MALAWI 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 clinical & severe malaria cases (critical data) Reported malaria-related deaths by age group (critical data) Malaria epidemiological profile at the district level (critical data) Malaria cases in HIV+ individuals (critical data) Economic burden of malaria		Update on current malaria situation (critical data)	Reported and confirmed clinical and severe malaria cases by age group (critical data) Reported malaria-related deaths by age group (critical data)
Other malaria interventions	Impact of existing malaria interventions (critical data) Country-specific impact of existing malaria interventions (critical data) Coverage of current malaria interventions (critical data) Cost-effectiveness estimates of existing malaria interventions (critical data)		Changes in impact and cost-effectiveness of other malaria interventions	Changes in impact and cost effectiveness of other anti-malaria interventions (critical data)
Malaria vaccine impact	Projected impact on mortality and morbidity in different age groups (critical data)	Absolute impact Marginal impact with other malaria interventions (critical data) Impact on epidemiology and morbidity by age group		Malaria vaccine coverage (critical data) Effectiveness, including impact on: • clinical disease • severe disease • anemia • parasitemia • mortality (critical data) Effectiveness study (critical data)
Economical and financial issues	Credible public-sector price estimate Preliminary cost-effectiveness estimates of malaria vaccine (critical data) Public health return on investment in terms of DALYs, impact on health budget, impact on GDP	Vaccine price for public sector (critical data) Donor subsidy of malaria vaccine and duration of subsidy (critical data) National affordability (critical data) Cost-effective-ness estimate of a malaria vaccine (critical data)	Duration of donor subsidy Sustainable national commitment (critical data)	Public health return on investment Updated malaria vaccine cost-effectiveness data (critical data) Estimated recurrent and indirect costs, including marketing and surveillance (critical data)
Malaria vaccine efficacy, quality and safety	Safety (critical data) Adverse events (critical data) Interaction with other vaccines (critical data)	Efficacy, including impact on: • clinical disease • severe disease • anemia • parasitemia • malnutrition (critical data) Efficacy in HIV+ populations (critical data) Duration of efficacy of the vaccine (critical data)	Efficacy, quality, and safety data from other countries (critical data)	Post-licensure safety data (critical data)
Programmatic considerations	Anticipated vaccine characteristics and presentation (critical data) Evidence of established policy, regulatory, and institutional pathways to support intervention (critical data)	Demand forecast (critical data) Supply availability (critical data) HS capacity to accommo-date a malaria vaccine (critical data) Info. on product character-istics and storage (critical data)	Defined targeted groups and a communica-tion plan (critical data) Evidence of established policy, regulatory and institutional pathways to support interventions (critical data)	Evidence of supply security (critical data)
Socio-cultural environment	Knowledge, attitudes, and practices of communities towards vaccines and malaria interventions Community expectations of malaria vaccines in clinical trial areas			Knowledge, attitudes, and practices about malaria vaccines, especially acceptability and compliance (critical data)

Key: National data Global data

MALAWI MALARIA VACCINE DECISION-MAKING FRAMEWORK—PROCESSES