Background

• The Malaria Vaccine Advisory Committee (MALVAC) was convened to advise WHO on activities related to the development of malaria vaccines

• MALVAC met 8 times between 2008-2013

• Last version of the WHO Malaria Vaccine R&D Technical Roadmap was produced in 2013

• The malaria vaccine landscape continues to evolve

• Timely to re-convene MALVAC
The evolving landscape

• Major changes in malaria epidemiology

• RTS,S/AS01:
  – Pilot implementation to start in 3 African countries mid-2018
  – Study to assess potential in highly seasonal transmission areas
  – Evaluation of potential to help interrupt transmission
  – Fractional dose of RTS,S regimen

• R21 – an RTS,S-like particle – showing promise

• Live sporozoite immunizations

• Other vaccine candidates, including against *P. vivax*
Global Observatory on Health R&D

Health products in the pipeline

Published: May 2017

Candidate health products (e.g. medicines, vaccines and diagnostics) that are currently under development are reported by disease, product name, type, and phase of development. When available, the developer's institution is also indicated.

- View version published January 2017

See also:
- Antibacterial products in clinical development for priority pathogens

Data visualization 1

Health products in the pipeline
by disease, product name, type and phase of development

- Resistant bacteria
- Chagas disease
- Chikungunya virus disease
- Dengue
- Ebola virus disease
- Enterotoxicgenic Escherichia coli
- HIV/AIDS
- Leprosy
- Lower respiratory infections
- Lymphatic filariasis
- Malaria

Number of products by type
- Medicines: 25
- Vaccines: 25
- Diagnostics: 23

Number of products by phase
- R&D: 24
- Clinical: 1

Data sources

www.who.int/research-observatory/monitoring/processes/health_products/en/
Developments in experimental design

• **Controlled human malaria infection (CHMI)** increasingly used
  – Repeat challenge studies to assess duration of protection
  – Development of CHMI platforms in malaria endemic countries

• **Low dose blood stage infection model** with potential to measure vaccine-induced blood stage immunity

• Development of human **malaria transmission experimental model** to evaluate transmission-blocking activity of sexual stage vaccines
Reconvening MALVAC

• Assist WHO in the prioritization of specific malaria vaccine R&D avenues
• Review the state-of-the-art in malaria vaccine development
• Define priority targets and preferred clinical development pathways, mindful of emerging data and changing public health priorities
• Update the vision for the role of vaccines in future malaria control and elimination efforts
• Jointly convened by WHO’s Initiative for Vaccine Research (IVR) & GMP
Terms of reference

• Provide advice to WHO on activities related to the development of malaria vaccines

• Facilitate coordination of the international malaria vaccine research and development (R&D) effort, with a special emphasis on public health needs of developing countries

• Facilitate coordination of malaria vaccine development activities in the context of ongoing global malaria control and elimination efforts

• Develop guidance on non-clinical and clinical evaluation of malaria vaccines to support the eventual development of norms and standards around these vaccines

• Identify opportunities for new - or neglected lines of research
The Committee

• Up to 12 members, appointed by Directors GMP and IVR
  – Expertise in clinical trials of vaccines, public health and epidemiology, vaccine implementation, malariology, malaria control, biostatistics, vaccine safety, immunology and vaccinology, biotechnology.

• Open call for nominations; broad geographic representation, gender balance

• Members act in their personal capacities and should be free of significant conflicts of interest
  – Initially appointed for 2 years, renewable up to two further 2-year terms
  – Chair appointed for 3 years, possibility of one renewal

• Committee may be supplemented by other experts, including those from other WHO advisory groups
Meetings

• As the need arises, no regular fixed interval
• All documents to be treated as confidential - confidentiality agreement upon appointment
• Standard Declaration of Interests procedures
• Observers may be nominated on an as-needed basis by GMP & IVR secretariat prior to each meeting
• A closed session, restricted to committee members and secretariat only, will be scheduled in each meeting
• May establish subcommittees, expert working groups or study groups required to address issues relevant to specific aspects of malaria vaccine development
Malaria Vaccine Consultation

Session 1

– Changing malaria epidemiology - potential roles for malaria vaccines
– Malaria vaccine landscape

Session 2

– Use of human infection models for evaluation of malaria vaccines
  • Mosquito and IV sporozoite inoculation, blood stage controlled infection, models for assessment of transmission blocking, *P. vivax* CHMI, use in malaria endemic countries
– Late stage evaluation
  • Lessons from RTS,S
  • Should RTS,S be considered the standard of care in clinical trials testing new malaria vaccines?
– Evaluation in pregnancy – when and how?
Session 3

- Different use scenarios
  - Low, middle and high endemicity settings
  - Contribution to malaria elimination
  - Vaccines to contain drug resistance
  - *P falciparum*, *P vivax* interplay
  - Vaccines against malaria in pregnancy
  - Seasonal vaccination

- Followed by the re-convening of MALVAC
  - Potential for working groups, e.g. to develop Preferred Product Characteristics for different use scenarios
MPAC is invited to comment on the merits of reconvening MALVAC and of organizing a malaria vaccine consultation.