health.

In some cases, we seek access to intellectual property through licensing, whereas in other cases, we simply seek access to the products made using the intellectual property—that is, we obtain specific pricing and supply guarantees to fulfill public-sector needs. Because PATH is not a manufacturer, we tend to be more interested in making a product available than in acquiring intellectual property for the product. In such cases, PATH typically gains access to our commercial partners' intellectual property only if agreed-upon supply and pricing commitments are not met.

PATH has often pursued the following approaches to reach agreements around intellectual property:

Invest in the intellectual property of our partners. PATH often invests in our partners' intellectual property without seeking to own or license it. In these cases, we focus on agreements around pricing and supply, with intellectual property rights that are triggered only if the partnership does not proceed as planned.

License for select markets and geographic regions. PATH may also seek an agreement in which our partner will license intellectual property for select geographic regions or markets. In several

partnerships, PATH has used this strategy so intellectual property can be sublicensed to an emerging-country manufacturer with a lower cost structure. In some cases, we distinguish between a product being manufactured or simply sold in those areas or to those markets.

Generate and out-license our own intellectual property. In some cases, PATH develops our own intellectual property or co-develops it with a partner. We sometimes develop or acquire intellectual property that we then license strategically in pursuit of our global health mission. In other cases, we place such intellectual property in the public domain for anyone to use. Whether we own the intellectual property or not, our goal is to ensure that intellectual property is effectively and efficiently applied to solve global health problems.

Finally, PATH works to ensure that the knowledge that we develop with our partners is made available to the broader scientific community. We work with our partners to develop a set of standards regarding what results will be published and when, both to protect critical intellectual property and to share findings that will accelerate discovery of solutions for global health problems.

Conclusion

Creative partnerships between the public sector and private firms can help to advance global health goals. Each of these mutually beneficial, collaborative relationships is unique. To structure successful partnerships, PATH begins with our shared goal of improving global health, builds on a mutual respect for each partner's contributions, and requires a skillful assessment of joint interests, capabilities, and opportunity costs. Our experience suggests that resulting collaborations can accelerate product development and access for poor populations while preserving commercial goals and building shareholder value—all while bringing health within reach to people around the world.