

Regional Malaria Vaccine Decision-Making Framework – Data

Malaria Disease Burden	Other Malaria Interventions	Malaria Vaccine Impact	Economic & Financial Issues	Efficacy, Quality, & Safety	Programmatic Considerations	Sociocultural Environment
PRE-LICENSURE (5 years)						
<p>Reported & confirmed clinical & severe malaria cases by age group</p> <p>Reported malaria-related deaths by age group</p> <p>Malaria transmission & epidemiological profile up to district level</p> <p>Malaria cases in pregnant women</p> <p>Malaria cases in HIV+ individuals</p> <p>Economic burden of malaria</p>	<p>Impact of existing malaria interventions</p> <p>Country-specific impact of existing malaria interventions</p> <p>Coverage of current malaria interventions</p> <p>Cost-effectiveness estimates of existing malaria interventions</p>	<p>Projected impact on mortality and morbidity in different age groups</p>	<p>Credible public-sector price estimate</p> <p>Preliminary cost-effectiveness estimates of malaria vaccine</p> <p>Public health return on investment in terms of DALYs, impact on health budget, impact on GDP</p>	<p>Safety</p> <p>Adverse events</p> <p>Interaction with other vaccines</p> <p>Efficacy</p>	<p>Anticipated vaccine characteristics and presentation</p> <p>Evidence of established policy, regulatory, and institutional pathways to support intervention</p>	<p>Knowledge, attitudes, and practices of communities towards vaccines and malaria interventions</p> <p>Community expectations of malaria vaccines in clinical trial areas</p>
AVAILABLE DATA - PHASE III						
		<p>Absolute impact</p> <p>Marginal impact with other malaria interventions</p> <p>Impact on epidemiology and morbidity by age group</p>	<p>Vaccine price for public</p> <p>Donor subsidy for malaria vaccine and sustainability of subsidy</p> <p>National affordability</p>	<p>Efficacy, including impact on:</p> <ul style="list-style-type: none"> clinical disease severe disease anemia parasitemia <p>Efficacy in HIV+ populations</p> <p>Duration of efficacy of the vaccine</p>	<p>Demand forecast</p> <p>Supply availability</p> <p>HS capacity to accommodate a malaria vaccine</p> <p>Info. on product characteristics and storage</p>	
LICENSURE (2 years)						
<p>Update on current malaria situation</p>	<p>Changes in impact and cost-effectiveness of other malaria interventions</p>		<p>Sustainability of donor subsidy</p> <p>Sustainable national commitment</p>	<p>Efficacy, Quality, and safety data from other countries</p>	<p>Defined targeted groups and a communication plan</p> <p>Evidence of established policy, regulatory and institutional pathways to support interventions</p>	
MALARIA VACCINE INTRODUCTION DECISION						
POST-LICENSURE (5 years)						
<p>Reported and confirmed clinical and severe malaria cases by age group</p> <p>Reported malaria-related deaths by age group</p> <p>Required data</p>	<p>Changes in impact and cost-effectiveness of other anti-malaria interventions</p> <p>National level data</p>	<p>Malaria vaccine coverage: use of morbidity and mortality indicators for impact studies</p> <p>Effectiveness, including impact on:</p> <ul style="list-style-type: none"> clinical disease severe disease anemia parasitemia mortality <p>Global level data</p>	<p>Socio-economic impact</p> <p>Updated malaria vaccine cost-effectiveness data</p> <p>Estimates of recurrent direct and indirect costs, including marketing and surveillance</p>	<p>Post-licensure safety and efficacy data</p>	<p>Evidence of supply security</p>	<p>Knowledge, attitudes, and practices about malaria vaccines, especially acceptability and compliance*</p>

Regional Malaria Vaccine Decision-Making Framework – Process

