

Developing a pneumococcal vaccine for poor countries



PATH/Susan Sola

Approximately 1.6 million people die each year from pneumococcal disease, caused by infection with *Streptococcus pneumoniae* bacteria. More than half of the deaths are among children less than five years old, mostly in lower-income countries. Although several pneumococcal vaccines are already on the market, they do not protect people against all strains of the bacteria, and they are expensive.

Developing a vaccine containing proteins that are common to all pneumococcus serotypes could provide broad protection to children worldwide. To advance such a vaccine, PATH partnered with the Austrian biotechnology firm Intercell AG, which has developed proprietary antigen discovery technology for a protein-based vaccine, but also has several

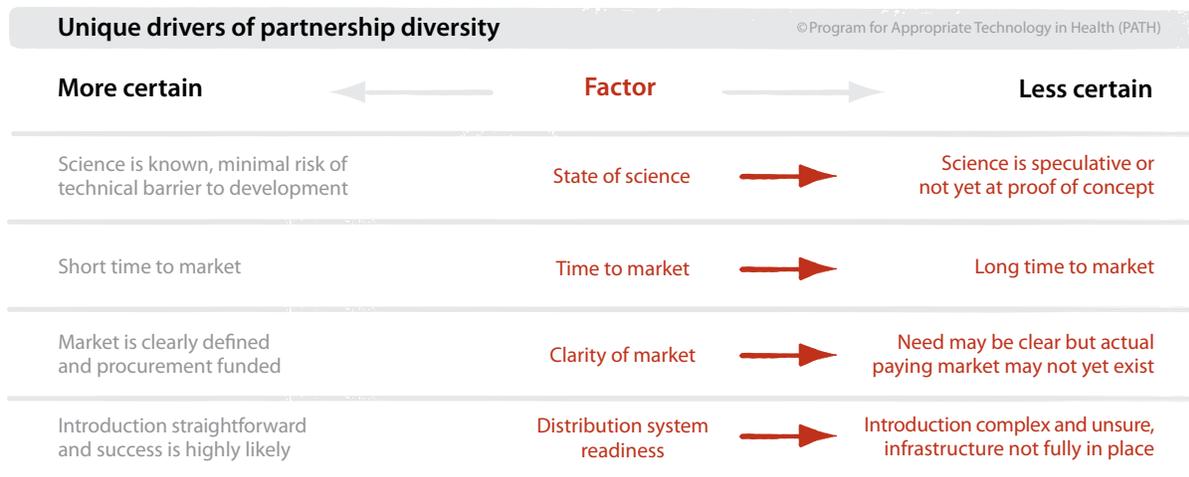
vaccines in late-stage clinical development and recently received approval of its Japanese encephalitis vaccine. PATH's ultimate goal is an affordable vaccine for distribution by public health systems in low-income countries.

Collaboration between PATH and Intercell

The partnership agreement between PATH and Intercell covers preclinical development through phase 2 clinical trials. It includes draft guidelines for a commercialization agreement to be negotiated before the start of phase 3 studies, to include specific commitments on price and supply of the vaccine for public-sector markets in low-income countries.

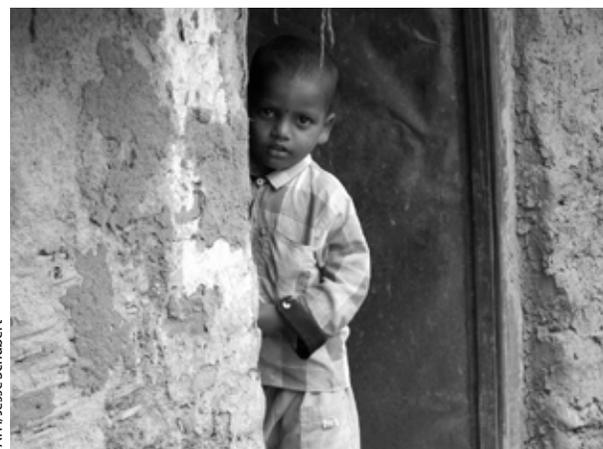
Each organization brings complementary expertise to the project, which is managed collaboratively through a joint development committee. Whereas Intercell's efforts have focused so far on discovery and preclinical development, PATH provides expertise in clinical trials (especially in lower-income countries), manufacturing, and vaccine introduction.

The partners also share development costs. Funding from PATH has covered almost half of preclinical development expenses, thus reducing Intercell's risk. Without this funding, Intercell would likely have focused solely on developing a vaccine for elderly people in Europe and the United States rather than



expanding the target market to include children in low-income countries.

Successful preclinical development from 2006 through 2008 has paved the way for a phase 1 clinical trial in healthy adults beginning in early 2009. The next step is to prepare for clinical development in children in developing countries including the supply of clinical trial material and necessary regulatory approval.



PATH/Jesse Schubert

Drivers of a unique partnership

Several critical factors make this partnership unique:

- **State of science:** The scientific approach is innovative, and there is no clear proof of concept. In addition, the regulatory pathway is untested. The partnership is thus structured with clearly defined milestones and a close working relationship, and the development work is funded in stages based on achievement of milestones.
- **Distribution system readiness, time to market, clarity of market:** These factors are much less certain for immunizing children in low-income countries than for immunizing older adults in high-income countries. The partnership is therefore structured to allow for divergence of vaccine development as work progresses to clinical trials involving very different populations in rich and poor countries. It also allows partners to address markets and pricing in a manner to support each of the final vaccine formulations and target populations.



info@path.org
www.path.org
Tel: 206.285.3500
Fax: 206.285.6619

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