

Independent Review Committee (IRC) Country Report
Gavi Secretariat, Geneva • [4-15 November 2024]

Country name Guinea-Bissau
Application type Malaria

1. Type of support requested

Table 1

Support type	Planned start	End of support	If vaccine request:				If cash request [VIG/Ops/HSS/ EAF/ITU/CCEOP /MICS]	Review outcome
			Total population estimate of relevant age cohort	Target coverage (% , per dose)	Wastage rate (%)	NVS presentation	Amount (US\$)	
Malaria VIG	January 2025	December 2026	Children 5-59 months 219,084 (2025, Year 1)	Dose1. 74% Dose2. 68% Dose3. 65%	7%	RTS,S/ASO1 2 doses/vial, lyophilised (Preferred vaccine)	100,000 US\$	Approval
			Children 5-11 months 48,928 (2026, Year 2)	Dose4. 50% Dose5. 50%				

2. Overview of the application

Application strengths

- NITAG and ICC endorsed the application.
- Well-defined rationale for malaria vaccine introduction, based on the epidemiological and programmatic context of Guinea Bissau.
- Well-documented prioritisation for selecting eight of the 11 regions (those with moderate and high transmission).
- Strong and close coordination across Malaria and EPI programs and with relevant partners
- Equity analysis based on the “Projeto de Saúde Bandim” on malaria vulnerability, rights protection and barriers to accessing health services
- Comprehensive training plan to build capacity of relevant staff involved in the vaccine introduction.
- Clear communication, social mobilization, and advocacy strategy.
- Technical Assistance needs well identified, with a 9-month TA for the supply chain, already planned
- Adequate storage capacity at all levels (central, regional and local)
- Funding for the vaccine introduction shared between different Gavi grants (HSS, CCEOP, CDS3).

Application weaknesses

- Limited description of measures to prevent a high dropout rate between the 3rd and 4th doses and to ensure catch-up for the 4th dose.
- Insufficient information regarding the existing second year of life (2YL) platform, which could provide opportunities for integration and synergies between the EPI and other Primary Health Care programs
- Few gender-responsive strategies in place, despite the identification of gender-related barriers

- No timeline outlining the preparation, implementation, and evaluation activities for the first two years of the malaria vaccine introduction
- Calculation of cold chain capacity only based on the three first doses and not four or potentially five.
- No budget allocated for costs in 2026. Guinea Bissau intends to roll out the first three malaria doses in 2025 (Year 1), the fourth in 2026 (Year 2), and the fifth in 2027 (Year 3), but the budget only covers costs for 2025.
- Missed opportunity to collaborate with supportive partners of immunization, such as the World Bank, European Union, and Rotary International to support the malaria vaccine introduction.
- Misalignment between the budget and the workplan, specifically regarding the procurement of vaccination cards.

Risks described in application or identified by IRC reviewer

- The malaria vaccine introduction may be postponed or face operational challenges as the vaccine supply is scheduled for May 2025, while the introduction is planned for June 2025.
- The vaccination coverage may decline if the country's financial situation worsens due to high out-of-pocket health expenses for households and limited or inexistent contributions to immunization from the government.
- There is an ongoing Effective Vaccine Management (EVM) assessment, with results expected in December 2024. It may reveal gaps that will not be addressed by the planned introduction date of June 2025.
- There is no assessment of the "piling-up" effect of doses required for malaria vaccine introduction in 2025, 2026 and subsequent years, that could potentially challenge the supply chain.

Mitigating strategies described in application

None

Lessons learnt described in application

Over the past 3 years, the country introduced three new vaccines (MCV2, MenA, and COVID-19) in the EPI schedule. Between 2018 and 2023, the country organised national vaccination campaigns against measles, polio, and MenA, as well as several response campaigns against COVID-19. These supplementary vaccine interventions have contributed to strengthening the capacity of the immunisation programs. Nonetheless, the country acknowledges that campaign reports are not always available, post-campaign evaluations have not consistently been conducted, and coverage targets have not always been achieved.

