

PDP/Commercial Partnerships: Key Drivers for Optimized Success

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PATH

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Private sector collaboration at PATH

Large companies



Emerging-market companies



INDIAN IMMUNOLOGICALS LIMITED



SERUM INSTITUTE OF INDIA LTD.

Small companies



SANARIA



Guiding Principles

Our Context for Partnering with Commercial Firms

PATH's Guiding Principles for Private Sector Collaboration

INTRODUCTION

PATH's mission is to improve health, especially the health of women and children. To achieve its mission, PATH identifies, develops, and applies appropriate and innovative solutions to public health problems, particularly in low-resource settings. Collaboration—including collaboration with the private sector—is a key element in PATH's approach.

PATH's goal for private sector collaboration is to achieve maximum sustainable benefit for public health through engaging private sector collaborators to apply their development, manufacturing, and distribution strengths toward innovative technologies that, in the absence of PATH involvement, would not be a private sector priority.

PURPOSE AND SCOPE

PATH developed these Principles for Private Sector Collaboration to:

- Articulate key institutional policies and positions regarding PATH collaborations with private sector companies.
- Provide PATH staff with guidance in managing private sector collaborations.
- Provide current and potential private sector collaborators with an overview of PATH's perspectives and expectations for collaboration.

PATH's Board of Directors and President fully endorse these principles. The principles convey both the broad direction and the specific actions that they expect of all PATH teams that form collaborations with private sector companies.

These principles primarily address the following types of collaborations:

Transfer of a Technology Developed or Owned by PATH. PATH develops a technology in-house and transfers the intellectual property to a private sector collaborator for further development, manufacturing, and distribution.

Support by PATH for Development of a Collaborator's Product. PATH provides significant resources or expertise (such as funding, management, co-development, and assistance with clinical studies) to a private sector collaborator to support the collaborator's development of a product.

Support by PATH for Introduction of a Collaborator's Product. PATH supports and/or undertakes significant programmatic activities (such as field trials, epidemiological studies, and advocacy programs) that demonstrate and communicate the public health value of a product produced by a private sector collaborator.

CLEAR LINK TO MISSION

PATH's collaborations with private-sector companies must lead to positive impact on availability, accessibility, and affordability of important health products for public health programs in developing countries.

RECOGNITION OF PRIVATE-SECTOR NEEDS

In collaborating with a private-sector company, PATH must recognize the company's need for commercial benefit in order to ensure a sustainable commitment to the collaboration.

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Our Context for Partnering

CLEAR DEFINITION OF ROLES, RESPONSIBILITIES, AND EXPECTATIONS

In all collaborations, the relationship between PATH and the private-sector company must be clearly defined through an appropriate written document or agreement.

TRANSPARENT COLLABORATION

As a publicly funded organization, PATH must maintain a level of transparency in its collaborations with the private sector.

APPROPRIATE SELECTION OF COLLABORATORS

Because the success of any collaboration depends on the selection of a good partner, PATH must conduct a thorough assessment before entering into a formal collaboration with a company.

APPROPRIATE MANAGEMENT OF RISK

PATH must carefully assess and manage both the broad institutional risks as well as the specific project risks when collaborating with a private-sector company.

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Our Context for Partnering

DISSEMINATION OF RESULTS

As a publicly funded organization, PATH has a fundamental obligation to ensure dissemination of the results of its private-sector collaborations.

AWARENESS OF POTENTIAL CONFLICTS OF INTEREST

In all collaborations with private-sector companies, PATH must carefully assess the potential for both perceived and real conflicts of interest at both the institutional and individual staff member level.

ENSURING HIGH STANDARDS OF QUALITY AND ETHICS

PATH must ensure that all collaborative research, product development, and introduction activities meet the highest standards of safety, quality, and integrity.

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.

Case study

Commercialization of food fortification technology

Nutritional deficiencies undermine health and life expectancy around the world. Each year, for example, iron deficiency causes death in more than 60,000 children, and lack of vitamin A leads to 1 million deaths, mostly among young children.

Much more gains with local rice. The technology works better than other fortification methods, but rice milling, in which nutrients were mostly degraded during storage, storage, and cooking.



Case study

Developing rapid screening tests for human papillomavirus

Current cancer tests approximate 270,000 women each year, mostly in low- and middle-income countries. Although screening programs using Pap smears have been successful in high-income countries, these programs don't work well in low-income settings.

It is possible for developing an appropriate test for low-income countries, replacing the test by clinical studies, and building a low-cost and commercial supply. PATH is working to provide high-quality tissue samples for product development, conducting marketing and industry assessments, conducting programs and product cost-effectiveness studies, and developing an industry network for public health programs. Both parties will aim to drive public attention and advance programs on cervical cancer prevention in low- and middle-income countries.



Case study

Development and use of the Uniject® device

Administration of medical injections has been problematic in many lower-income countries. Many areas have had limited health care workers with the necessary skills. Health care workers have conducted a type of self-injection without sterile drugs and vaccines—both within health facilities and in homes and communities where they are often needed most.

In the 1990s, PATH began developing technology to address the need for self-injections in low-income settings. We first collaborated with Merck, which had developed, but then shelved, a promising self-injector needle-pusher prototype. After obtaining initial feedback from Merck and funding from the U.S. Agency for International Development, PATH entered a joint drug licensing agreement with Merck and the Uniject device was born. After additional development and testing, PATH licensed the technology in 1996 to Baxter, Dickinson & Co. (BDC), the world's largest syringe manufacturer. BDC invested at least US\$2 million to establish a manufacturing facility in Singapore and another BDC facility to launch the product globally.



