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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How will the partners ensure that trials are conducted safely and ethically?

Phase III trials, like those that preceded in Phase I and Phase II, are conducted according to the International Conference on Harmonization (ICH), Good Clinical Practice guidelines (CGP), and on-site clinical trial monitoring is conducted by GSK Biologicals. The RTS,S trials are reviewed by national regulatory authorities, and international, national and local institutional and/or ethical review boards. In addition, an Independent Data Monitoring Committee (IDMC) oversees the trials, supported by local safety monitors (LSM) at each of the research centres. The main objectives of the IDMC and the LSM are to oversee the safety data and data collection processes, and to check that the study participants' rights are respected.

Safety is always our most important concern, and if at any point it is determined that children's safety would be at risk, the trial will be stopped.