IRC comments for consideration

- Consider documenting the implementation of the innovative malaria introduction hybrid approach through high-quality and data-driven operational research.
- Consider leveraging Gavi's support to encourage immunisation donors, such as the World Bank, the European Union, and Rotary International, to address the numerous health system weaknesses.
- Consider exploring, with Gavi and partners, to vaccinate children aged 3 and 4 years with the 4th dose during the Year 2 of malaria vaccine introduction, in 2026

3. Findings

Guinea-Bissau, located in West Africa, covers an area of 36,125 km² and is bordered by Senegal, Guinea, and the Atlantic Ocean. The country experiences a subtropical climate, characterized by a dry season from November to May and a rainy season from May to November. As of 2024, the population is approximately 2,150,766, with an annual growth rate of 2.2%. This figure includes 365,630 children under five. Most of the population (62%) is below 24 years, and women represent 51.1%. Most inhabitants (64.3%) live in rural areas. Recent immigration and population changes require new health strategies.

Between 2018 and 2022, no vaccine included in the EPI achieved the 90% coverage target set in the Comprehensive Multi-Year Plan. According to WUENIC data, DTP3 vaccine coverage increased from 49% in 2000 to 74% in 2023. However, measles vaccine coverage (MCV1) remained consistently below 80% during the same period, with MCV2 coverage at 50% in 2023 after its introduction in 2022. The drop-out rate from DTP1 to DTP3 remains high at 12%. Differences in vaccination coverage were observed between WUENIC 2023 and MICS 2018-2019, varying by 11 to 16 percentage points depending on the vaccine.

Malaria presents a significant public health challenge in Guinea-Bissau, where it is endemic across the entire country, with moderate transmission of the disease. The annual incidence of malaria decreased from 389 per 1,000 inhabitants in 2015 to 284 per 1,000 in 2022. In 2022, there were 185,161 confirmed cases of malaria, of which about 26,668 cases (14%) occurred in children under five years of age. During this period, there were 461 recorded deaths from malaria (19.5 deaths per 100,000 inhabitants), including 118 deaths (26%) in children under five. The overall case-fatality rate was 0.24%. Malaria accounts for over 17% of the demand for health services.

The introduction of the malaria vaccine in Guinea-Bissau aims to significantly reduce morbidity and mortality associated with malaria-related illnesses in children under five years of age.

The vaccine will be deployed in eight out of 11 regions, targeting areas with high to moderate transmission of *P. falciparum*, where malaria incidence and prevalence are highest. Children receiving the vaccine will represent 73% of all children in this age group nationwide.

The vaccine schedule will administer five doses over three years, using a hybrid strategy combining:

- primary immunization according to age, in the 1st year of life of the child: vaccination at 5, 6 and 7 months for the first, second and third dose, respectively.
- seasonal vaccination in June (before the high-transmission season) for the 4th and 5th doses, in the 2nd and 3rd years of life.

The target population for the 1st year of introduction (2025) will include children aged 5-59 months as part of a Big Catch-up policy for at-risk children up to 5 years of age. In the second year of introduction (2026), only children aged 12 to 24 months who have received the first three doses of the malaria vaccine will be eligible for the administration of the 4th dose. Malaria vaccine will be integrated into routine immunization activities across all delivery strategies (fixed, advanced, and mobile) and complement other malaria control efforts. Initiatives to ensure vaccination equity and demand generation will also be implemented in partnership with key stakeholders in the country.

Support type: Malaria

Table 2

#	Review Criteria	Detailed question	Guardrail	Findings
1	Equity			
1.1	Has the country provided a clear and robust analysis to approximate the number of zero-dose children and missed communities at national and sub-national levels, including: - a quantitative and qualitative analysis of trends in vaccination coverage (absolute numbers and rates) - analysis of root causes, barriers, and/or bottlenecks for non- or partial-vaccination (drop-outs between DTP1/3 and MCV1/MCV2) in those specific geographies or populations (e.g. have gender-related barriers to immunisation been identified? Socioeconomic barriers?) [E1]		Not Critical / Nice to have	Met
	Rationale/Comments: The country has provided a clear and comprehensive analysis to estimate the number of zero-dose children and missed communities at national and subnational levels [<i>section Equity analysis 1.5 of the plan</i>]. The proportion of zero-dose children rose from 8% in 2018 to 19% in 2023, up an estimated 14,019. Four regions account for more than 60% of zero-dose children. The 2019 Equality analysis report identified dispersed populations, nomads, migrants, and those living in urban and peri-urban areas as underserved by vaccination services. Moreover, a study conducted by Projeto de Saúde Badim in 2019 highlighted that the populations most at risk or vulnerable to malaria are children, pregnant women, and older adults due to their biological characteristics and reliance on others for seeking care.			
1.2	Has the country prioritized and targeted zero-dose children in the application? Is the target for reducing the number of zero-dose children: a) reasonable given current coverage and trends; and b) ambitious enough given the resources that are being requested? c) Are estimates provided for targets at the national and subnational level? [E2]		Moderately Critical	Met

