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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Does the vaccine work equally well across the clinical trial sites (across diverse malaria transmission settings?)

Among children aged 5-17 months at first vaccination, RTS,S provided protection across a wide range of malaria transmission settings. Vaccine efficacy varied between the 11 sites.[a] This site variation (VE ranging from 40-70%) was statistically significant over the first 20 months of follow-up,[a] but differences in vaccine efficacy between sites were not statistically significant when compared over the entire study period.[b]

In infants aged 6-12 weeks (at first dose) there is no statistical evidence that VE against clinical malaria varied according to *P. falciparum* transmission intensity (Malaria-055). [b]

Strictly internal use:[c]

Children aged 5-17months ATP* cohort 30 months of follow-up after dose 3	**Vaccine efficacy against clinical malaria (95% CI)**	
	Primary vaccination only	**Primary and booster vaccination**
Low transmission intensity (Pp** < 5%)	58% (35;73)	58% (35;74)
Moderate transmission intensity (Pp** 5-40%)	39% (30;47)	48% (40;56)
High transmission intensity (Pp** >40%)	28% (21;35)	43% (36;49)

* According-to-protocol (ATP) cohort: all children immunised according to schedule, N= total number in all 3 study groups
** *P. falciparum* parasite prevalence (Pp)

a. *RTS,S Clinical Trial Partnership. PloS Medicine 2014; doi/10.1371/journal.pmed.1001685*

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

c. *Mosquirix Global Data sheet v03, 2015*