

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

Why is RTS,S only partially or moderately efficacious?

We currently do not know why the RTS,S malaria vaccine candidate is only moderately efficacious, but it is not overly surprising given that even people living in malaria endemic regions develop only partial immunity against malaria, despite being exposed regularly to infection by the malaria parasites.

A pre-erythrocytic malaria vaccine like the RTS,S malaria vaccine candidate should help the body's immune system kill sporozoites before they can infect a significant proportion of red blood cells and cause disease. However, only one sporozoite escaping the vaccine induced defence mechanisms is sufficient to start a blood stage infection resulting in clinical disease. Vaccine efficacy against clinical disease refers to the reduction in the risk of a child becoming infected and experiencing malaria disease and reflects the reduction of the number of malaria episodes for any child vaccinated.

In the phase III efficacy study, for every thousand vaccinees RTS,S was able to prevent more than thousands of clinical malaria cases in some of the trial sites over the four years of the study thus demonstrating the substantial public health benefit which can be provided by a vaccine with moderate efficacy on top of other control measures such as bednets.