



## Global strategy aims for effective malaria vaccine by 2025

4 DECEMBER 2006 | BANGKOK -- A report by the world's leading international health organizations today calls for joint action to accelerate the development and licensing of a highly effective malaria vaccine.

The *Malaria Vaccine Technology Roadmap*, a new global strategy, is being launched today in Bangkok at the Global Vaccine Research Forum which is taking place from 3 to 6 December.

"Having a highly protective malaria vaccine and putting it into widespread use in affected areas would be a true achievement for public health. It would fulfill an urgent need," said Dr Marie-Paule Kieny, Director of the Initiative for Vaccine Research, World Health Organization (WHO). "The *Roadmap* marks the first concerted global attempt at mapping out a shared plan of action for making a preventive malaria vaccine reality."

The *Roadmap* is a pathway towards reaching the goal of developing a malaria vaccine by 2025 that would have a protective efficacy of more than 80% against clinical disease and would provide protection for longer than four years. An interim landmark would be to develop and license a first-generation vaccine by 2015 with 50% protective efficacy against severe disease and death that would last longer than one year.

Every year, there are 300-500 million cases of malaria and the disease kills more than one million people, mainly African children. The plan calls for the malaria vaccine community — scientists, funding organizations, policy experts and national and global decision-makers — to work together to develop an effective vaccine that prevents severe disease and death caused by *Plasmodium falciparum*, the most deadly form of the malaria parasite.

In the WHO South-East Asia Region, which includes Thailand, nearly 19 million estimated cases of malaria and an estimated 99 000 deaths occurred in 2005.

More than 230 experts representing 100 organizations from 35 countries collaborated to develop and publish the *Roadmap* over a two-year period. Leading malaria community representatives, experts, and funders held a series of meetings to determine ways to overcome challenges facing the development of a malaria vaccine.

Challenges include: scientific unknowns such as the lack of full understanding of mechanisms of malaria infection, disease and immunity, inadequate resources, limited private-sector involvement, and uncertain mechanisms for procuring and distributing a successful vaccine.

The *Roadmap* puts into motion a strategic plan for aligning research and for developing and making available a safe, effective and affordable vaccine to prevent malaria in children under five years of age in sub-Saharan Africa and other highly endemic regions. It presents 11 priorities within four major areas of work that must be undertaken — in a more coordinated manner than previously — by diverse parties towards the development of a malaria vaccine. They are:

- Research: standardizing procedures to compare immune responses generated by vaccine candidates, using state-of-the-art approaches and sharing information via the web to strengthen the connection between laboratories and clinics.
- Vaccine development: including pursuing multi-antigen, multi-stage, and weakened whole-parasite vaccine approaches.
- Key capacities: establishing readily accessible formulation and scale-up development capacity, and building good clinical practice clinical trial capacity in Africa and other malaria-endemic areas.
- Policy and commercialization: dialoguing with countries and providing data to facilitate policy decisions; securing sustainable financing; and developing novel regulatory strategies to expedite the approval of a safe vaccine.

"The pace of progress towards a malaria vaccine could dramatically accelerate if these priority areas are successfully pursued," said Dr Melinda Moree, Director of the PATH Malaria Vaccine Initiative which coordinated the development of the *Roadmap*. "Information sharing and collaboration needs to be stepped up to enhance learning across studies and eliminate redundant work. Above all, continued commitment to this initiative is vital. Developing an effective malaria vaccine is an enormous challenge, but it is within reach."

The development of the *Roadmap* was sponsored by the Bill & Melinda Gates Foundation and the Wellcome Trust. These two

foundations, as well as others from the "malaria vaccine funders' group" (see below), are investing resources into priority *Roadmap* activities. They have recently been joined in this endeavor by the Fondazione Monte dei Paschi di Siena who had never before funded malaria vaccine projects.

Scientists have recently confirmed that it is possible to develop a malaria vaccine. Currently, there are more than 30 potential vaccine candidates under development—far more than there is capacity or funding to investigate in clinical trials, especially in endemic countries.

Additional resources will be needed to support research on vaccine candidates and to advance promising candidates through clinical development. New and existing donors are urged to support priorities identified in the *Roadmap*.

## Malaria vaccine funders' group

WHO, PATH MVI, the Bill & Melinda Gates Foundation and the Wellcome Trust, together with representatives of the European and Developing Countries Clinical Trials Partnership (EDCTP), the European Malaria Vaccine Initiative (EMVI), the European Commission (Directorate General for Research), the United States National Institute for Allergy and Infectious Diseases (NIAID), and the United States Agency for International Development (USAID) form part of a malaria vaccine funders' group, with the WHO Initiative for Vaccine Research as its focal point. The group's participation and support was critical to the Roadmap process.

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