

## 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 are the symptoms of clinical and severe malaria?**

Malaria gets progressively more dangerous as the number of parasites in the blood increase. A malaria infection becomes “clinical malaria” when the child develops symptoms associated with that infection as it progresses. Typically, clinical malaria is characterised by a fever associated with a significant proportion of red blood cells infected with *Plasmodium falciparum* malaria parasites. Other symptoms of malaria may include shivering, vomiting and headache. Symptoms of malaria vary however with age. In addition, they are nonspecific and common to many other diseases. It is therefore not possible to accurately diagnose malaria based on clinical criteria, and the diagnosis of malaria needs to be confirmed by laboratory testing (blood smear microscopy or Rapid Diagnostic Test, RDT).

In some cases this can develop into severe malaria, with more severe consequences affecting the blood, brain and kidneys. Severe anaemia and respiratory distress are the most frequent causes of hospitalization due to malaria and occur usually in younger children around one year of age. Neurological manifestations (cerebral malaria) are less frequent but can lead to long-term sequelae. Cerebral malaria tends to occur later in life with a peak incidence between 2 and 3 years of age. In some cases severe malaria may cause death.