	Rationale/Comments: The Malaria Vaccine Introduction Plan (MVIP) notes an increase in zero-dose children from 8% in 2018 to 19% in 2023 and highlights geographical disparities. Four regions account for more than 60% of zero-dose children. A map of the distribution of zero-dose children in 2023 highlights disparities across the country, allowing for targeting intervention areas. However, there are concerns regarding the data quality, as figures vary by source, making it challenging to determine the number of zero-dose children accurately. To prioritize reaching ZD children, the MVIP proposes adequate tailored strategies such as a systematic verification of vaccination status during any interaction with health services (such as infant consultations, curative consultations, family planning, postnatal consultations, and special health days); intensifying routine vaccination activities through fixed and advanced strategies; a strengthened communication and social mobilization activities, including digitizing data; monitoring and addressing vaccine hesitancy. The MVIP proposes a survey to identify and determine the number of unvaccinated children so that a catch-up plan can be developed if the target is not reached.			
1.3	Are the proposed strategies differentiated to reach vulnerable, hard-to-reach, and un- or under-vaccinated populations, addressing regions with low immunisation rates comprehensively (including addressing demand and supply side barriers) and sufficiently tailored to the needs/ contexts of those areas/ populations? [E3]		Critical	Met
	Rationale/Comments: The MVIP identifies the regions with the lowest vaccination rates and geographic and socioeconomic barriers to access to care (i.e. distance to health centers, lack of transportation, and associated costs) and proposes differentiated strategies to reach vulnerable, hard-to-reach, and unvaccinated or under-vaccinated populations: - Combination of fixed, advanced and mobile strategies to reach target populations based on their proximity to health centers. - Community mobilization using religious and traditional leaders, healers, mothers' associations and community health workers. Targeted communication and social mobilization strategies will be developed for migrants, nomadic populations and "Penha ricas" (intellectuals and wealthy people). - Integration of malaria vaccination with other health interventions (i.e. distribution of insecticide-treated mosquito nets and seasonal malaria chemoprevention) to maximize vaccination opportunities and reduce the number of zero-dose children.			
1.4	Have gender-related barriers to immunisation been identified, and have gender-responsive or transformative interventions been considered, planned, and budgeted for? [E4]		Not Critical / Nice to have	Partially met
	Rationale/Comments: The MVIP identifies key gender-related barriers to vaccination and proposes gender-sensitive interventions to address these issues. Gender-related barriers identified for women are low decision-making power, less access to transportation, lack of financial resources and under-representation among Community Health Workers. Gender-sensitive interventions proposed are to engage men in vaccination discussions to highlight its importance, to train health workers on women's needs, and to empower women, notably in social mobilization and access to immunization information.			

	However, no gender-responsive or transformative interventions were considered, given that the application is for the introduction of the malaria vaccine. The IRC acknowledges that (i) a completed gender analysis was conducted by the University of Lisbon and local researchers in 2024; (ii) that technical assistance with gender specialists is planned to support the MoH in implementing the recommendations from this gender analysis, and (iii) that an EAF will be launched featuring significant CSO engagement focused on communication and social mobilization.			
2	Strategy & Planning			
2.1	Is there a robust epidemiological justification for the request, including relevant demographic analyses, immunisation coverage, gaps, and trends and use of surveillance data)? [SP1]		Critical	Met
	Rationale/Comments: The application presents a robust epidemiological analysis showing high malaria burden, demographic analysis and gaps in vaccination coverage to justify the choice of the vaccine schedule, the target population, the selected regions for the introduction and the proposed vaccination interventions.			
2.2	Is the programmatic justification, and choice of implementation strategies, in line with the epidemiological analysis and WHO SAGE guidance? [SP2]	For Malaria: Strategies that will be implemented to minimise sub-optimal vaccine use and wastage (using the proxy of national drop-out rate between DTP3 and MCV1) and reduce drop-out rates between the 3rd and 4th dose.	Critical	Met
	Rationale/Comments: The justification and choice of implementation strategies (hybrid strategy combining age-based vaccination for the first three doses and season-based vaccination for the 4 th and 5 th doses) align with the epidemiological analysis and WHO SAGE guidance. The assumptions for malaria vaccine coverage per dose (74-67-65-50-50) also follow the observed national vaccine coverages for DTP3, drop-out DTP1-DTP3 and MCV2.			
2.3	Are activities in line with Gavi Strategic priorities and suggested investments in the Gavi Guidelines? [SP3]		Critical	Met
	Rationale/Comments: The application proposal is in line with Gavi strategic priorities			
2.4	Does the proposal outline how identified needs and current gaps will be addressed via proposed objectives and activities? [SP4]		Moderately Critical	Unmet
	Rationale/Comments: The application identifies the needs and gaps in the country's health system and immunization program. It highlights key challenges, especially financial ones. Delays in co-financing payments have caused vaccine shortages. Additionally, there are delays in transferring funds to local levels and justifying immunisation expenses, which often leads to blocked accounts and insufficient resources for implementation and cMYP activities.			

