



# Malaria Vaccine Technology Roadmap

## Executive Summary

August 2006

**MALARIA  
VACCINE**  
TECHNOLOGY  
ROADMAP





## Vision

The malaria vaccine community will develop an effective vaccine that prevents severe disease and death caused by *Plasmodium falciparum* malaria in children under five in sub-Saharan Africa and other highly endemic regions. Efficient global coordination and collaboration will stimulate the malaria vaccine pipeline and accelerate progress towards this achievement.

## Strategic Goal

By 2025, develop and license a malaria vaccine that has a protective efficacy of more than 80% against clinical disease<sup>1</sup> and lasts longer than four years.

## Landmark

By 2015, develop and license a first-generation malaria vaccine that has a protective efficacy of more than 50% against severe disease and death and lasts longer than one year.

<sup>1</sup> While the relationship between vaccine impact on clinical disease and death is complicated, many scientists believe that a vaccine that provides protection against clinical disease will provide an equivalent or higher protection against severe disease and death.

The world urgently needs a malaria vaccine to relieve the human suffering associated with the parasitic disease that kills more than one million people—most of them African children—every year. Hundreds of millions more people suffer from the effects of malaria. While drugs, insecticide-treated bednets, and other interventions are being used to reduce malaria's impact, the disease remains a tenacious adversary. A safe, effective, and affordable malaria vaccine would create a powerful public-health benefit by closing the gap left by other interventions.

Scientists have been working for decades to develop a preventive malaria vaccine. While they have successfully demonstrated that such a vaccine is possible, many challenges continue to impede progress on the road to an effective malaria vaccine. As a result, the Malaria Vaccine Advisory Committee to the World Health Organization (WHO), coordinated by the WHO Initiative for Vaccine Research (IVR), called for a collective effort to explore and address the challenges. This effort resulted in the Malaria Vaccine Technology Roadmap process.

The Malaria Vaccine Technology Roadmap process was jointly sponsored by the Bill & Melinda Gates Foundation, the PATH Malaria Vaccine Initiative (MVI), and the Wellcome Trust. A Roadmap Working Group, consisting of representatives of the sponsors and IVR, guided the process. Members of the malaria vaccine funders group<sup>2</sup> served as active participants and advisors. Energetics Incorporated assisted with the coordination of the process.

Over the course of a year and a half, the Roadmap process, described below, involved more than 230 experts representing 100 organizations from 35 countries. During the first two meetings, leading representatives from the malaria vaccine community identified the challenges facing malaria vaccine development, established a vision and goal,

<sup>2</sup> The malaria vaccine funders group, an informal group of some of the key funders of malaria vaccine development, includes the Bill & Melinda Gates Foundation, the European & Developing Countries Clinical Trial Partnership, the European Malaria Vaccine Initiative, the European Union, the PATH Malaria Vaccine Initiative, the US Agency for International Development, the US National Institute of Allergy and Infectious Disease, the Wellcome Trust, and the World Health Organization Initiative for Vaccine Research.

and developed a shared plan to accelerate malaria vaccine development. In a series of subsequent Stakeholder Meetings and consultation through the internet, the process sought input from the wider malaria vaccine community.

- Participants at the Vision Meeting, held in October 2004, in Hinxton, UK, identified a vision and goals and defined the challenges which need to be addressed to accelerate progress in malaria vaccine development.
- The Roadmap Workshop, held in March 2005, in Provence, France, convened participants to address the challenges identified during the Vision Meeting—creating action plans and identifying the highest priority initiatives that could accelerate malaria vaccine development.
- Three Stakeholder Meetings, held in Bethesda, Maryland, USA; Durban, South Africa; and Oxford, UK during 2005, provided additional opportunities to share results and to seek feedback from the broader malaria vaccine community regarding their expectations and potential roles in implementing a holistic malaria vaccine development strategy.

These five meetings were then followed by a synthesis process. Key experts reviewed the results of the meetings, considering carefully the collective input of the malaria vaccine community. These experts then provided recommendations about which activities could serve as strategic areas of investment to accelerate significantly



the development of a malaria vaccine. Based on further discussions with the malaria vaccine funders group, these recommendations were collated into the priority areas described in this document, the *Malaria Vaccine Technology Roadmap*.

## Priorities

To achieve the vision and goals, the malaria vaccine community has identified 11 priority areas that, if pursued, could accelerate the pace of progress. These priorities, composed of both new initiatives and ongoing efforts that require additional resources, represent the top priorities of the community. The priorities fall into four categories: research, vaccine development, key capacities, and policy and commercialization. They are described briefly below and in greater detail in the body of the Roadmap.

## Research

1. Develop a standard set of immunological assays with standardized procedures and reagents to enable comparisons of the immune responses of vaccines.
2. Standardize clinical trial design and assessment to allow comparison of data and to determine correlates of protection.
3. Use state-of-the-art approaches, including functional genomics, to characterize the biological functions of proteins at the interface of host-parasite interactions and to identify novel potential antigen candidates.
4. Develop web-based information-sharing tools to strengthen connections between the laboratory and the clinic.

## Vaccine Development

5. Establish a systematic approach for prioritizing sub-unit vaccine candidates using accepted pre-clinical criteria.
6. Pursue multi-antigen, multi-stage, and attenuated whole-parasite vaccine approaches.

## Key Capacities

7. Establish readily accessible formulation and scale-up process development capacity for malaria vaccines.
8. Build and broaden good clinical practice (GCP) clinical trial capacity in Africa and other malaria-endemic regions to accommodate the growing number of trials required for malaria vaccine development.

## Policy and Commercialization

9. Establish and maintain country-level dialogues to facilitate decision-making on malaria vaccine policy.
10. Secure sustainable financing for future procurement of vaccines.
11. Develop novel regulatory strategies to expedite approval while ensuring safety.

These priorities originated from the 55 key activities that were drawn from more than 225 specific scientific and policy challenges identified through the consultative roadmap process. If appropriately resourced, implementing these priorities could considerably shorten the time required to develop and implement a malaria vaccine.

Existing funders of malaria vaccine development have extended their support to the Roadmap process as a mechanism for better coordination and improved resourcing for malaria vaccine research and development. The malaria vaccine funders group calls upon new and existing partners to join them in supporting these priority areas by using the Roadmap as a path to continue to accelerate progress toward the goal of an effective malaria vaccine.



For more information, please visit  
[www.MalariaVaccineRoadmap.net](http://www.MalariaVaccineRoadmap.net)

The eventual success of the Roadmap depends on the ongoing commitment of all to realize the vision of the process—to develop a preventive malaria vaccine that can save millions of lives.



Photos courtesy of:  
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