

MALAWI MALARIA VACCINE DECISION-MAKING FRAMEWORK—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 clinical & severe malaria cases <i>(critical data)</i>	Reported malaria-related deaths by age group <i>(critical data)</i>	Malaria epidemiological profile at the district level <i>(critical data)</i>	Malaria cases in HIV+ individuals <i>(critical data)</i>	Economic burden of malaria						Update on current malaria situation <i>(critical data)</i>	Reported and confirmed clinical and severe malaria cases by age group <i>(critical data)</i>	Reported malaria-related deaths by age group <i>(critical data)</i>	
Other malaria interventions	Impact of existing malaria interventions <i>(critical data)</i>	Country-specific impact of existing malaria interventions <i>(critical data)</i>	Coverage of current malaria interventions <i>(critical data)</i>	Cost-effectiveness estimates of existing malaria interventions <i>(critical data)</i>							Changes in impact and cost-effectiveness of other malaria interventions	Changes in impact and cost effectiveness of other anti-malaria interventions <i>(critical data)</i>		
Malaria vaccine impact	Projected impact on mortality and morbidity in different age groups <i>(critical data)</i>				Absolute impact	Marginal impact with other malaria interventions <i>(critical data)</i>	Impact on epidemiology and morbidity by age group				Malaria vaccine coverage <i>(critical data)</i>	Effectiveness, including impact on: • clinical disease • severe disease • anemia • parasitemia • mortality <i>(critical data)</i>	Effectiveness study <i>(critical data)</i>	
Economical and financial issues	Credible public-sector price estimate	Preliminary cost-effectiveness estimates of malaria vaccine <i>(critical data)</i>	Public health return on investment in terms of DALYs, impact on health budget, impact on GDP	Vaccine price for public sector <i>(critical data)</i>	Donor subsidy of malaria vaccine and duration of subsidy <i>(critical data)</i>	National affordability <i>(critical data)</i>	Cost-effectiveness estimate of a malaria vaccine <i>(critical data)</i>	Duration of donor subsidy	Sustainable national commitment <i>(critical data)</i>	Public health return on investment	Updated malaria vaccine cost-effectiveness data <i>(critical data)</i>	Estimated recurrent and indirect costs, including marketing and surveillance <i>(critical data)</i>		
Malaria vaccine efficacy, quality and safety	Safety <i>(critical data)</i>	Adverse events <i>(critical data)</i>	Interaction with other vaccines <i>(critical data)</i>	Efficacy, including impact on: • clinical disease • severe disease • anemia • parasitemia • malnutrition <i>(critical data)</i>	Efficacy in HIV+ populations <i>(critical data)</i>	Duration of efficacy of the vaccine <i>(critical data)</i>	Efficacy, quality, and safety data from other countries <i>(critical data)</i>	Post-licensure safety data <i>(critical data)</i>						
Programmatic considerations	Anticipated vaccine characteristics and presentation <i>(critical data)</i>		Evidence of established policy, regulatory, and institutional pathways to support intervention <i>(critical data)</i>	Demand forecast <i>(critical data)</i>	Supply availability <i>(critical data)</i>	HS capacity to accommodate a malaria vaccine <i>(critical data)</i>	Info. on product characteristics and storage <i>(critical data)</i>	Defined targeted groups and a communication plan <i>(critical data)</i>	Evidence of established policy, regulatory and institutional pathways to support interventions <i>(critical data)</i>	Evidence of supply security <i>(critical data)</i>				
Socio-cultural environment	Knowledge, attitudes, and practices of communities towards vaccines and malaria interventions		Community expectations of malaria vaccines in clinical trial areas							Knowledge, attitudes, and practices about malaria vaccines, especially acceptability and compliance <i>(critical data)</i>				

Key: National data Global data

MALAWI MALARIA VACCINE DECISION-MAKING FRAMEWORK—PROCESSES

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	Establishment of Technical Working Group <i>(critical processes)</i>	Signal vaccine demand (1-3 years before)	Engage local private-sector partners and pharmaceutical companies	Develop communication plan on the malaria vaccine (1 year before)	National regulatory authority reviews vaccine in consultation with technical working group (within 1 year of licensure) <i>(critical processes)</i>	Advocacy with national decision makers and major stakeholders <i>(critical processes)</i>	Develop plan for procurement and resource mobilization for financial sustainability <i>(critical processes)</i>	Incorporate malaria vaccine into national budgeting processes <i>(critical processes)</i>	Update the communication plan for implementation and engage media (one year after introduction) <i>(critical processes)</i>	Monitor vaccine performance and safety <i>(critical processes)</i>	Monitor implementation of the vaccine and evaluate impact on health system <i>(critical processes)</i>
	Assess and strengthen regulatory, ethics and data management processes in-country <i>(critical processes)</i>	Integrate use of malaria vaccine in national health policies			National expert group/technical working group issues recommendation regarding vaccine introduction <i>(critical processes)</i>	MOH makes a decision about integration of vaccine into EPI <i>(critical processes)</i>		Elaborate the vaccine introduction plan and programmatic guidelines (logistics, training, pharmacovigilance) <i>(critical processes)</i>	Examine sustainability of existing funding and how to encourage in-country financing <i>(critical processes)</i>		
	Integrate the malaria vaccine in countries' multiyear strategic plans (4-5 years before) <i>(critical processes)</i>	Conduct advocacy to solicit government support									
Global processes	Integrate country requirements into product development plans (5 years before) <i>(critical processes)</i>	Conduct global advocacy to leverage funding <i>(critical processes)</i>	Share information on vaccine research <i>(critical processes)</i>	Conduct global advocacy to leverage funding <i>(critical processes)</i>	WHO issues policy recommending use of vaccine <i>(critical processes)</i>	Donors provide funding to support vaccine <i>(critical processes)</i>	WHO publishes vaccine management and introduction guidelines (licensure) <i>(critical processes)</i>	WHO pre-qualification (within 1 year of licensure) <i>(critical processes)</i>	International agencies plan for procurement (within 1 year of licensure) <i>(critical processes)</i>	Monitoring of vaccine performance, including evaluation of vaccine impact, safety, and pharmacovigilance	

Key: ■ National process ■ Global process