	Some regions do not budget for action plans, and efforts to gather local resources for immunization have been minimal. Furthermore, there is a lack of consultation among the different Ministries and partners regarding planning, budgeting, and vaccine procurement. These challenges have not been addressed or discussed in the application.			
2.5	Has the country reflected on past learning from implementation experience (campaigns, RI, and switches) and best practices and incorporated learnings into their programme planning? [SP5]		Critical	Met
	Rationale/Comments: The MVIP applied lessons from past experiences with new vaccine introductions, particularly those for Rota, PCV13, and HPV, as well as follow-up and catch-up campaigns [Section 1.3.7 of the plan]. It has strengthened the EPI program's capacity, expanded cold chain capabilities, and improved health worker training and knowledge. As a result, it has informed the development of a practical and adaptable strategy for malaria vaccine introduction,			
2.6	Has the country considered the cost of the programme and ways in which to minimise the cost i.e. integration with other services and reduction of duplication? Noting where technical references exist they should be followed (or reasons for not following should be sound). [SP6]	For NVS: Where multiple products exist, has the country opted for the most cost-effective option for their context?	Critical	Partially met
	Rationale/Comments: The application focuses on several key areas, including capacity building, a communication plan, surveillance, validation of training modules, and project costs. The budget also includes expenses for vaccination cards, program coordination, management tools, vaccine distribution, and evaluations after the introduction. It is unclear whether these costs will be funded by this requested grant (operational funds) or the HSS2 grant. There was no discussion about how to reduce costs.			
3	Implementation & Capacity			
3.1	If the country has noted capacity gaps in their immunisation programme (e.g. staff, structures, technical capabilities, processes, tools, campaign support staff, materials, etc.), are they requesting Gavi or other donor support with corresponding interventions to address them? [IC1]	For NVS: Where there are noted gaps in a country's capacity to conduct campaigns or introduce a vaccine, has the country proposed mitigating strategies/asked for Gavi support (eg. staff, material support) to help?	Critical	Partially met
	Rationale/Comments: The country has identified critical gaps in its EPI, particularly in human resources, program management, cold chain logistics, waste management, and communication. Issues include a lack of qualified personnel, insufficient training, inadequate supervision, data quality concerns, low vaccination awareness, distrust in services, and misinformation. The EPI is supported by Gavi, as			

	well as the World Bank, the European Union, and Rotary International. However, the introduction of the malaria vaccine lacks financial support, even from the government. All expenses are currently covered only by Gavi, either through this VIG or other grants.			
3.2	If the country has noted any programmatic bottlenecks, have they proposed any mitigating strategies or interventions to address them and do they seem realistic? [IC2]		Critical	Unmet
	Rationale/Comments: The MVIP identifies programmatic bottlenecks in Human Resources (HR), finances, EPI performances/vaccine coverages, and communication and social mobilization [<i>Section 4 of the plan</i>]. No specific mitigation strategies are proposed to address these bottlenecks, except the indication of reinforcement of HR for 2023-2030 (without further details). In a financially constrained environment, cost efficiencies need to be sought and leveraged from other donors and the government.			
3.3	For NVS: Has the country articulated plans for generating demand and their approaches to social mobilisation, including the integration of communication materials, messages, channels, and how efforts will target across genders and to missed communities? [IC4]		Critical	Met
	Rationale/Comments: The country has articulated detailed plans for demand generation and strategies for social mobilization for malaria vaccine, including the integration of communication materials (i.e. leaflets for door-to-door visits, posters for health facilities and public spaces, roll-up banners, flip charts, videos), adapted messages (i.e. spots, microprograms, theatre et infographic), channels (TV, radio, social media) and targeting also different missing communities (i.e. migrants, intellectuals, hard-to-reach populations and nomads).			
3.4	For NVS: Has the country outlined if and where TA support will be utilized for social mobilisation efforts? Has the country detailed the integration of different community-based organizations (e.g. CSOs, and Faith-Based Organizations) where applicable, and have they highlighted their active roles and contributions. [IC5]		Critical	Met
	Rationale/Comments: The MVIP emphasizes the importance of technical assistance for social mobilization over the 12-month period, identifying UNICEF and WHO as potential funding sources and technical partners. Additionally, the MVIP outlines the roles of various community-based organizations in promoting malaria vaccination. These organizations include Islamic associations, evangelical churches, traditional leaders, traditional health practitioners, mothers' associations, village development committees, and women's vendors associations.			

