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 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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Why did you start the study with children 5-17 months of age rather than in infants, who are the target population?

The target for this vaccine is children aged 6 weeks to 17 months based on evidence of high malaria disease burden in sub-Saharan-Africa in children below 2 years of age.

The study was designed to assess vaccine efficacy in infants 6-12 weeks old and children 5-17 months old. These two age categories were selected based on the existing Expanded Program for Immunization (EPI) of the WHO in African countries, offering at least 4 vaccination visits at 6, 10 and 14 weeks, and 9 months of age. The age categories were selected to be completely aligned with the EPI schedule (infants 6 to 12 weeks), or to be completely out of the time frame of the EPI schedule (children 5 to 17 months) in order to not jeopardise the compliance to the EPI vaccination schedule. Since in study Malaria-055, EPI vaccines were given to infants 6 to 12 weeks as per protocol, no children were enrolled between these two age ranges.

The older children were enrolled first because they were already available in the study areas at the time the trial started. The younger infants took longer to enrol because we had to wait for them to be born. Starting enrolment in the younger age category first would have had serious impacts on speed of enrolment of older children, since many of the potential study participants would already have been enrolled at an earlier age.