

THE PATH MALARIA VACCINE INITIATIVE (MVI) is a global program established at PATH through an initial grant of \$50 million from the Bill & Melinda Gates Foundation. MVI's mission is to accelerate the development of malaria vaccines and ensure their availability and accessibility in the developing world. MVI's vision is a world free from malaria. For more information, please visit www.malariavaccine.org.

Founded in 1977, **PATH** is an international, nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH's work improves global health and well-being. For more information, please visit www.path.org.

SBRI advances global health. Our infectious disease research is the foundation for new drugs, vaccines, and diagnostics that benefit those who need our help most: the 14 million who will otherwise die each year from infectious diseases. A nonprofit organization founded in 1976, SBRI has nearly 250 staff members working in research labs in Seattle and field labs in Tanzania. By partnering with key collaborators around the globe, we ensure that our discoveries will save lives sooner. For more information, visit www.sbri.org.

Accelerating the Quest for Malaria Vaccines by Expanding Capacity for "Human Challenge" Trials

THE PROJECT: Establishing a Human Challenge Center

The PATH Malaria Vaccine Initiative (MVI) is collaborating with the Seattle Biomedical Research Institute (SBRI) to establish a center devoted to testing the safety and efficacy of malaria vaccine candidates in humans. The new Human Challenge Center (HCC) at SBRI will be one of only a handful of facilities of its kind worldwide and will help meet the growing demand to test new interventions against the deadly malaria parasite. Slated for completion in late 2009, the Human Challenge Center is the critical foundation of the Malaria Clinical Trials Center (MCTC) at SBRI and will help expedite clinical assessment of malaria vaccine candidates.

MVI is providing technical and financial support for the development of the MCTC as part of its efforts to accelerate the assessment of malaria vaccine candidates and thereby ensure that only the most promising candidates advance to field trials.

THE POTENTIAL: Progressing Vaccine Candidates into Advanced Trials

Malaria kills close to one million people every year, most of them children in sub-Saharan Africa. The malaria parasite's complexity and adaptability have ensured its survival for millennia, despite a diversity of tools to fight and prevent the disease. The world urgently needs a safe and effective vaccine to add to the arsenal of weapons against this disease.

The Human Challenge Model

After a malaria vaccine candidate has been tested for safety in a small number of healthy adult volunteers, some candidates (typically those targeting the early stage of malaria infection) may undergo a challenge phase of testing. During the challenge phase, volunteers vaccinated with a malaria vaccine candidate are deliberately infected with malaria through the bite of malaria-infected mosquitoes to assess whether or not the candidate vaccine can prevent or delay malaria infection.

The HCC has the potential to impact the entire malaria vaccine development community by helping to meet the growing demand to test new interventions against the deadliest malaria parasite, *Plasmodium falciparum*, as well as provide new insights into the mechanisms of malaria immunity and malaria vaccinology.