

# TANZANIA 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 and confirmed cases (clinical and severe) and deaths presented as trends by age <i>(critical data)</i>			Malaria epidemiology (community based prevalence) <i>(critical data)</i>	Reported malaria anemia cases	Cases in pregnant women			Reported and confirmed cases of malaria				
Other malaria interventions	Impact of malaria interventions	Coverage of malaria interventions <i>(critical data)</i>	CE estimates of malaria interventions <i>(critical data)</i>					Changes in impact of malaria interventions					
Malaria vaccine impact	Preliminary estimate of impact on disease burden			Marginal impact with other malaria interventions on disease burden <i>(critical data, action plan identified)</i>				Estimate of effectiveness including impact on: • clinical disease • severe disease • anemia • parasitemia • transmission <i>(critical data, action plan identified)</i>		Malaria vaccine coverage <i>(critical data)</i>	Effectiveness, including impact on: • clinical disease • severe disease • anemia • parasitemia • transmission <i>(critical data, action plan identified)</i>		
Economical and financial issues	Credible public-sector price estimate	Preliminary CE and CB estimates <i>(critical data, action plan identified)</i>	Public health return on investment	Economic costs of malaria <i>(critical data, action plan identified)</i>	Public-sector vaccine price <i>(critical data, action plan identified)</i>	Donor subsidy of malaria vaccine <i>(critical data, action plan identified)</i>	National affordability <i>(critical data, action plan identified)</i>	Sustainability of donor subsidy and duration of commitment <i>(critical data)</i>	Sustainable national commitment <i>(critical data)</i>	Updated CE and CB estimates <i>(critical data, action plan identified)</i>	Public health return on investment	National or regional production	Sustainability of donor subsidy <i>(critical data)</i>
Malaria vaccine efficacy, quality and safety	Safety <i>(critical data)</i>	Adverse events <i>(critical data)</i>		Efficacy against: • clinical disease • severe disease • anemia • parasitemia <i>(critical data)</i>	Duration of protection <i>(critical data)</i>	Quality to meet regulatory standards (TFDA) <i>(critical data)</i>	Duration of protection <i>(critical data, action plan identified)</i>		Post-licensure safety data and adverse events <i>(critical data)</i>	Monitor for mutants	Duration of protection <i>(critical data, action plan identified)</i>		
Programmatic considerations	Vaccine presentation <i>(critical data)</i>			Cost of introduction <i>(critical data)</i>	Demand estimate <i>(critical data, action plan identified)</i>			Supply availability <i>(critical data, action plan identified)</i>		Health system capacity to accommodate malaria vaccine <i>(critical data, action plan identified)</i>			
Socio-cultural environment	Knowledge attitudes, and practices (KAP) toward: • EPI vaccines • malaria interventions • malaria vaccines <i>(critical data, action plan identified)</i>		Community acceptability of malaria vaccines in trial areas and beyond <i>(critical data, action plan identified)</i>						KAP toward malaria vaccines in trial areas and beyond <i>(critical data, action plan identified)</i>				

Key:  National data  Global data

# TANZANIA 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	Assess and strengthen regulatory, ethics, and data management <i>(critical processes, action plan identified)</i>	Create multi-sectoral national expert groups to track vaccine development and steer process <i>(critical processes, action plan identified)</i>	Government and partners incorporate preparatory activities for a malaria vaccine into multi-year strategic plans (4-5 years before) <i>(critical processes, action plan identified)</i>	Government and partners signal demand (1-3 years before) <i>(critical processes, action plan identified)</i>	National expert/professional groups issue recommendation regarding vaccine introduction <i>(critical processes, action plan identified)</i>	National regulatory authority reviews vaccine (within 1 year of licensure) <i>(critical processes, action plan identified)</i>	Strengthen human resources and infrastructure capacity to deliver vaccines	Government issues special programmatic guidelines for implementation (within 1 year of licensure) <i>(critical processes)</i>	Government develops communications package for implementation (within 1 year of introduction decisions) <i>(critical processes)</i>	Monitor vaccine performance <i>(critical processes)</i>
			Conduct national-level advocacy to support malaria vaccines <i>(critical processes, action plan identified)</i>	Government and partners develop preliminary communications package about malaria vaccine decision making (1 year before) <i>(critical processes, action plan identified)</i>						Government and partners monitor implementation and evaluate for impact (includes post-introduction evaluation) <i>(critical processes, action plan identified)</i>
Global processes	Integrate country requirements into product development plans (5 years before)		Conduct global advocacy to leverage funding <i>(critical processes, action plan identified)</i>		WHO prepares and issues policy recommending use of vaccine <i>(critical processes)</i>	Partners provide funding to support vaccine <i>(critical processes)</i>	WHO publishes vaccine management guidelines (licensure) <i>(critical processes)</i>	International agencies plan for procurement (within 1 year of licensure) <i>(critical processes)</i>	WHO pre-qualification (within 1 year of licensure) <i>(critical processes)</i>	Technology transfer for local vaccine production

Key: ■ National process ■ Global process