

MALI 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	Malaria cases confirmed by biology <i>(critical data, action plan identified)</i>	Severe cases (hospitalized cases)	Reported malaria deaths <i>(critical data, action plan identified)</i>	Cases by age group	Malaria cases in pregnant women <i>(critical data, action plan identified)</i>	Malaria cases in specific groups (HIV-malaria co infection) <i>(critical data, action plan identified)</i>	Economic burden <i>(critical data, action plan identified)</i>										
Other malaria interventions	Impact of malaria interventions in Mali <i>(critical data, action plan identified)</i>		Data on the coverage of the different interventions (ITN, ACTs, epidemics, IPT with SP) <i>(critical data, action plan identified)</i>		Data on the resistance to ACTs and SP <i>(critical data, action plan identified)</i>		Cost-effectiveness estimates of malaria interventions	Cost-effectiveness estimates of malaria interventions <i>(critical data)</i>				Changes in impact from other malaria interventions					
Malaria vaccine impact	Impact on mortality and morbidity in different age groups <i>(critical data)</i>							Absolute impact <i>(critical data)</i>	Impact in specific groups <i>(critical data)</i>	Marginal impact with other malaria interventions <i>(critical data)</i>	Impact on the occurrence of severe cases, anemia, death rate of malaria by age group <i>(critical data)</i>			Vaccine coverage <i>(critical data, action plan identified)</i>	Efficacy, including impact on: • clinical disease • severe disease • anemia • parasitemia <i>(critical data)</i>	Post-marketing surveillance system <i>(critical data, action plan identified)</i>	
Economical and financial issues	Credible public-sector price estimate		Preliminary cost-effectiveness estimates of malaria vaccine		Return on investment			Cost-effectiveness estimate <i>(critical data, action plan identified)</i>	Credible public sector price estimate <i>(critical data)</i>	Donor subsidy of malaria vaccine	Support donor funding for at least 10 years <i>(critical data)</i>	Sustain national policy to take care of immunization after donor funding <i>(critical data, action plan identified)</i>	Recurring cost estimate <i>(critical data, action plan identified)</i>	Updated malaria vaccine cost-effectiveness data <i>(critical data)</i>	Return on investment		
Malaria vaccine efficacy, quality and safety	PHASE 1 (ADULTS) Safety / immunogenicity <i>(critical data)</i>		PHASE 2 (INFANTS) Safety / immunogenicity <i>(critical data)</i>		Adverse events <i>(critical data)</i>			Efficacy, clinical / biological tolerance and interference with antigens of the program <i>(critical data)</i>		Efficacy, including impact on: • clinical disease • severe disease • anemia • parasitemia <i>(critical data)</i>	Duration of efficacy of the vaccine		Implement post-marketing surveillance <i>(critical data, action plan identified)</i>	Advocacy to have laboratories able to carry out hepatic/renal and blood profiles <i>(critical data, action plan identified)</i>	Implement post-marketing surveillance <i>(critical data)</i>	Post-licensure safety data	Data on quality control <i>(critical data, action plan identified)</i>
Programmatic considerations	Presentation of the vaccine			Evidence of established policy, regulatory, and institutional pathways to support intervention <i>(critical data, action plan identified)</i>				Health staff training <i>(critical data, action plan identified)</i>		Supply availability		Define targeted groups and a communication plan <i>(critical data, action plan identified)</i>		Make vaccine procurement an expense of sovereignty <i>(critical data, action plan identified)</i>			
Socio-cultural environment	Knowledge, attitudes, and practices of communities towards vaccines and malaria interventions <i>(critical data, action plan identified)</i>			Community expectations of malaria vaccines in clinical trial areas <i>(critical data, action plan identified)</i>				Implement a communication plan for behavior change <i>(critical data, action plan identified)</i>		Make immunization a multisector approach <i>(critical data, action plan identified)</i>				Sensitize vaccine manufacturers to promote the vaccine <i>(critical data, action plan identified)</i>			

Key: National data Global data

MALI 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	Declaration of interest based upon country-specific indicators <i>(critical process, action plan identified)</i>	The country integrates the malaria vaccine in the multiyear strategic plan (4-5 years before) <i>(critical process, action plan identified)</i>	The country informs on vaccine demand (1-3 years before)	The country takes into account the existing results to support the declaration of interest for the malaria vaccine <i>(critical process)</i>	The country issues a communication plan on the malaria vaccine (1 year before) <i>(critical process, action plan identified)</i>	The country respects the process of vaccine introduction <i>(critical process)</i>	National expert groups issue recommendation regarding vaccine introduction <i>(critical process, action plan identified)</i>	Advocacy to the highest national authorities for vaccine introduction <i>(critical process, action plan identified)</i>	The country informs international agencies on its actual vaccine demand <i>(critical process, action plan identified)</i>	The country issues programmatic guidelines (creation of a malaria vaccine introduction plan) for implementation (within 1 year of licensure) <i>(critical process, action plan identified)</i>	National regulatory authority reviews vaccine (within 1 year of licensure)	The country updates the communication plan (one year after introduction) <i>(critical process)</i>	The country monitors vaccine performance <i>(critical process)</i>	The country monitors implementation of the immunization programme and evaluates the vaccine impact <i>(critical process)</i>	
Global processes	Integrate country requirements into product development plans (5 years before) <i>(critical process, action plan identified)</i>	Sharing information about the results of clinical trials <i>(critical process, action plan identified)</i>	Global consensus on the validity of clinical trials <i>(critical process, action plan identified)</i>	Advocate for the commitment of public and private partners for the financing of vaccines <i>(critical process, action plan identified)</i>	Promises and commitment from partners to provide funding to support vaccine <i>(critical process, action plan identified)</i>	Establishment of a WHO committee of technical experts who propose guidelines and write technical reports <i>(critical process, action plan identified)</i>	WHO issues policy recommending use of vaccine <i>(critical process, action plan identified)</i>	Implement a regional laboratory in charge of the quality control of vaccine lots <i>(critical process, action plan identified)</i>	WHO pre-qualification (within 1 year of licensure) <i>(critical process, action plan identified)</i>	International agencies plan for procurement (within 1 year of licensure) <i>(critical process, action plan identified)</i>	Plan the QC/RA activities for vaccine lots used in countries <i>(critical process, action plan identified)</i>	Implement a dissemination, communication and notification plan <i>(critical process)</i>			
						Availability of data from interference effects with the EPI vaccines <i>(critical process, action plan identified)</i>	WHO publishes vaccine management and introduction guidelines (licensure) <i>(critical process, action plan identified)</i>	Decision endorsement by the World Health Assembly <i>(critical process, action plan identified)</i>							

Key: National process Global process