ETHIOPIA 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 clinical and severe (hospitalized) malaria cases by age group **(critical data)**	Reported malaria-related deaths by age group **(critical data)**	Cases of P. vivax vs. cases of P. falciparum **(critical data)**	Malaria epidemiology and transmission at zonal / woreda level **(critical data)**	Malaria cases in pregnant women and HIV + individuals **(critical data)**	Economic burden of malaria at national and household level						Reported and confirmed clinical and severe (hospitalized) malaria cases by age group **(critical data)**	Reported malaria-related deaths by age group **(critical data)**
Other malaria interventions	Impact of malaria interventions **(critical data)**	Country-specific impact of malaria interventions **(critical data)**	Coverage of current malaria interventions **(critical data)**	Cost-effectiveness estimates of malaria interventions **(critical data)**						Changes in impact and cost-effectiveness of other malaria interventions and other public health interventions **(critical data)**		Changes in use of other interventions at zonal / woreda level **(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, in different transmission settings **(critical data)**			Malaria vaccine coverage **(critical data)**	Effectiveness, using routinely reported data to measure impact on: • clinical disease • severe disease • anemia • parasitemia • mortality **(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 impact on health budget, impact on GDP				National affordability compared to cost of current interventions **(critical data)**	Public sector vaccine price **(critical data)**	Donor subsidy of malaria vaccine and sustainability of subsidy **(critical data)**	Sustainability of donor subsidy	Sustainable national commitment **(critical data)**	Public health return on investment	Updated malaria vaccine cost-effectiveness data **(critical data)**	Estimated recurrent and hidden 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)**	Preliminary estimates of efficacy **(critical data)**			Efficacy, by age group, including impact on: • clinical disease • severe disease • anemia • parasitemia • HIV + • malnutrition **(critical data)**		Duration of efficacy of the vaccine **(critical data)**	Efficacy in Ethiopia in different settings (e.g. types of malaria transmission, communities)		Post-licensure data on safety and adverse events following immunization **(critical data)**	
Programmatic considerations	Anticipated vaccine characteristics and presentation, especially implications for cold chain **(critical data)**		Evidence of established policy, regulatory, and institutional pathways to support intervention **(critical data)**				Supply availability and lead-time for delivery **(critical data)**	Final product characteris-tics over time in varying environmen-tal settings **(critical data)**	HS capacity to accommo-date a malaria vaccine **(critical data)**	Demand forecast **(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 and health personnel towards vaccines and malaria interventions **(critical data)**		Community expectations of malaria vaccines in clinical trial areas				Knowledge, attitudes, and practices of communities and health personnel towards vaccines and malaria interventions **(critical data)**					Knowledge, attitudes, and practices of communities and health personnel towards vaccines and malaria interventions **(critical data)**	

Key: National data Global data

ETHIOPIA 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

- Integrate the malaria vaccine in the multiyear strategic plan (4-5 years before) (critical process)
- Signal vaccine demand (1-3 years before)
- Strengthen national surveillance systems (critical process)
- Assess, strengthen, and support regulatory, ethics, and data management processes in-country, building upon regional collaborations, such as WHO capacity building initiatives (critical process)
- National expert group / technical working group formed to monitor malaria vaccine development, trials in Ethiopia, and the analysis of Phase III data (critical process)
- Engage local public and private-sector partners and pharmaceutical companies
- Develop communication plan on the malaria vaccine (1 year before) (critical process)
- National expert group/technical working group issues recommendation regarding vaccine introduction (critical process)
- National regulatory authority reviews vaccine (within 1 year of licensure) (critical process)
- Advocacy with national decision-makers (critical process)
- MOH makes a decision about integration of vaccine into EPI (critical process)
- Strengthen human resources, infrastructure to deliver vaccines and national surveillance systems (critical process)
- Incorporate malaria vaccine into national budgeting processes trials (critical process)
- Develop plan for procurement and resource mobilization for financial sustainability (RP)
- Issue programmatic guidelines for implementation of a malaria vaccine (within 1 year of licensure) (critical process)
- Examine sustainability of existing funding and how to encourage in-country financing (critical process)
- Update the communication plan for implementation (1 year after introduction) (critical process)
- Monitor vaccine performance and safety (ongoing after implementation) (critical process)
- Monitor implementation of the vaccine and evaluate impact on health system infrastructure (1 year after introduction) (critical process)

Global processes

- Integrate country requirements, including qualifications relevant to health programs and infrastructure, into product development plans (5 years before) (critical process)
- Share information on vaccine research (critical process)
- Conduct global advocacy to leverage funding through traditional (e.g., UNICEF) and non-traditional donor sources (e.g., segmenting market between public and private and target subsidy) (critical process)
- Strategies (e.g. advocacy) for reaching different target groups (critical process)
- Donors, with support and monitoring from partners like WHO and PATH MVI, provide funding to support vaccine (critical process)
- WHO issues policy recommending use of vaccine (critical process)
- WHO publishes vaccine management and introduction guidelines (licensure) (critical process)
- Reinforce regional and national capacities, such as the establishment of a regional quality control laboratory (critical process)
- WHO pre-qualification (within 1 year of licensure) (critical process)
- International agencies plan for procurement (within 1 year of licensure) (critical process)
- Monitor of vaccine performance, including evaluation of vaccine impact and pharmacovigilance (critical process)

Key: National process; Global process