Case study

Increasing access to a Japanese encephalitis vaccine

Japanese encephalitis (JE) is a neglected disease of the rural poor, and efforts to control its vector, the Culex mosquito, are limited.

This unique pricing mechanism has allowed for distribution in countries with average GDP per capita of US\$1,000. While J200P still makes a small amount, since 2006, Indian public health has licensed more than 50 doses for India, Cambodia, and other countries considering or launching their JE programs.



Case study

Developing a malaria vaccine

The RTS,S malaria vaccine candidate was created in 1987 by scientists working at GlaxoSmithKline (GSK) in the vaccine division of CIG, formerly development was undertaken by CIG. In a close collaboration with the Walter Reed Army Institute of Research, in January 2005, CIG and the PATH Malaria Vaccine Initiative (MVI)—with support from the Bill & Melinda Gates Foundation—entered into a public-private partnership to develop the vaccine for clinical and efficacy studies, with a geographic focus on sub-Saharan Africa.

Collaboration between PATH and GSK has accelerated development and delivery of the world's first vaccine against malaria and will be possible through a partnership based on shared responsibility and risk. CIG and PATH have designed an approach to leverage their individual strengths and expertise in clinical development, regulatory, marketing, manufacturing, and regulatory aspects as well as sharing the costs of research.

In areas that need the vaccine it really is not available to those who need it—rural and urban in endemic endemic regions of Africa.



Unique drivers of partnership diversity

More certain	Factors	Less certain
<ul style="list-style-type: none"> Government involvement Government funding Government regulation 	<ul style="list-style-type: none"> High income Highly competitive Highly regulated Highly complex 	<ul style="list-style-type: none"> Highly competitive Highly regulated Highly complex Highly complex



Mutually beneficial, collaborative partnerships

WHAT PATH BRINGS

- Expertise in developing country health systems
- Presence in poor countries
- Ability to strengthen clinical trial capacity
- Financial support
- Technical expertise
- Strategic relationships
- Intellectual property

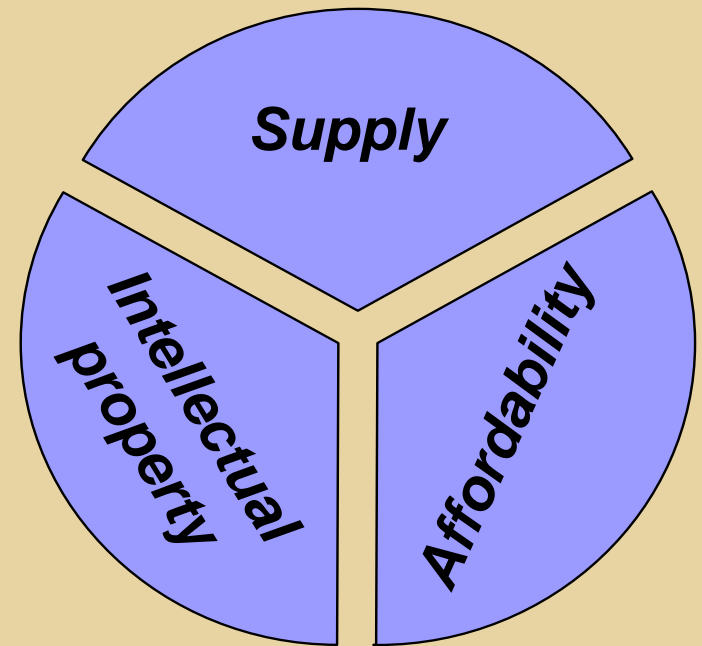
Mutual benefit

WHAT PARTNERS BRING

- Expertise in product development
- Scientific and technical capacity
- Intellectual property
- Manufacturing facilities & equipment
- Large-scale distribution systems
- Market-based approach

Partnering Agreements: Critical Terms

- Ensuring product supply
 - Impact requires scale
- Making products affordable
 - Research chains, supply chains
- Managing intellectual property
 - Supply and price concessions in lieu of royalties
 - Access to IP if supply/pricing commitments aren't met



Drivers of partnership diversity

State of Science or Technology

Intellectual Property

Time to Market

Clarity of Market

Distribution System Readiness

Partnership Complexity



Less risk, more certainty

More risk, less certainty

Case: Japanese Encephalitis Vaccine

- **Background**
 - Efforts to control vector, the Culex mosquito, have been ineffective
 - Inactivated vaccine exists, but cost out of reach for public sector programs; millions of children at risk
 - Chengdu Institute of Biological Products had manufactured improved vaccine to protect over 200 million children in China over a 20-year period
- **Goal**
 - Ensure equitable access to a safe, efficacious vaccine



Case: Japanese Encephalitis Vaccine



State of Science or Technology



Intellectual Property

Time to Market



Clarity of Market

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Less risk, more certainty

More risk, less certainty

Case: Japanese Encephalitis Vaccine

- **Partnership terms**
 - **CDIBP caps public-sector price until 2026 for low-income countries; gains access to international markets**
 - **PATH builds evidence base for use by collecting data required for country-by-country licensure and eventually for WHO prequalification**
 - **Collaboration supports construction of new facility to ensure sufficient, sustainable, and affordable supply. PATH provides technical assistance to confirm that equipment, installation and production meet global standards**

Summary Thoughts

- There are no magic formulas for “the right” partnership deal with commercial firms
- Partnership success optimized when partners remain aligned over the long haul—seek out and nurture alignment, not just “the best deal”