3.5	For NVS: Crisis Communication: Has the country considered strategies for crisis communication and demonstrated preparedness in handling and responding to issues related to vaccination (e.g. HPV, misinformation, AEFI, etc). [IC6]		Critical	Met
	Rationale/Comments: The country considered communication strategies [section 5.8.6 of the plan] to manage crises and maintain trust between immunization service providers and communities. Clear communication strategies will include at least training pre-identified spokespersons, preparing responses to common questions and rumours with clear and simple messages, and using opinion leaders to reinforce the credibility of the messages broadcast. Differentiated approaches will be implemented for migrants, hard-to-reach populations, and health experts. Additionally, the communication plan will promote the acceptability and coverage of the malaria vaccine. A comprehensive communication campaign will be conducted before the peak malaria transmission period, featuring advocacy efforts, radio, television, outreach, and posters. This communication campaign aims to reduce the number of ZD children in the country.			
3.6	For NVS: Training and Orientation: Are there plans for the training and orientation of healthcare providers involved in vaccination efforts? [IC7]		Critical	Met
	Rationale/Comments: The training program [section 5.7 of the plan] will cover specific elements related to malaria vaccination introduction, including malaria epidemiology, the 5-dose vaccination schedule, management of adverse events following immunization and stock management, as well as integration of the malaria vaccine with other malaria prevention and control measures.			
3.7	For NVS: Vaccine Logistics and Waste Management: Has the country outlined comprehensive strategies for handling vaccine logistics, waste management, and controlled temperature chain (CTC) where appropriate. Are the country's planned activities to handle immunisation waste appropriate given the country context and the activity? [IC8]		Critical	Partially met
	Rationale/Comments: The country has outlined comprehensive strategies for managing vaccine logistics, waste management, and the cold chain for temperature-sensitive storage. Additionally, it remains unclear whether the existing capacity gaps in the cold chain and incineration facilities will be fixed by June 2025, including those identified by the current vaccine management evaluation (EVM), with results expected in December 2024.			
4	Alignment, integration, and sustainability			

4.1	Do the activities and proposed strategy align with the country's national strategy(ies) (for example an NIS or other national immunisation strategic plan, a Malaria, Yellow Fever, Measles/Rubella, and/or Cholera national plans, or other national guiding document provided by the country)? If there is notable non-alignment, has the country provided adequate explanation? [AIS1]	For Malaria: strategy should exist. For all: Per previous (4.0) strategy, country application needed to align with an active cMYP. This requirement no longer holds.	Critical	Met
	Rationale/Comments: The MVIP is aligned with the National Health Development Plan (2023-2028) already incorporated in the National Immunization Strategy (2024-2028), and adequately in line with the National Malaria Control Plan (2023-2027, 5 th version).			
4.2	Is there complementarity of funding? a. complementarity within Gavi funding (e.g. does Innovation Top-Up build on HSS or vice-versa? Is there complementarity between HSS and VIGs, Ops, CCEOP, EAF? etc.) b. complementarity of funding from Government/MoH and other donors? (e.g. to ensure that introductions /campaigns are fully funded; co-investment for CCEOP; complementary health system support, etc. [AIS2]		Nice to have	Partially met
	Rationale/Comments: The application outlines complementary financing within Gavi grants, specifically HSS and CDS3. It also highlights support for the immunization program from the World Bank, the European Union, and the Rotary Club. However, it does not mention any government or donor funding contributions for the introduction of the malaria vaccine.			
4.3	Immunisation --> PHC: Has the country described the role of vaccines in extending reach of current health services (e.g., utilising demand for malaria vaccine to offer other health services and support catch-up vaccination)? [AIS3]		Moderately Critical	Met
	Rationale/Comments: The MVIP suggests that the malaria vaccine introduction would provide opportunities to reduce the number of ZDC. The country also plans to take advantage of any visit to health facilities (early childhood development consultations, family planning consultations, prenatal or postnatal consultations), to identify children who have missed out on vaccination against malaria and other antigens These children will then be referred to vaccination facilities.			

