

RTS,S MEDICAL AND SCIENTIFIC QUESTIONS & ANSWERS

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Disclaimer

The primary focus of this resource is to be an internal training tool for RTS,S malaria vaccine candidate, containing related data in the format of a Q&A for Medical Affairs personnel. Information presented here is not for external distribution.

Whilst this document can be inspirational for reactive responses to experts or medical enquiries, local regulations, the GSK Code of Practice, scientific engagement principles and/or medical information processes should be followed appropriately.

Please Note

- For media enquiries, please refer to the specific reactive Q&A for Media Enquiries and notify the Global Pipeline Communications team before you respond to a request for an interview so that they can help you to prepare (contact person: Aoife Pauley at aoife.x.pauley@gsk.com).
- The vaccine RTS,S/AS01 has completed phase 3 clinical program and positive regulatory assessment from the European Medicines Agency, but is not yet authorized for marketing in any country. The RTS,S vaccine is being developed in Public Private Partnership with PATH-MVI, as an additional tool to be added to the currently available malaria preventive interventions and for implementation through the national immunization programs in malaria endemic regions in sub-Saharan African countries.
- When referencing clinical data on RTS,S any statements should be prefaced by "In this study...", to make it clear that it is too early to make any general statement on the vaccine profile outside the context of the ongoing clinical trials.
- Have you found what you were looking for? If you have any suggestions for information which should be included in this tool please contact us at the following address: Carys Calvert at carys.calvert@gsk.com.

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What are the FMP2.1/AS02 trial results that were published in 2011 in the NEJM, and how do they relate to the RTS,S malaria vaccine candidate?

The results of a Phase II proof of concept trial examining the efficacy of FMP2.1/AS02, a blood-stage malaria vaccine candidate, in adults and children in Mali, were published in the September 2011 issue of the NEJM^(a). In general the study revealed that FMP2.1/AS02 did not provide significant protection against clinical malaria although secondary and exploratory endpoints suggested that it may warrant further investigations. Even though this vaccine candidate is no longer actively pursued, the results of this study provide useful information to generate new strategies for the development of vaccines targeting the blood stage of the *Plasmodium falciparum* parasite.

This Phase II study was a collaboration between the Malaria Research and Training Centre (MRTC) at the University of Bamako, Mali, the Centre for Vaccine Development at the University of Maryland, the United States Agency for International Development (USAID), the Walter Reed Army Institute of Research in Washington DC (WRAIR), National Institute of Allergy and Infectious Diseases (NIAID), the US National Institutes of Health (NIH), NIAID (NIH) and GSK Biologicals.

a. Thera M, et al. NEJM 2011; 365: 1004-13.