

## 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](mailto: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 trials.
- 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](mailto:carys.calvert@gsk.com).

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#### **What additional trials of RTS,S planned in the future?**

GSK and MVI are committed to further monitoring the safety and assessing the real-life effectiveness of RTS,S, its benefit/risk profile in infants and young children living in malaria endemic regions, and its compatibility with current immunisation schedules. The studies below have been agreed upon with European Medicines Agency as part of the approved Risk Management plan <sup>(a)</sup>

Malaria-073<sup>(a)</sup>, is a Phase IIb study to further evaluate co-administration with measles, rubella and yellow fever vaccines.

Malaria-076<sup>(b)</sup> is an open-labelled Phase IIIa study to follow-up children in three centres of the Malaria-055 (Nanoro, Korogwe and Kombewa) to further evaluate efficacy and safety over an additional 3 years (January 2014 to December 2016).

Phase IV studies are also being developed for pharmacovigilance and impact of the vaccine, as part of a post-approval plan to accompany first widespread implementation. Additional operational and health-economic studies are also planned. Currently, three studies are included in the post-approval program.

EPI-MAL-002<sup>(c)</sup>: A prospective epidemiological pre-licensure surveillance study to assess baseline incidence of adverse events of specific interest (AESI), of other adverse events leading to hospitalization and death and of meningitis in 40,000 infants and children below 3 or 5 years of age. Study started in 2015 in some centres in geographical areas with Health and Demographic Surveillance System.

EPI-MAL-003<sup>(d)</sup>: A post-approval safety-surveillance study in 40,000 infants and children vaccinated with RTS,S/AS01 in sub-Saharan Africa by public health sector. This study will also measure impact of the vaccine on malaria disease as measured by malaria diagnosed at health facilities.

EPI-MAL-005<sup>(e)</sup>: A study of malaria epidemiology running alongside the EPI-MAL-002 and 003 will measure changes over time in parasite prevalence among vaccinated and unvaccinated populations and monitor changes in usage of malaria prevention measures in areas where these other studies will take place.

EPI-MAL-010 <sup>(f)</sup>: This study will use samples from the EPI-MAL-005 to monitor the genetic diversity in CS sequences in parasite populations pre- and post- introduction of RTS,S.

Malaria-094 <sup>(g)</sup>, is a Phase IIb open-label study to evaluate efficacy in children of different timings of the fourth dose, as well to evaluate the efficacy of additional vaccine doses either as full dose or fractional (1/5<sup>th</sup> of standard) vaccine doses. Planned study start from the end of 2016.

a. *Malaria-073, (GSK study ID 200596)*

b. *Malaria-076; GSK study ID 200599; [clintrials.gov](https://clinicaltrials.gov) NCT number NCT02207816*

c. *EPI-MAL-002; GSK study ID 115055; NCT02374450*

d. *EPI-MAL-003; GSK study ID 115056*

e. *EPI-MAL-005; GSK study ID 116682; NCT02251704*

f. *EPI-MAL-010; GSK study ID 205071*

g. *Malaria-094; GSK study ID 204889*