	Additionally, mass campaigns for other vaccines will be implemented to ensure that children complete their malaria vaccine series before the high transmission season begins.			
4.4	Is the country planning to integrate (partially and/or co-delivery) the proposed interventions with other vaccine launches or health interventions (immunisation, PHC, WASH, nutrition or other), or provide a justification if the country does not plan integration? [AIS4]		Moderately Critical	Met
	Rationale/Comments: The MVP mentions the integration of malaria vaccination with other health interventions [section 3.5 of the plan]: (i) seasonal malaria chemoprevention carried out every year (from August to November); (ii) LLIN distributions to children > 1 year; (iii) micronutrient supplementation and deworming (vitamin A, mebendazole) and (iv) the intensification week (no further details are provided regarding this last intervention). In addition, the intensive communication/social mobilisation period (April to June) preceding the malaria seasonal administration will offer to increase awareness of the parents and the community on the relevance of completing malaria vaccination and identify malaria-vaccinated children who need their 4 th dose.			
4.5	For accelerated & transitioning countries, has the country provided evidence that there is the necessary experience, expertise, access to information, and effective processes to sustain available services and procure high-quality vaccines at affordable prices? [AIS5]	For campaigns: Note exception/flexibility for one time campaigns given one-off nature.	Moderately Critical	Exempt
	Rationale/Comments: Not applicable			
5	Budget & Financial Management			
5.1	Has the country adequately planned and budgeted for the interventions being proposed? [BFM1]		Critical	Partially met
	Rationale/Comments: Due to the country's size and limited vaccination targets, the budget is also constrained, with a Gavi ceiling of US\$100,000. Since this amount is insufficient, and the country seeks additional resources from other Gavi funds. Although malaria vaccine introduction is planned from 2025 to 2027, all budget costs are only allocated to 2025 and not in 2026. and 2027.			
5.2	Have issues been identified concerning the country's compliance with fiduciary requirements to-date, including submission of audit and financial reports, fulfilling of a Gavi payment	Key fiduciary compliance requirements include: - Grant management requirements (GMRs), - Periodic Financial reports (quarterly or six-monthly, as applicable), - Annual Audit reports	Critical	Partially met

	plan, and/or responses to capacity assessment findings indicating the need for additional investment in controls or assurance? [BFM3]			
	Rationale/Comments: The application points out several important financial compliance issues. Firstly, administrative technicians do not have enough skills to manage funds effectively. Secondly, the manuals and procedures for managing administrative, financial, and accounting tasks have not been approved. Lastly, there are delays in preparing and sending half-yearly and annual financial reports to MoH and EPI. However, the new PMU accompanied by a fiscal agent is in place to address these issues as they have approved management procedures.			
5.3	Have issues been identified concerning the reasonableness of unit costs with regard to official/ unofficial price references, past budgets or actual expenditures, and other relevant benchmarks or analytics? [BFM4]	For Core Standard countries: not subject to PFM pre-review. We take a 'light touch' approach with these countries so some of this information may not be given.	Critical	Met
	Rationale/Comments: Unit costs were provided on a separate document			
5.4	Are there any ineligible costs in accordance with the Budget Eligibility Guide? [BFM5]	For all: If activities that are discouraged or require exceptional approval are included, is there sufficient justification provided to merit funding of said activities?	Critical	Met
	Rationale/Comments: No ineligible costs were identified.			
5.5	Does the requested funding and budget align with the proposed objectives, activities, and/or targets across the application documents? [BFM6]	For all: For material budget items (depending on the materiality of cost input and/or budget line), is there a clear link between programmatic scale/nature, budgeted volumes and costing? For example, for vaccinator allowances are cost drivers clear, such as target population, vaccination sites and vaccinator days?? Are budgeted volumes reasonable, feasible, correctly calculated & aligned with known value-for-money benchmarks? For NVS: Is the budget overall aligned with the POA/NVIP? If applicable, are differentiated strategies/approaches reflected in the budget? For campaigns: Are the numbers of vaccinators, supervisors etc. aligned with the WHO campaign guide 'benchmarks'?	Critical	Partially met
	Rationale/Comments: The requested funding is aligned with the targets and the activities, but not the timeframe.			

