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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Who is responsible for the development of RTS,S?

The clinical development of the RTS,S malaria vaccine candidate is being implemented by the Clinical Trials Partnership Committee, a collaboration of leading African research institutes, their Northern academic partners, MVI and GSK. The trial sites were selected for their track record of world-class clinical research, strong community relations and commitment to meeting the highest international ethical, medical, clinical and regulatory standards. With support from the Malaria Clinical Trials Alliance (MCTA) the partnership ensured capacity building at clinical trial sites to prepare them for the conduct of high-quality trials. This included building of infrastructure, provision of equipment such as laboratory equipment and X-ray machines, establishment of quality systems and staff training.

MVI is involved in the technical design of the trials, conducts ongoing training for trial sites, participates in oversight of the trials, and funds the sites' conduct of the trials. GSK takes the lead in the clinical development and assumes all the clinical trial sponsorship responsibilities according to the GCP guidelines. GSK takes also the lead in the interactions with regulatory agencies and is responsible for the manufacturing and distribution of the RTS,S malaria vaccine candidate once regulatory approvals and recommendations for use have been obtained.