



External Evaluation of the Malaria Vaccine Development Program Conducted in 2016
USAID Management Response
September 9, 2016

The United States Agency for International Development (USAID) welcomes the findings and recommendations of the external evaluation of the Malaria Vaccine Development Program (MVDP) during the ten-year period since the last external evaluation in 2003 (i.e., 2003-2015). USAID views the evaluation findings as important to inform our continued investments in developing and implementing a highly efficacious, durable, and cost-effective malaria vaccine. USAID commissioned this evaluation to obtain the advice of infectious disease and vaccine development professionals and stakeholders on the appropriateness of current MVDP priority investments as well as recommendations for future direction. The evaluation team consisted of three consultants selected based on their individual expertise: Dr. Peter Nsubuga, an evaluation specialist, Dr. Deepak Gaur, a preclinical malaria vaccinologist, and Dr. Mark Polhemus, an infectious disease clinician with significant experience in malaria vaccinology. Three overarching questions were asked as part of the evaluation:

1. What has been the value added of the MVDP to the current status of malaria vaccine development?
2. How is the MVDP complementary to other programs funding malaria vaccine development?
3. Given the historical role of the MVDP, is this role critical going forward, or, given the changing funding environment for malaria vaccine development, should the focus of the USAID MVDP strategy be modified?

The evaluation team's findings in response to the three evaluation questions and their recommendations were based on what was learned through an evaluation methodology consisting of interviews with MVDP partners, selected experts, and other stakeholders in person and through a survey instrument. The team's conclusions in answering the questions posed were that (1) "The MVDP has used its limited resources to catalyze the process through strategic research on the continuum of malaria vaccine development, particularly in the approach of pre-erythrocytic and blood stages" and that (2) "the MVDP has a unique niche as a catalyst in the malaria vaccine development community, using its expertise and flexible funding to support policy and science." Further, the team concluded that (3) "The MVDP is appropriately focused on the development of pre-erythrocytic and erythrocytic vaccines to prevent and control clinical disease."

The evaluation team provided five main recommendations to USAID for further enhancement of MVDP efforts. USAID agrees with the findings and considers these recommendations relevant and useful for

informing future MVDP investments. USAID reviewed the report and has developed the following responses for each of the five recommendations:

Recommendation 1: With the limited funding globally, which is focused on vaccines to impact malaria morbidity and mortality, the MVDP should continue to support this area and evaluate where it can have the most impact as a funder. Based on the surveys and key informant interviews, MVDP could have the greatest impact now by focusing on:

- a. Continued evaluation of new antigens (pre-erythrocytic and blood-stage) that could be added to RTS,S or replace it;**
- b. Methods to select which vaccine candidates to advance or down-select;**
- c. Transitioning preclinical successes into clinical development through evaluation of vaccine platforms, funding GMP lots and toxicology studies and evaluating vaccine efficacy in CHMI models.**

Management Response: USAID agrees with the recommendation and will continue to focus MVDP investments on those elements recommended in the evaluation. Action: The USAID MVDP will continue to support the recommended elements, incorporating a balanced portfolio approach that evaluates and takes advantage of emerging technologies while also adhering to traditional vaccine development practices.

Recommendation 2: In the continued evaluation of where the MVDP can have the most impact, an expanded role for the SCG (Scientific Consultants Group) should be considered. The SCG could play a prospective role in determining areas to fund and meet in smaller groups more often to take stock of ongoing projects.

Management Response: USAID agrees with the recommendation and highly values the critically important technical input and guidance that the SCG provides to guide and shape program priorities and investments decisions. USAID will seek to increase consultation with individual SCG members on an ad hoc basis in addition to convening the annual meeting of the SCG as a whole, taking into account the time demands and numerous competing professional priorities of SCG members. Given the real time limitations of SCG members, efforts to assemble the group as a whole more than once a year have not proven feasible. Action: USAID will proactively target consultations with individual SCG members for advice in areas of specific expertise in response to the recommendation and enhance consultation with the full SCG as much as their availability allows.

Recommendation 3: The MVDP should consider publishing or communicating its current mechanisms for collaborating with partners outside the DOD. The Leidos contract may sufficiently extend the capabilities of the MVDP to entertain research and development efforts not available through the DOD, but currently this is not well understood in the greater malaria vaccine development community, including with some longstanding partners.

Management Response: USAID agrees with the recommendation and will take action to raise the visibility of the USAID MVDP portfolio, such as updating the USAID Global Health Bureau webpage, disseminating the USAID Research Report to Congress in which the MVDP portfolio is mentioned, identifying external

venues where key global stakeholders will be present (relevant scientific fora) and creating a space to summarize the MVDP portfolio as a whole, etc. The MVDP portfolio is multifaceted by design. In addition to interagency agreements with WRAIR (Walter Reed Army Institute of Research), NMRC (Naval Medical Research Center), and NIAID (National Institute of Allergy and Infectious Diseases), USAID has competitively awarded a five-year contract to the Leidos Corporation to support USAID's malaria vaccine research and development projects. The Leidos contract is the mechanism through which the USAID MVDP is able to fund non-U.S. Government collaborators. The Leidos contract was awarded through an open and competitive process consistent with USG rules and regulations. The Leidos contract works through sub-contractors, which are groups that execute the specific research projects and who are selected through standard subcontracting procedures.

Recommendation 4: Plan for the long lead time it will take to train successors for Dr. Diggs and Dr. Soisson. USAID has been served remarkably and admirably by Drs. Carter Diggs and Lorraine Soisson. A succession plan that reflects the need for continuity of the technical team and supports the continuation of MVDP's relationships and broad impact will be useful to USAID.

Management Response: USAID agrees with the recommendation and will develop a staff succession plan to ensure institutional continuity of the technical team. USAID welcomes and appreciates the recognition of the remarkable expertise and leadership of Drs. Diggs and Soisson and is mindful that it will take time to grow expertise and experience close to what exists in the current team now. Action: USAID will develop a staff succession plan that includes the exploration of mechanisms that allow for overlap of potential successors with current staff.

Recommendation 5: Evaluate current funding levels for the MVDP. The overall funding for malaria vaccine development is limited. The potential impact of MVDP funding has increased with the movement of BMGF funding to transmission blocking. Many of the areas suggested for MVDP focus (GMP lot manufacturing, toxicology studies and CHMI human trials) are expensive, multi-year endeavors. Thus, given the unique role and critical niche MVDP has in the malaria vaccine development community, increased funding could support more of the areas of research suggested as most important for MVDP funding and speed vaccine development efforts through critical milestones.

Management Response: USAID appreciates the observation that overall funding for malaria vaccine development globally is limited. USAID remains committed to continued investment of resources in malaria vaccine development through the MVDP partners. Action: USAID will continue to prioritize investments in malaria vaccine development with an eye to the long-term.

Conclusion: USAID thanks the MVDP evaluation team and the numerous malaria vaccine development stakeholders who contributed to this evaluation. The recommendations provided will sharpen USAID's focus on the goal of development and implementation of an efficacious, durable, and cost-effective malaria vaccine for use in control programs to mitigate morbidity and mortality due to *Plasmodium falciparum* malaria.