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 trails.
- 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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Are you sure that your disease surveillance did not miss a lot of malaria cases?

The attack rate for malaria reported in the trial is an average of 1 clinical attack per year per child, over the different participating sites. This varied considerably from less than 0.1 episode per year to more than 5 episodes per year in high transmission areas.

In the phase III efficacy trial, over the first 20 months of follow-up, approximately 180,000 outpatient sick visits happened, of which almost 100,000 were for febrile illnesses. According to the study protocol[a,b], a blood test was done to confirm or eliminate the diagnosis of malaria in all children presenting with a febrile illness. Malaria was found in 16-17% of the febrile cases, but the high rate of clinic visits indicates a very robust surveillance system for malaria in this trial, making it highly unlikely that malaria cases would have been missed.

a. *Leach A, et al. Malaria Journal 2011; 10: 224.*

b. *Lievens M. et al. Malaria Journal 2011; 10: 222*