

# KENYA 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	Proven malaria cases <i>(critical data)</i>	Severe cases (inpatient or hospitalized cases) <i>(critical data)</i>	Reported malaria deaths <i>(critical data)</i>	Cases by age group <i>(critical data)</i>	Loss of productivity	Vector bionomics and community infection	Percent of malaria of total disease burden <i>(critical data)</i>	Transmission based on parasitemia rates <i>(critical data)</i>	Disease burden analysis <i>(critical data)</i>			Changes in disease burden by age and location <i>(critical data)</i>		Malaria specific mortality by age groups <i>(critical data)</i>				
Other malaria interventions	Impact of malaria interventions <i>(critical data)</i>	Cost-effectiveness (CE) estimates of malaria interventions <i>(critical data)</i>		Impact of current malaria interventions <i>(critical data)</i>	Total MOH malaria funding (relative to other programs) <i>(critical data)</i>					Changes in impact and CE of malaria interventions <i>(critical data)</i>		Changes in impact and CE of malaria interventions <i>(critical data)</i>			Changes in impact of, use, and CE of malaria interventions <i>(critical data)</i>			
Malaria vaccine impact	Projected impact in different age groups (model) <i>(critical data)</i>		All causes mortality rates for children			Projected impact (refined model) <i>(critical data)</i>		Impact on epidemiology and morbidity in older age groups			Projected impact (refined model) <i>(critical data)</i>			Immunization coverage (malaria and other imm) <i>(critical data)</i>	Effectiveness, including impact on: • clinical disease and severe disease • anemia • parasitemia • low birth weight • vector trans. • herd effect to other age groups • outpatients visits <i>(critical data)</i>			
Economical and financial issues	Credible public-sector price estimate <i>(critical data)</i>	Preliminary programmatic/delivery costs <i>(critical data)</i>	Preliminary CE estimates <i>(critical data)</i>	Private-sector demand	Preliminary public health return on investment	National affordability <i>(critical data)</i>	Possibility of local / regional production	Public-sector vaccine price <i>(critical data)</i>	Development partner subsidy of malaria vaccine <i>(critical data)</i>	Sustainability of subsidy <i>(critical data)</i>	Public health return on investment <i>(critical data)</i>	Sustainable national commitment <i>(critical data)</i>	National level CBA <i>(critical data)</i>	Updated malaria vaccine cost-effectiveness data <i>(critical data)</i>	Cost of post-licensure marketing, surveillance, and other hidden costs <i>(critical data)</i>	Public health return on investment <i>(critical data)</i>	Effect on school/ work absenteeism <i>(critical data)</i>	
Malaria vaccine efficacy, quality and safety	Safety <i>(critical data)</i>	Adverse events <i>(critical data)</i>		Interference with other vaccines <i>(critical data)</i>		Efficacy on: • clinical and severe disease • anemia • parasitemia <i>(critical data)</i>		Efficacy & safety in special populations: • HIV/AIDS • low birth weight • hemoglobin disorders <i>(critical data)</i>		Duration of protection <i>(critical data)</i>	Duration of protection <i>(critical data)</i>			Efficacy and safety in special populations: • all age groups • pregnant women • non-immune adults <i>(critical data)</i>		Post-licensure safety data <i>(critical data)</i>		
Programmatic considerations	Anticipated vaccine characteristics and presentation <i>(critical data)</i>	Health system capacity to implement malaria vaccine <i>(critical data)</i>	Immunization coverage <i>(critical data)</i>	Acceptability of immunization schedule by communities and programs <i>(critical data)</i>		Supply availability and demand forecast <i>(critical data)</i>	Final product characteristics and presentation and impact on health system <i>(critical data)</i>		Alternative delivery schedules <i>(critical data)</i>		Vaccine manufacturers <i>(critical data)</i>	Immunization coverage <i>(critical data)</i>	Health system capacity to implement malaria vaccine <i>(critical data)</i>	Supply security (e.g., demand forecast, production capacity, and/or additional manufacturers) <i>(critical data)</i>		Other malaria vaccine candidates <i>(critical data)</i>	Immunization coverage <i>(critical data)</i>	
Socio-cultural environment	Knowledge, attitudes, and practices (KAP) of communities toward: • malaria • malaria vaccines • other malaria interventions • non-specific fevers		Community expectations and acceptability of malaria vaccines in clinical trial areas <i>(critical data)</i>								Changes in KAP toward: • malaria • malaria vaccines • other malaria interventions • non-specific fevers <i>(critical data)</i>			Changes in KAP toward: • malaria • malaria vaccines • other malaria interventions • non-specific fevers <i>(critical data)</i>				

Key:   National data   Global data   National and global data

# KENYA 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		Establish technical working group to collect info, monitor trends, and advise malaria program (3-4 years before) <i>(critical processes)</i>	Kenya considers incorporating new malaria vaccine in national strategic and/or operational plans (3 years before) <i>(critical processes)</i>	Involve local partners from private-sector and pharmaceutical companies early to avoid critical reaction <i>(critical processes)</i>	Kenya develop communications package and identifies advocacy champion(s) to promote support for the vaccine within the government <i>(critical processes)</i>	Technical working group feeds info. to KEPI TAG and malaria ICC to issue formal recommendation to joint ICC regarding vaccine introduction; identify possible partners in country; influence government support <i>(critical processes)</i>	Incorporate malaria vaccine into MTEF and other national budgeting processes <i>(critical processes)</i>	Steering Committee, following joint ICC recommendation, issues programmatic guidelines for implementation (within 1 year of decision) <i>(critical processes)</i>	National regulatory authority monitors vaccine <i>(critical processes)</i>	Monitor vaccine performance; pharmacovigilance <i>(critical processes)</i>	
				Educate community on clinical trials sites population of vaccine <i>(critical processes)</i>	Kenya signals demand after conducting wider consultation in country with stakeholders (3 years before) <i>(critical processes)</i>	Strengthen demographic surveillance system to monitor: duration of protection, adverse events, changes in epidemiology, and increase in prevalence (Phase 3 thru post-licensure) <i>(critical processes)</i>	Kenya develop communications package and identifies advocacy champion(s) to promote support for the vaccine within the government <i>(critical processes)</i>	Countries develop communications package for users (within 1 year of introduction decisions) <i>(critical processes)</i>	Countries monitor implementation and evaluate for impact <i>(critical processes)</i>		
Global processes		Integrate country requirements into product development plans (5 years before) <i>(critical processes)</i>	Educate community on clinical trials sites population of vaccine <i>(critical processes)</i>	Create strategic advisory group of experts to guide development of communications strategy <i>(critical processes)</i>	Develop communications and technical strategy to support countries to achieve buy-in <i>(critical processes)</i>	Build advocacy strategy and groups at regional and global level <i>(critical processes)</i>	WHO issues policy recommending use of vaccine <i>(critical processes)</i>	Development partners provide funding to support vaccine <i>(critical processes)</i>	Procurement agencies plan for procurement (within 1 year of licensure) <i>(critical processes)</i>	Examine sustainability of existing funding and how to encourage in-country financing strategies <i>(critical processes)</i>	Technical support strategies and groups at regional and global level to support post-licensure studies <i>(critical processes)</i>
						WHO publishes vaccine management guidelines (licensure) <i>(critical processes)</i>	WHO pre-qualification (within 1 year of licensure) <i>(critical processes)</i>				

Key: ■ National process ■ Global process