Central Africa Malaria Vaccine Decision-Making Framework - Data Needs

Efficacy,

Malaria

Malaria Other Malaria **Economic & Programmatic** Sociocultural Vaccine Quality, & Disease Burden Interventions Financial Issues **Considerations Environment Impact** Safety PRE-LICENSURE (5 years) Impact of existing Projected impact Credible public-Safety Anticipated Knowledge, attitudes, and confirmed clinical malaria on mortality and sector price estimate vaccine interventions characteristics and practices of and severe Adverse events malaria cases by different age presentation . communities towards vaccines groups age group Preliminary cost and malaria interventions Interaction with effectivenéss other vaccines stablished policy nálaria estimates of malaria vaccine related deaths by age group nstitutional perceptions of malaria vaccines athways to Public health urrent malaria return on ntervention in clinical trial nterventions investment in transmission and areas epidemiological profile up to the district level terms of DALYs, impact on health budget, impact on GDP Cost-effectiveness estimates of existing malaria Malaria cases in pregnant women interventions HIV+ individuals Economic burden of malaria **AVAILABLE DATA - PHASE III** Direct impact vaccine price for public sector Efficacy, including Demand forecast clinical disease Indirect impact Supply availability severe disease Donor subsidy for with other malaria interventions HS capacity to parasitemia and sustainability HIV ccommodate a of subsidy Impact on epidemiology and morbidity by age malaria vaccine **Duration of** affordability efficacy of the group vacciné **LICENSURE AND DECISION (2 years)** Changes in impact Sustainability of donor subsidy Defined targeted and cost-effectiveness of communication other malaria interventions national commitment stablished policy, nstitutional support nterventions MALARIA VACCINE INTRODUCTION DECISION **POST-LICENSURE (5 years)** Knowledge Malaria vaccine Socio-economic ost-licensure Evidence of confirmed clinical fety and supply security attitudes, and impact and severe malaria cases by nortality nalaria vaccines. Updated malaria especially acceptability and compliance* /accine costimpact studies effectiveness data Reported malariaelated deaths by Effectiveness, Estimate of age group including impact current direct and indirect costs. clinical disease including marketing and severe disease surveilland parasitemia mortality Required data National level data Global level data

Central Africa Malaria Vaccine Decision-Making Framework – Process Needs

Global Level Processes National Level Processes PRE-LICENSURE (5 years) Integrate country requirements into product development plans (5 years before) Integrate country requirements into product development plans (5 years before) Assess and strengthen regulatory, ethics and data management processes in-country Integrate the malaria vaccine in countries multiyear strategic plans (4-5 years before)and revise EPI and NMCP multi-year strategic plans Signal vaccine demand and (1-3 years before) **AVAILABLE DATA - PHASE III** Engage local private-sector partners and Share information on vaccine research pharmaceutical companies Conduct global advocacy to leverage funding Develop communication plan on the malaria vaccine (1 year before)and integrate it to multi-year EPI and NMCP plans including a contingency plan **LICENSURE AND DECISION (2 years)** WHO issues policy recommending use of where possible (within 1 year of licensure) vaccine National expert group/technical working group Donors provide funding to support vaccine issues recommendation regarding vaccine introduction WHO publishes vaccine management and introduction guidelines (licensure) Advocacy with national decision makers MOH makes a decision about integration of vaccine into EPI Develop plan for procurement and resource mobilization for financial sustainability Incorporate malaria vaccine into national budgeting processes MALARIA VACCINE INTRODUCTION DECISION WHO pre-qualification Elaborate the vaccine introduction plan and (within 1 year of licensure) programmatic guidelines (within 1 year after licensure) International agencies plan for procurement (within 1 year of licensure) Update the communication plan for implementation (one year after introduction) Examine sustainability of existing funding and how to encourage in-country financing **POST-LICENSURE (5 years)** Monitoring of vaccine performance, including Monitor vaccine performance and safety evaluation of vaccine impact and pharmacovigilance Monitor implementation of the vaccine evaluate impact on health system Evaluate vaccine introduction impact on health system