

REGIONAL MALARIA VACCINE DECISION-MAKING FRAMEWORK—DATA (To see Processes, click here)

Key: ■ National data ■ Global data

	Pre-licensure 5 years before licensure					Available data - Phase 3			Licensure 2 years after licensure		Post-licensure 5 years after licensure		
MALARIA VACCINE INTRODUCTION DECISION													
Malaria disease burden	Reported and confirmed cases by age group (critical data)	Reported malaria-related deaths by age group (critical data)	Malaria epidemio profile by district (critical data)	Malaria cases in pregnant women and HIV+ population (critical data)	Economic burden of malaria				Update on current malaria situation (critical data)	Reported and confirmed clinical and severe malaria cases by age group (critical data)			
Other malaria interventions	Impact of current malaria interventions (critical data)	Coverage of current malaria interventions (critical data)	Impact of current malaria interventions (critical data)	Cost-effectiveness estimates of current malaria interventions (critical data)				Changes in impact and cost-effectiveness of other malaria interventions		Changes in impact and cost-effectiveness of other anti-malaria interventions (critical data)			
Malaria vaccine impact	Impact on mortality and morbidity by age group (critical data)					Absolute impact	Marginal impact with other malaria interventions (critical data)	Impact on epidemiology and morbidity by age group			Vaccine coverage: use of morbidity and mortality indicators for impact studies (critical data)	Effectiveness, including impact on: • Clinical disease • Severe disease • Anemia • Parasitemia (critical data)	
Economical and financial issues	Credible public-sector price estimate	Cost-effectiveness estimates of malaria vaccine (critical data)		Public health return on investment (DALYs, impact on health budget, impact on GDP		Vaccine price for public (critical data)	Donor subsidy and sustainability of subsidy (critical data)	National affordability (critical data)	Sustainability of donor subsidy (critical data)	Sustainable national commitment (critical data)	Socio-economic impact (critical data)	Updated malaria vaccine cost-effectiveness data (critical data)	Estimates of recurrent costs, including marketing and surveillance (critical data)
Malaria vaccine efficacy, quality and safety	Safety	Adverse events (critical data)	Interaction with other vaccines (critical data)	Efficacy (critical data)	Efficacy, impact: • Clinical disease • Severe disease • Anemia • Parasitemia (critical data)	Efficacy in HIV+ populations (critical data)	Duration of efficacy (critical data)	Efficacy, quality, and safety data from other countries (critical data)	Post-licensure safety and efficacy data (critical data)				
Programmatic considerations	Anticipated vaccine characteristics and presentation (critical data)					Supply availability (critical data)	HS capacity to accommodate vaccine (critical data)	Product Characteristics and storage information (critical data)	Defined target groups and communication plan (critical data)		Evidence of supply security (critical data)		
Socio-cultural environment	Knowledge attitudes, and practices of communities towards vaccines and malaria interventions			Community expectations of malaria vaccines in clinical trial areas							Community knowledge, attitudes, and practices related to vaccines and malaria interventions (critical data)		

REGIONAL MALARIA VACCINE DECISION-MAKING FRAMEWORK—PROCESSES

Key: ■ National process ■ Global process

Pre-licensure 5 years before licensure						Licensure 2 years after licensure						Post-licensure 5 years after licensure	
AVAILABLE DATA - PHASE 3						MALARIA VACCINE INTRODUCTION DECISION							
National processes	Establish technical working group (critical data)	Assess and strengthen regulatory, ethics and data management processes (critical data)	Integrate the vaccine into countries' multiyear strategic plans. Revise EPI and NMCP strategic plans. (critical data)	Engage local private-sector partners and pharmaceutical companies	Develop communications plan on malaria vaccine (1 year before) and integrate it to multi-year EPI and NMCP plans including contingency plan	National regulatory authority reviews vaccine in consultation with technical working group (within 1 year of licensure) (critical data)	National expert group/technical working group issues recommendation on vaccine introduction (critical data)	Incorporate malaria vaccine into national budgeting processes (critical data)	Elaborate the vaccine introduction plan and programmatic guidelines (logistics, training, pharmacovigilance) (critical data)			Monitor vaccine performance and safety (critical data)	Monitor vaccine implementation (critical data)
	Signal vaccine demand (1-3 years before)	Integrate use of malaria vaccine in national health policies		Conduct advocacy to solicit government support		Conduct advocacy with national decision-makers and major stakeholders (critical data)	MOH makes decision about integration of vaccine into EPI (critical data)	Develop plan for procurement and resource mobilization for financial sustainability (critical data)	Update communications plan for implementation and engage media (1-year after introduction) (critical data)	Examine sustainability of existing funding and how to encourage in-country financing (critical data)	Engage media (critical data)	Evaluate vaccine Introduction impact on health system (critical data)	
Global processes	Integrate country requirements into product development plans (critical data)	Conduct global advocacy to leverage funding (critical data)	Share information on vaccine research (critical data)			WHO issues policy recommending vaccine use (critical data)	Donors provide funding to support vaccine (critical data)	WHO issues prequalification (within 1 year of licensure) (critical data)	International agencies plan for procurement (within 1 year of licensure) (critical data)			Monitor vaccine performance, including evaluation of vaccine impact, safety, and pharmacovigilance (critical data)	
			Conduct global advocacy to leverage funding (critical data)			WHO publishes vaccine management and introduction guidelines (critical data)							