Consultation on malaria vaccines and biologicals research and development
15-16 July 2019, Salle C, WHO, Geneva, Switzerland

In 2017, malaria caused an estimated 219 million illness cases and 435 000 deaths. Although there were fewer cases in 2017 than in 2010, data for the period 2015–2017 showed stagnation of progress in malaria control. New tools are needed to help achieve global control and elimination targets.

No vaccine is currently available to prevent malaria and its complications. RTS,S/AS01 has received a favourable European Medicines Agency (EMA) scientific opinion and has recently started pilot implementation evaluation, as called for by the World Health Organization (WHO). Next generation malaria vaccines able to provide a higher level of protection and reduce transmission will be required.

The Malaria Vaccine Advisory Committee (MALVAC) has been established for expert input to help WHO articulate its vision, product preferences and recommendations on malaria vaccine research and development (R&D) priorities. WHO plans to review its recommendations, with the aim of supporting acceleration of product development and future policy decisions.

WHO is organizing a consultation to review the state-of-the-art in malaria vaccine development. New developments in the field will be presented, key challenges and opportunities will be discussed.

The **AIMS** of this consultation are

- Provide a landscape status of malaria vaccine R&D
- Discuss potential malaria vaccine use cases, taking into account recent changes and the heterogeneity of malaria epidemiology
- Consider key product profile attributes and programmatic suitability
- Discuss early and late development data packages for decision making
- Highlight challenges and opportunities in malaria vaccine evaluation pathways

Expected **OUTCOMES** of this consultation will

- Inform the formulation of a WHO vision for malaria next generation vaccines
- Inform update of the WHO R&D technology roadmap, expression of preferred product characteristics and a milestone-based framework for product development
- Facilitate the emergence of new collaborative initiatives and investments in support of malaria vaccine development

Meeting chairs: Kate O'Brien, Pedro Alonso
MALVAC Chair: Chetan Chitnis

DAY 1

8:30 –9:00	**Welcome and Introductions**:	Welcome from WHO Kate O'Brien, Pedro Alonso
	Articulating global needs and programmatic suitability	
9:00-9:20	Immunization programs: present challenges and a life course vision of the future	Kate O'Brien
9:20-9:40	Recent changes in malaria epidemiology	Pedro Alonso
9:40-10:00	For information: RTS,S Malaria Vaccine Introduction Project	Mary Hamel
	COFFEE	
	Use cases and key product attributes	
10:20-11:20	Articulation of use cases in various epidemiologic settings - High endemicity areas in Africa - Seasonal transmission and low endemicity settings in Africa - Vaccine need for Asia - Vaccine need for South America - Preventing pregnancy-associated malaria	 Kwakupoku Asante Alassane Dicko Kevin Baird Socrates Herrera Myriam Laufer
11:20-11:50	Key learnings from modelling	Tom Smith
11:50-12:30	Panel discussion: data packages supportive of policy decision for flexible vaccine use according to epidemiological need	All
	LUNCH	
	WHAT CHANGED IN RECENT YEARS? **Controlled human malaria infection models (CHMI)**	
14:00-14:20	Sporozoite challenge	Chris Ockenhouse
14:20-14:40	Blood stage challenge	Simon Draper
14:40-15:00	Assessing reduction of man-to-mosquito transmission	Katharine Collins
	TEA	
	WHAT CHANGED IN RECENT YEARS? **Trial design in conditions of natural exposure**	
15:20-16:00	Pivotal endpoints, trial design, rebound: key considerations for next generation malaria vaccines	Peter Smith, Azra Ghani
16:00-16:20	Assessing reduction of transmission	Chris Drakeley
16:20-17:00	Oriented discussion: creating a milestone-based framework for product development	All

DAY 2

	CLINICAL DEVELOPMENT LANDSCAPE ANALYSIS	
9:00-9:20	Understanding vaccine elicited protective immunity: report from a recent NIH-BMGF workshop	Annie Mo
9:20-9:40	RTS,S/AS01: beyond MVIP, clinical studies	Lode Schuerman
9:40-10:10	Live sporozoite immunization - Safety and efficacy results from trials in conditions of natural exposure - Target Product Profile and clinical development pathway - Programmatic suitability and cost-effectiveness	Steve Hoffman
	COFFEE	
10:30-11:00	Malaria vaccine research at the Jenner Institute, UK R21: - Key results - Target Product Profile and clinical development pathway - Programmatic suitability and cost-effectiveness Pathway to a multi-component multi-stage vaccine	Adrian Hill, Harish Rao
11:00-11:30	Malaria vaccine research at the National Institute of Health, USA Sexual stage vaccines research portfolio - Key results - Target Product Profile and clinical development pathway - Programmatic suitability and cost-effectiveness	Patrick Duffy
11:30-11:50	Malaria vaccine research at Osaka University	Toshihiro Horii
11:50-12:10	A role for monoclonal antibodies against malaria?	Rick King, Jean-Luc Bodmer
12:10-12:30	*Plasmodium vivax* vaccine development	Chetan Chitnis
	LUNCH	
14:00-15:00	**Coordinating malaria vaccine development** Panel: PATH Malaria Vaccine Initiative, BMGF, GMRI, NIH, EVI, EDCTP, USAID	Ashley Birkett, Jean-Luc Bodmer, David Kaufman, Nicola Viebig, Annie Mo, Lorraine Soisson, Mickael Makanga
15:00-15:20	**Industry Involvement in malaria vaccine development:** GSK perspectives	Lode Schuerman
15:20-16:20	**Integrated end-to-end vision of malaria vaccine development: opportunities and challenges** Panel: GAVI, UNITAID, BMGF, PATH, WHO	Aurelia Nguyen, Jean-Luc Bodmer, Alexandra Cameron, Soumya Swaminathan, Ashley Birkett
16:20-16:40	MALVAC activities	WHO secretariat
16:40-17:00	Conclusions and adjournments	Chairs

LIST OF PARTICIPANTS

MALVAC members	
Edwin Asturias	University of Colorado School of Medicine (USA)
Chetan Chitnis	Institut Pasteur (France)
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