

East and Southern Africa Malaria Vaccine Decision-Making Framework –

Data Needs

Malaria Disease Burden Other Malaria Interventions Malaria Vaccine Impact Economic & Financial Issues Efficacy, Quality, & Safety Programmatic Considerations Sociocultural Environment

PRE-LICENSURE (5 years)

Reported and confirmed clinical and severe malaria cases by age group	Impact of existing malaria interventions	Projected impact on mortality and morbidity in different age groups	Credible public-sector price estimate	Safety	Anticipated vaccine characteristics and presentation	Knowledge, attitudes, and practices of communities towards vaccines and malaria interventions	
Reported malaria-related deaths by age group	Country-specific impact of existing malaria interventions		Preliminary cost-effectiveness estimates of malaria vaccine	Adverse events	Evidence of established policy, regulatory, and institutional pathways to support intervention		
Malaria epidemiology and transmission at province level	Coverage of current malaria interventions		Public health return on investment in terms of DALYs, impact on health budget, impact on GDP	Interaction with other vaccines			Community expectations of malaria vaccines in clinical trial areas
Malaria cases in pregnant women and HIV + individuals	Cost-effectiveness estimates of existing malaria interventions						
Economic burden of malaria							

AVAILABLE DATA - PHASE III

		Absolute impact	Public sector vaccine price	Efficacy, including impact on: • clinical disease • severe disease • anemia • parasitemia • HIV +	Supply availability	
		Marginal impact with other malaria interventions	Donor subsidy of malaria vaccine and sustainability of subsidy		Duration of efficacy of the vaccine	Demand forecast
		Impact on epidemiology and morbidity by age group	National affordability		HS capacity to accommodate a malaria vaccine	
					Info. on product characteristics & storage	

LICENSURE AND DECISION (2 years)

Update on current malaria situation	Changes in impact and cost-effectiveness of other malaria interventions		Sustainability of donor subsidy	Data on efficacy, quality, and safety from other countries	Defined targeted groups and a communication plan	
			Sustainable national commitment		Evidence of established policy, regulatory and institutional pathways to support interventions	

MALARIA VACCINE INTRODUCTION DECISION

POST-LICENSURE (5 years)

Reported and confirmed clinical and severe malaria cases by age group	Changes in impact & cost effectiveness of other anti-malaria interventions	Malaria vaccine coverage	Public health return on investment	Post-licensure safety data	Evidence of supply security	Knowledge, attitudes, and practices about malaria vaccines, especially acceptability and compliance
Reported malaria-related deaths by age group		Effectiveness, including impact on: • clinical disease • severe disease • anemia • parasitemia • mortality	Updated malaria vaccine cost-effectiveness data			
			Estimated recurrent and hidden costs, including marketing and surveillance			
Required data	National data point	Global data point				

East and Southern Africa Malaria Vaccine Decision-Making Framework – Process Needs

