Case study

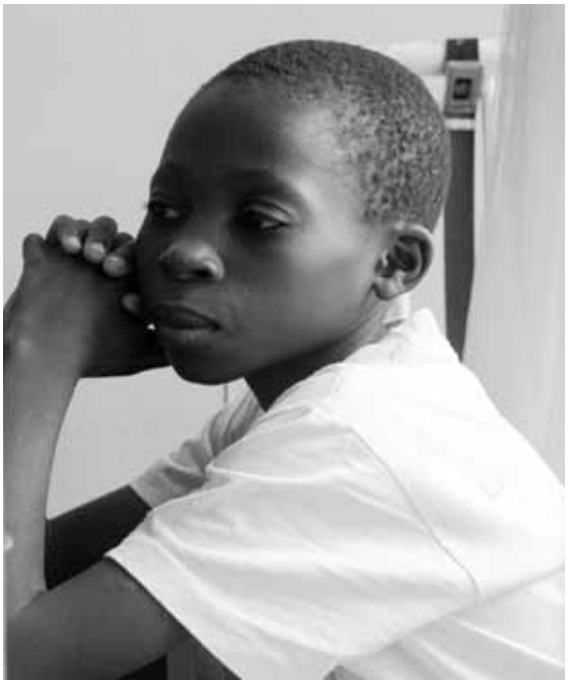
Developing a malaria vaccine

The RTS,S malaria vaccine candidate was created in 1987 by scientists working at GlaxoSmithKline Biologicals (GSK Bio), the vaccine division of GSK. Its early development was undertaken by GSK Bio in close collaboration with the Walter Reed Army Institute of Research. In January 2001, GSK Bio 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 infants and young children, with a geographic focus on sub-Saharan Africa.

Collaboration between PATH and GSK Bio

Successful development and delivery of the world's first vaccine against malaria can only be possible through a partnership based on shared responsibility and risk. GSK Bio and MVI have designed an approach to leverage their individual strengths and expertise in clinical development, capacity-building, manufacturing, and regulatory aspects as well as sharing the financial burden.

A multicenter Phase 3 efficacy trial began in May 2009. The trial will seek to more precisely define the vaccine's efficacy and continue to closely monitor safety. MVI and GSK Bio have defined commitments to ensure that once the vaccine is ready, it will be available to those who need it—infants and children in malaria-endemic regions of Africa.



David Jacobs

Unique drivers of partnership diversity

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
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
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

Drivers of a unique partnership

Key factors shaping development of PATH's partnership with GSK Bio include the following:

- State of science: The science of malaria vaccine development is extremely challenging, due in large part to the complexity of the parasite. No vaccine against a parasite has ever been approved for use in humans.

- Time to market: The many scientific and logistical challenges that accompany the development of a malaria vaccine do impact time to market. If the Phase 3 trial progresses as expected, RTS,S could be submitted for regulatory review as early as 2012. Depending on the final clinical profile of the vaccine and the timetable of the regulatory review process, the first vaccine introduction could take place over the next three to five years.

- Clarity of market: Malaria remains a massive public health burden, but the market for a malaria vaccine—particularly a first-generation vaccine with partial efficacy—was unclear at the start of the collaboration. To better understand the potential demand for malaria vaccines, MVI has engaged with stakeholders in African countries and projected uptake of a first malaria vaccine.

- Partnership complexity: Due to the size and complexity of the RTS,S program, the PATH–GSK Bio collaboration has expanded. The clinical development of RTS,S is managed by the Clinical Trial Partnership Committee, a collaboration of leading African research institutes, northern academic partners, MVI, and GSK Bio that works with government partners to ensure that the trial adheres to the highest clinical, ethical, and safety standards.

Aurelio Ayala III

PATH
A catalyst for global health

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

Printed on recycled paper
November 2009