

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 malaria vaccine candidate Ad35.CS.01 x RTS,S and how is it different from RTS,S

In this collaborative study^(a), a prime-boost approach i.e., a single dose of Crucell's Ad35.CS.01 malaria candidate vaccine, followed by two doses of RTS,S/AS01 was compared to three doses of the RTS,S/AS01 candidate vaccine alone. The Ad35.CS.01 is a viral vector, Adenovirus 35, encoding the CS protein which is also present in RTS,S.

Results of an interim analysis^(b) showed that the Ad35.CS.01-RTS,S/AS01 combination failed the study objective to increase by at least 50% the vaccine efficacy provided by RTS,S/AS01 alone. This vaccine combination is no longer pursued.

a. *clinicaltrials.gov* NCT01366534

b. Ockenhouse, C. et al. LB-166, November 13, 2012, 61st annual meeting of the American Society for Tropical Medicine and Hygiene