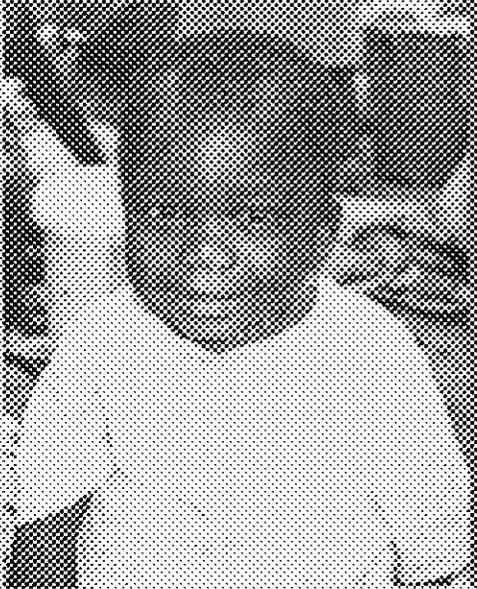


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Annual Report

Submitted by Program for Appropriate Technology in Health  
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## **Executive Summary**

PATH carried out the following activities from October 1, 2004, through September 30, 2005.

The agreement between PATH and the US Agency for International Development (USAID) was signed on October 8, 2004. Subsequent conversations led to a defined scope of work and budget submitted November 23, 2004, and approved by USAID on December 3, 2004.

### **FMP-1 Phase 2b Clinical Trial**

The clinical plan was approved by the U.S. Food and Drug Administration, PATH's Human Subjects Protection Committee, the Kenya Medical Research Institute Institutional Review Board (IRB), and the Department of Defense Human Subjects Research Review Board. The clinical trial was initiated and 400 children were recruited. All three doses of vaccines have been delivered and the subjects have been followed according to the IRB-approved protocol up through study day 200. Surveillance is continuing. There have been no vaccine-related serious adverse events. Completion of the six-month primary efficacy period is anticipated in Q4 2005 with preliminary data being available toward the end of Q1 2006. A total of \$1,100,000 USAID funds have been used to support the trial activities in Kenya.

### **Malaria Vaccine Market Assessment**

During this period, the PATH Malaria Vaccine Initiative (MVI) continued to work under a subcontract with the Boston Consulting Group (BCG) to conduct a comprehensive malaria vaccine market assessment, which started in mid 2004. In collaboration with MVI, BCG developed a flexible modeling tool (based on extensive primary and secondary research) that for the first time makes it possible to:

- Develop sophisticated projections of potential public and private demand for a malaria vaccine.
- Identify barriers to and drivers of malaria vaccine demand and which of these might have the biggest impact on demand.
- Highlight key points in the areas of financing, policy, and advocacy where planning and intervention by the public and private sectors can have the greatest impact on demand and supply conditions for public immunization programs.

The assessment is complete, and presentations on the results have been made in the United States, Africa, and Europe.

Building upon this work, MVI subcontracted with BCG to develop an investment case for malaria vaccines, adding components to the demand model that project estimates of both financial return on investment to companies and social return on investment to the public sector

if they support the use of a vaccine. Key lessons learned from this work have driven the prioritization of MVI's activities and supported analysis and decision-making in the areas of policy, financing, and advocacy related to planning the introduction of malaria vaccines. A notable example of this is MVI's work to support discussions (with G8 governments and the World Bank) of advanced market commitments for malaria vaccines, where MVI's modeling tools have been used in the analysis and evaluation of such financing mechanisms.

A separate proposal to conduct primary research in additional countries in support of the analysis described above has been put forward. This additional work to enhance the model will increase its effectiveness and accuracy as a modeling tool and provide MVI and the field with better information upon which to focus work to support the high-impact introduction of malaria vaccines.

### **Decision-Making Framework**

There has been significant progress towards developing a decision-making framework. A Steering Committee (SC) has been established and meets regularly by telephone conference. Members of the committee represent a broad range of organizations including: ministries of health; World Health Organization (WHO), Headquarters and Africa Regional Office; USAID; United Nations Children's Fund, Headquarters; PATH's Malaria Control and Evaluation Partnership in Africa; and MVI.

The SC has endorsed an initial structure for the decision-making framework. Informing this structure are seven briefing papers, six of which are at a late-draft stage. They cover critical contextual issues, such as past experiences with and existing guidelines on the introduction of new malaria interventions and vaccines. The papers will be finalized in early 2006.

Unused resources from 2005 will be used to implement a consultation with approximately 13 African countries and partner organizations on the initial decision-making framework. The consultation will occur in Cotonou, Benin, on January 24-26, 2006, with WHO leading logistics development and the Minister of Health, Benin, as the host. The consultation participants will work together to develop the detailed structure within the framework.

A separate proposal has been put forward for fiscal year 2006 seeking support to begin to validate and roll out the framework by applying it in a limited number of Africa countries.

Materials described above and meeting summaries are available on request.

### **Financial Review**

PATH's quarterly financial report will be submitted by November 3, 2005, per the agreement terms.