

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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Sanaria Inc. recently tested a whole-sporozoite approach in humans with very promising results and says that it could be available for use within five years. Why don't we just wait for that?

We have been following the development of Sanaria and other vaccine candidates with interest. These vaccine candidates are in less advanced stages of development. What we do know is that typical vaccine development takes many years and has many hurdles to overcome. We are highly focused on RTS,S, the most advanced malaria vaccine candidate that is in a Phase 3 trial—the stage leading to submission for regulatory approval.

These are preliminary results of a first phase I trial with this vaccine injected directly in the bloodstream (intravenously)^(a). It showed high protective efficacy in 6 volunteers who received 5 successive vaccinations with high doses of vaccine. Efficacy was lower (60%) for those volunteers that received 4 vaccinations with the highest vaccine dose and no efficacy was seen for lower vaccine doses. The authors point out that these results will need to be confirmed in larger numbers of volunteers, including African volunteers living in malaria endemic areas.

The editorial in *Science* points out that the further development of this vaccine still has a long way to go and will take several years. In addition manufacturing processes, the storage conditions in liquid nitrogen, and the intravenous route of vaccine administration are all mentioned as significant logistical challenges that still to be overcome.

Similar results for RTS,S (6 volunteers fully protected out of 7) were already published in 1997^(b).

a. Seder et al. *Science* 2013 ; 341 (6152):1359-65

b. Stoute J. et al. *NEJM* 1997; 336: 86-91