6	Governance & Leadership			
6.1	Does the country have a Coordination Forum (ICC/HSCC or equivalent body) that is representative of a range of relevant stakeholders that are involved in the country health and immunisation sector (government, key donors, partners, women-led organizations, key implementers, CSOs)? [GL1]	For all: Is the country supporting civil society and community engagement in national, sub-national, and Alliance health sector planning processes?	Critical	Partially met
	Rationale/Comments: The country has a national coordination mechanism known as the Inter-agencies Coordination Committee (ICC), which is chaired by the Ministry of Health (MoH) and includes all relevant partners, such as various departments of the MoH, financial and technical partners like the European Union, UNICEF, Global Funds, Plan International, Rotary and Red Cross. However, the role of civil society organizations or local women-led organizations involved in this coordination process remains unclear.			
6.2	Has the Coordination Forum been adequately involved in the development of the request, including providing clear oversight and coordination with clear outcomes and endorsement? [GL2]		Critical	Partially met
	Rationale/Comments: The ICC endorsed this application through collaboration with its partners. Although the application includes meeting minutes from June 7, June 27, and September 20, 2024, it lacks a narrative detailing which partners, particularly civil society organizations (CSOs) and women-led associations, contributed to the development of the request.			
6.3	For NVS: Does the application include minutes from the NITAG (or equivalent body) meeting that endorses the introduction of the vaccine and the selected dosing schedule? [GL3]		Critical	Met
	Rationale/Comments: The application includes NITAG meeting minutes (18-20 Sept. 2024) that endorse the malaria vaccine introduction and selected dosing schedule with a hybrid approach (5 doses over 3 years).			
7	Monitoring, Evaluation, and Data Use			
7.1	Does the application include appropriate activities to strengthen AEFI monitoring / surveillance systems or, if not, is there evidence that these systems are functional? [MED3]		Moderately Critical	Partially met

	Rationale/Comments: The application mentions several key elements necessary for preparing to manage AEFI in relation to the introduction of the malaria vaccine. These elements include designated and trained focal points, tools for AEFI case management, and the implementation of the ODK tool for monitoring. However, the country encounters significant challenges, such as unmet surveillance indicators, slow data transmission, and insufficient active case searches for AEFI. Although interventions have been proposed to address these issues, it remains unclear how the malaria vaccine will be incorporated into these AEFI management strategies, as well as how the country plans to fund monitoring efforts and enhance data transmission and reporting systems.			
7.2	Does the application reflect efforts to consider different data sources in determining the most appropriate population estimates (eg. for birth cohort or zero-dose children estimation)? [MED4]	For all: For population size, ideally multiple sources will be listed, with a rationale for why one source or one methodology of averaging is utilized over the others.	Critical	Met
	Rationale/Comments: The application reflects efforts to consider different data sources in determining the most appropriate population estimates for zero-dose and targeted population for malaria vaccine introduction.			
7.3	Is the country planning a Rapid Convenience Monitoring (RCM), Mop-up, post introduction evaluation (for Routine introductions) or a post campaign coverage survey (for Campaign) per Gavi Vaccine Funding Guidelines? Does it follow WHO guidelines and is it budgeted for? [MED6]		Critical	Partially met
	Rationale/Comments: The MVIP includes a post-introduction evaluation (PIE) but lacks specific details about the evaluation methodology used. The plan also highlights the need for TA to implement this evaluation, and a budget for the PIE is allocated.			
7.4	Are there adequate systems in place for disease surveillance, or if not, are these planned and budgeted for? [MED7]		Critical	Met
	Rationale/Comments: The country already has malaria surveillance and monitoring in place, with a DHIS2/RTM (Real-Time monitoring module) implemented since 2022, that enables daily data entry in about 145 health areas. The country also piloted the Malaria Program's Logistics Management Information System in 2 regions in February 2022, with daily data entry collecting malaria treatment and prevention product information with confirmed cases. Moreover, there is a small amount in the budget for disease surveillance.			
7.5	For NVS: Are activities included to modify the HMIS as needed to capture		Critical	Met

