

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 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.

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Why should the international community start preparing now, if RTS,S will not be rolled out for several years and there is no guaranteed funding for its purchase?

We have learned from other interventions that if planning for a decision is not started years in advance, the intervention may ultimately, and unfortunately, remain unused for years after its availability. The planning and decision-making process - as well as the generation or collection of needed data - takes time and careful evaluation. The goal for the RTS,S malaria vaccine candidate is to minimise, to the extent possible, delays between regulatory approval, possible recommendations for use, and initiation of uptake.

In November 2015, WHO recommended 3-5 large pilot implementation projects in sub-Saharan Africa with moderate-to-high malaria transmission to understand how to best use RTS,S to protect young children against malaria. ^(a) Continued partnership with global organisations for malaria control and immunisation as well as funders will be needed to support the introduction and implementation of Mosquirix™ in countries who have adopted the vaccine. A shared risk approach from development to access is necessary to make sure that this vaccine candidate is available to those that need it.

- The regulatory post-marketing requirements are significant, given the not-for-profit nature of this vaccine. PATH and GSK are working together to identify potential sources of funding for these studies. The Gates Foundation continues to support RTS,S through PATH that is funded to help ensure informed decision-making by malaria-endemic countries; partial funding for the baseline PhIV study.
- African countries will need support to develop different methods for post-marketing surveillance eg sentinel sites to further evaluate safety and impact and in parallel, preparing for vaccine implementation.
- Gavi has included malaria vaccine in their Vaccine Investment Strategy. ^(b) They are now looking into their role (and that of Global Fund against AIDS, Tuberculosis and Malaria) in supporting pilot introduction projects recommended by WHO.
- By beginning the process now of gathering data and establishing systems to aid in decision-making, countries can determine the appropriate role of a malaria vaccine in their malaria control and EPI programs without undue delay.

a. WHO Q&A on malaria vaccines Nov 2015: who.int/immunization/research/development/malaria_vaccine_qa/en/

b. Gavi Vaccine Investment Strategy, 2013, www.gavialliance.org/about/strategy/vaccine-investment-strategy/