

# Update on RTS,S Malaria Vaccine Implementation Programme

October 2018, Geneva, Switzerland

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## Background

The Malaria Vaccine Implementation Programme (MVIP) has been developed to execute the 2016 WHO recommendation for pilot implementation of the of the RTS,S/AS01 malaria vaccine<sup>1</sup> to address several outstanding questions related to the public health use of the vaccine. The MVIP supports the routine introduction of the malaria vaccine in selected areas of three pilot countries (Ghana, Kenya and Malawi) and rigorous evaluation of the programmatic feasibility of administering the required four doses, the vaccine's impact on mortality, and its safety in the context of routine use.

The Programme is jointly coordinated by the Global Malaria Programme (GMP), the Immunization, Vaccines & Biologicals (IVB) Department and the WHO Regional Office for Africa, collaborating closely with other WHO departments and country offices, Ministries of Health in pilot countries, PATH and other partners. The introduction of the malaria vaccine is country-led.

## Update since March 2018

Following a joint review convened by the African Vaccine Regulatory Forum (AVAREF), the national regulatory authorities in all three MVIP countries granted special authorization for use of the RTS,S malaria vaccine in the pilot areas. This is a key milestone on the path towards vaccine introduction.

Following a competitive bidding process, research consortia in MVIP pilot countries were selected to lead the evaluation of the RTS,S vaccine introduction; contracts are in the process of being finalized. The first investigators' meeting was held in Ghana in July 2018 to review all components of the evaluation in detail, and consider timelines for protocol development, ethical review and evaluation readiness. Country-specific protocols are under development.

The updated timelines for evaluation activities have enabled the EPI Programmes to revise the vaccine introduction dates, shifting from Q3/Q4 2018 to Q1/Q2 2019, possibly Q3 2019 in the third country. The revisions were necessary to account for the time required to secure ethics approval of the evaluations in each country, set up the relevant surveillance

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<sup>1</sup> Malaria vaccine: WHO position paper – January 2016. Geneva: World Health Organization; 2016 (<http://www.who.int/wer/2016/wer9104.pdf>).

systems and accommodate the RTS,S introduction into the busy activity schedule of the EPI Programmes. Preparations are underway for a January 2019 announcement of vaccine introductions in Malawi and Ghana. Communications plans, including a crisis communications strategy, are in place or being finalized. Vaccine supply is ready for shipment.

A competitive process to identify an external monitor is almost complete, and negotiations are underway with a reference laboratory to undertake the definitive analyses of CSF samples from sentinel hospitals.

A consultant statistician and a data manager have been contracted to support the development of the statistical analysis plan and data management platform, respectively. The hiring of dedicated staff in the WHO Regional Office for Africa and the three pilot countries is progressing.

Besides regular updates to the MVIP Q&A on the WHO website,<sup>2</sup> additional external communications materials have been developed, including:

- MVIP Brochure: <http://www.who.int/malaria/publications/atoz/first-malaria-vaccine/en/>
- MVIP information and resources on the WHO website: [http://www.who.int/immunization/diseases/malaria/malaria\\_vaccine\\_implementation\\_programme/en/](http://www.who.int/immunization/diseases/malaria/malaria_vaccine_implementation_programme/en/)

The MVIP Programme Advisory Group and the Data Safety and Monitoring Board have met quarterly and provided guidance to the programme. A comprehensive update on the MVIP was provided to SAGE in April 2018.<sup>3</sup> As suggested by MPAC and SAGE, a working group (including two MPAC members) has been constituted to develop the Framework for Policy Decision. An initial teleconference was held in June 2018 and a face-to-face meeting is planned for December 2018. Progress on the Framework will be reported back to MPAC in 2019.

## Priorities for the next 6 months

Key priorities in the coming months include supporting the EPI Programmes to launch the RTS,S vaccination programmes in Q1/Q2 2019 (including finalization of monitoring and reporting tools, supply of vaccines and devices, training of health workers, social mobilization and communications, etc.), and supporting the evaluation partners to finalize protocols, conduct the baseline household surveys and ensure the hospital- and community-based surveillance systems are fit for purpose.

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<sup>2</sup> MVIP Q&A: <http://www.who.int/malaria/media/malaria-vaccine-implementation-qa/en/>

<sup>3</sup> The background documents and presentations for the April 2018 SAGE meeting are available here: [http://www.who.int/immunization/sage/meetings/2018/april/presentations\\_background\\_docs/en/](http://www.who.int/immunization/sage/meetings/2018/april/presentations_background_docs/en/)  
The SAGE meeting report is available here: <http://apps.who.int/iris/bitstream/handle/10665/272782/WER9323.pdf>

In 2019, the MVIP team will engage with funders to secure funding for the second phase of the 6-year Programme (i.e. from 2021 to completion of the pilots).

## **Contact**

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