

RTS,S MEDICAL AND SCIENTIFIC QUESTIONS & ANSWERS

For internal use only - NOT FOR DISTRIBUTION

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.

RTS,S MEDICAL AND SCIENTIFIC QUESTIONS & ANSWERS

For internal use only - NOT FOR DISTRIBUTION

What is the effect of RTS,S on different parasite strains?

RTS,S will only induce protection against malaria caused by *Plasmodium falciparum*. Neafsey et al investigated the genetic diversity of *P falciparum* and the protective efficacy of RTS,S^(a). The authors conclude that their results suggest that among children 5 to 17 months of age, the RTS,S vaccine had greater activity against malaria parasites with the matched circumsporozoite protein allele than against mismatched malaria. The overall vaccine efficacy in this age category will therefore depend on the proportion of matched alleles in the local parasite population.

Since in the efficacy trial, less than 10% of parasites had matched alleles, it also means that the results of the Malaria-055 trial are representative of the vaccine efficacy in an environment where the malaria parasites with the matched circumsporozoite protein allele are relatively rare. Genetic diversity will be actively monitored in the phase 4 program to evaluate if widespread RTS,S use has the potential to change parasite genetic diversity.

a. Neafsey D et al. *N Engl J Med* 2015; 373:2025-2037