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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Were any deaths reported in this Phase III efficacy trial?

Sadly, deaths in children under the age of five from disease, malnutrition, and other illnesses are not uncommon in sub-Saharan Africa, and have unfortunately also occurred in children enrolled in the RTS,S clinical trials. However, no deaths were considered by the investigators to be caused by the study vaccines. In addition, the Independent Data Monitoring Committee (IDMC) also closely reviewed serious adverse events, including deaths, occurring in the RTS,S clinical trials, and did not raise any concern that would have required modifying or halting any trials. In the large Phase III efficacy study, mortality rates were similar in both the control and RTS,S study groups[(a)] and lower than that observed in the general population[(b)], possibly related to the close follow-up and high quality of medical care provided to the study participants.

a. *RTS,S Clinical Trial Partnership. The Lancet, 2015. dx.doi.org/10.1016/S0140-6736(15)60721-8.*

b. *Hamel, et al. ASTMH 2014, 63rd annual meeting; Abstract 631*