

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 is the study evaluating a delayed fractional dose of RTS,S?

This proof-of concept study (Malaria-071)^(a) aims to evaluate an increased capacity of RTS,S/AS01 to protect naïve adults against a sporozoite challenge when administered as an alternative dose/schedule (third dose is a 1/5th of the standard dose and given at month 7) as compared to the standard dose and schedule (months 0, 1 and 2). A previous study^(b) had previously indicated a potential for this concept using RTS,S with another adjuvant system, AS02. Results are expected in 2014.

a. *ClinicalTrials.gov* - NCT01857869

b. *Stoute J. et al. NEJM* 1997; 336: 86-9