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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What is the informed consent process for the RTS,S clinical trials?

Informed consent is a critical process in any clinical trial to ensure that participants and/or their parents understand the objectives of a research endeavour, and the potential risks and benefits of participation. This is also an important educational and community outreach aspect of the clinical development of the RTS,S malaria vaccine candidate.

The RTS,S clinical trials follow the usual process, i.e. before the start of the trial the teams at each of the research centres hold public meetings and informational sessions. This is done with the participation of local leaders including the chiefs of the local villages. If the local community and its leaders agree that the study can be conducted, parents who are interested in the studies are invited to come to the health clinic. Prior to confirming individual consent, individual or group sessions are held with parents where they are informed in detail about previous results and the forthcoming study. Parents are encouraged to ask the clinical trial investigators any questions they would have. It is stressed that participation is voluntary.

Written informed consent using approved forms in the appropriate local language is obtained before study procedures begin. Those parents who are illiterate are informed about the consent form's content and indicate approval by using a thumbprint with a signature from an independent literate witness to the consent procedure.