	the new vaccine and monitor vaccine uptake after introduction? [MED9]			
	Rationale/Comments: The MVIP includes several activities to modify the Health Information Management System (HMIS) to capture data on malaria vaccination/vaccine following introduction: revised data collection tools, integration into DHIS2, and the establishment of an electronic vaccination registry.			
8	Supply Chain & Cold Chain Readiness			
8.1	NVS & CCEOP: Is waste management and/or decommissioning of CCE appropriately accounted for? [SC6]		Moderately Critical	Partially met
	Rationale/Comments: Waste management has been appropriately addressed. The malaria vaccine introduction into EPI will use existing waste management systems. However, details regarding installation dates for new incinerators are not provided. Additionally, the volume of waste was not estimated using WHO's sizing tool.			
8.2	For NVS: Does the application include an indication of sufficient cold chain capacity, particularly at the lower levels? If not, do they have budget and / or planned activities to expand (even if temporarily) cold chain capacity in accordance with vaccine requirements? [SC7]		Critical	Partially met
	Rationale/Comments: The application indicates sufficient cold chain capacity, particularly at lower levels. The WHO's sizing tool was utilized, although it has not been included in this application. Recent grants allowed the EPI program to acquire and install 334 refrigerators, 287 coolers, and 1,212 vaccine carriers. As a result, cold chain capacity will not face any challenges at the central, intermediary, and peripheral levels. The application also notes that a recent EVM assessment of the cold chain was done, and the results will be available by the end of December 2024. However, if the EVM outcomes reveal any issues, new remedial actions will unlikely be implemented by June 2025.			
8.3	For NVS: If the country has noted any vaccine stock issues or bottlenecks, have they proposed any mitigating strategies or interventions to address them and do they seem realistic? [SC8]		Moderately Critical	Unmet
	Rationale/Comments: The application does not mention mitigation strategies to address vaccine stock issues or bottlenecks.			

4. Conclusions

Table 3

Overall:	
Malaria	Guinea-Bissau has submitted a well-structured and comprehensive application for the introduction of a malaria vaccine into its routine immunization program. This application is based on strong epidemiological data and clearly identifies the targeted population, prioritizing eight regions for the vaccine's introduction. The Malaria Vaccine Introduction Plan (MVIP) is thorough and aligns with national strategies as well as WHO guidelines and recommendations. Guinea-Bissau intends to implement the malaria vaccine using a hybrid schedule, with seasonal administration for the 4th and 5th doses. Drawing from past experiences with supplemental immunization activities, the plan emphasizes the identification and vaccination of zero-dose and under-immunized children, along with focusing on areas and population groups that are often overlooked. There is strong leadership and coordination within the immunisation program and service, which involves the government, UN agencies, NGOs, and other partners. Moreover, the challenges associated with introducing the malaria vaccine, along with other malaria control and healthcare interventions, have been well-articulated. These challenges are framed within the context of an immunization system that faces limited financial support from the government, as well as constraints related to financial management systems and tools. However, the application lacks detailed work plans and microplanning, which still need to be developed and refined to effectively address programmatic challenges.

5. Recommendations

Table 4

[Approval / Re-review]	
Malaria	Approval

Table 5

Issues for Country	Action Points
Detailed chronogram	1. Provide a chronogram with the expected timelines of the key steps of the malaria vaccine introduction, including preparatory activities with training and microplanning sessions.
Target population for the 5 th dose	2. Provide the number of children to be reached for the 5 th dose in 2027
Cold chain and waste management	3. Given that the introduction of malaria vaccination into EPI will target a large age range of children (up to 59 months) in 2025, conduct an assessment to identify potential issues in storage, transportation/distribution, and waste management, and if needed, propose solutions to address these issues.
Other Gavi funding resources	4. Confirm where additional resources are being sourced for the malaria vaccine introduction, either from the Gavi country operational costs or from the HSS2 grant.

Budget	5. Provide the operational costs for implementing the 4th dose in 2026, for the target population of children aged 5-11 months 6. Resolve inconsistencies between the amount for procurement of vaccination cards (i.e., US\$ 54,400 in the budget template versus US\$ 41,295 in the workplan)
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Issues for Follow-Up by the Secretariat/Alliance Partners

Table 6

Issues	Action points	Responsible
Political engagement	1. Follow up with the country on the signature of the Minister of Finance.	Gavi secretariat
Technical Assistance in supply chain	2. Assess if technical assistance in the supply chain should be provided sooner to support the EPI in addressing existing cold chain deficiencies.	UNICEF