Lessons from developing a PPP, a Roadmap, and a PDP – the Malaria Vaccine Initiative
Reasons for establishing a Malaria Vaccine PPP and/or PDP

R&D PPP
- Align on vision, strategic goals
- Focus R&D priorities
- Leverage/pool/optimize the sum of resources
- Optimize the use of available knowledge and resources
- Foster open innovation

Product Development Partnership
- Share risk and development costs
- Address topics that require a neutral/multi-stakeholder environment
The lead up to The Malaria Vaccine Technology Roadmap

- Step 1: The call to action by a normative body
- Step 2: Sponsorship of the process—the PPP
- Step 3: The drafting process
- Step 4: The synthesis process

And

- Step X: The update
Malaria Vaccine Technology Roadmap: Vision and Strategic goals

**Vision**

Safe and effective vaccines against *Plasmodium falciparum* and *P. vivax* that prevent disease and death and prevent transmission to enable malaria eradication.

**Strategic goals**

By 2030, license vaccines targeting *Plasmodium falciparum* and *P. vivax* that encompass the following two objectives, for use by the international public health community:

- Development of malaria vaccines with *protective efficacy of at least 75 percent against clinical malaria* suitable for administration to appropriate at-risk groups in malaria endemic areas.
- Development of malaria vaccines that *reduce transmission of the parasite and thereby substantially reduce the incidence of human malaria infection*. This will enable elimination in multiple settings. Vaccines to reduce transmission should be suitable for administration in mass campaigns.
Priority areas

Research

1. Develop immunological assays with standardized procedures and reagents to enable comparisons of the immune responses of vaccines.
2. Standardize clinical trial design and assessment to allow comparison of data.
3. Use state-of-the-art approaches to identify novel potential candidate vaccine targets.
4. Confirm candidate vaccine targets and mechanisms of protection, using controlled human malaria infection models as appropriate.
5. Ensure that results from all funded malaria vaccine clinical trials are publicly available within 12 months of the last visit of the last subject for the primary endpoint, and encourage public sharing of all funded nonhuman primate studies within 12 months of completion of the primary immunological endpoint.

Development

6. Establish a systematic approach for prioritizing vaccine candidates (including multi-antigen, multi-stage, and attenuated whole-parasite vaccine approaches). Candidates will be prioritized, taking into account PPCs, back-validation from clinical to nonclinical models, immune correlates, and/or head-to-head comparisons.
7. Develop immunological correlates of vaccine-induced protection and surrogate efficacy endpoints to advance vaccine development and licensure timelines.

Key Capacities

8. Access to low-cost vaccine manufacturing under current Good Manufacturing Practices (cGMPs) for late-stage development and commercial production.
9. Promote sufficient and sustainable Good Clinical Practice (GCP) clinical trial, regulatory, and ethics capacity in malaria-endemic regions to accommodate a variety of clinical trials (including clinical trials with human-to-mosquito transmission endpoints) required for malaria vaccine development.
10. Develop approaches to address the need for appropriate, post-approval pharmacovigilance and effectiveness testing capacity in malaria-endemic regions in order to ensure timely malaria vaccine introduction and implementation.

Policy and Commercialization

11. Ensure data are available to support timely, evidence-based decision-making by national immunization and malaria control programs.
12. Develop and encourage responsible stewardship and support for malaria vaccine development and implementation through appropriate project management and investment strategies (e.g., through developing a business case).
13. Develop novel regulatory strategies to expedite approval while ensuring quality and safety.

http://www.who.int/immunization/topics/malaria/vaccine_roadmap/en/
A new feature: WHO Preferred Product Characteristics (PPCs)

Target audience for this update

- **The vision** and strategic goals are intended to inform leadership within international and national donor, financing, research, and public health agencies, as well as governments of malaria-endemic countries.

- **The strategic goals** are also of interest to malaria vaccine developers in academia, government agencies, public-private partnerships, and industry.

- **The WHO** malaria vaccine PPCs are intended to inform a technical audience in R&D in industry, public-private partnerships, academia, and government agencies who have an interest in developing malaria vaccines to meet the public health need in malaria-endemic countries.
Why a PDP?
RTS,S/AS01: 28+ years of effort

- GSK & WRAIR initiate collaboration
- RTS,S is first created by combining the malaria CS protein and hepatitis B surface antigen
- First clinical tests in humans begin in adults in US
- Key PoC study in adults in the Gambia
- Key PoC study shows 6 of 7 volunteers in challenge trial are 100% protected
- First trials in Africa begin in the Gambia
- GSK-MVI partnership initiated
- Key PoC study in children in Mozambique
- Phase 2 results in African children and infants published in Lancet and NEJM
- Phase 2 results in African children and infants published
- Key Phase 2 efficacy results in African children and infants
- Phase 3 study start
- Phase 3 study end Final results over 32 months of follow-up
- Phase 3 study Second set of results in 5-17 month olds
- Phase 3 study Third set of results in 6-12 week olds
- RTS,S Clinical Trials Partnership. NEJM 2011; DOI: 10.1056/NEJMoa1102287.

References:
Lessons learned?

- A normative body (Malaria TRM = WHO) and key funder group can provide an important forum for input, synthesis, launching and sustaining the roadmap.
- Plan to refresh the roadmap based on new data and/or change in strategy (and do so in a timely manner), but change only what is necessary.
- Map target audiences and include elements tailored to each.
Thanks to