Gavi Malaria Vaccine Support

Abbreviated form for countries participating in the Malaria Vaccine Implementation Programme (MVIP) to access continued malaria vaccine support through Gavi

- 1. The request to access Gavi support will need to be endorsed by the Minister of Health and Minister of Finance, or their delegated authority.
- The completed request, together with any supporting documents must be submitted to Gavi by e-mail to <u>proposals@gavi.org</u>, copying the Senior Country Manager, by 13 September 2022.
- 3. Following submission, the request will be tabled for review at the next meeting of the Independent Review Committee (IRC).

PART 1: COUNTRY REQUEST

Country	Ghana
Ministry	Ghana Ministry of Health
Contact details of the country	Name: Dr. Kwame Amponsa-Achiano
focal point for this request	Email: kaash8@yahoo.com
	Telephone: +233 244 767 757
Is there confirmation of the	
country's decision to continue	Yes X No
malaria immunisation in areas	
covered by MVIP beyond	If yes, please submit the confirmation together with this
December 2023 (e.g., Minister of	request form.
Health sign off, NITAG meeting	
minutes, Immunization Inter-	
agency Coordination Committee	
(ICC) minutes)?	
Will the country maintain the joint	
EPI/ National malaria control	Yes X No
programme (NMCP) coordination	
mechanism (or other mechanism)	If no, please provide further explanation.
that will continue to oversee the	
coordination of the malaria	
vaccine implementation beyond	
the life of the MVIP?	

A. Continuation of malaria vaccination in geographic areas covered by the MVIP (implementation and comparator areas)

Anticipated dose requirement:

Assumptions: 85% coverage (2024) and 90% coverage (2025), wastage rate of 5%, 4 doses for the fully immunized child for. Differentiated population growth rates applied by region (based on the 2021 National Population and Housing Census)

Region	number of districts	target population (<1 year) 2024	total vaccines required for 1 year (doses) 2024	target population (<1 year) 2025	total vaccines required for 1 year (doses) 2025	total vaccines required for 2 years
Ahafo	6	25,588	91,610	26,202	99,327	190,937
Bono	12	48,784	174,656	49,955	189,369	364,026
Bono East	11	47,322	169,422	48,600	184,233	353,655
Central	22	109,600	392,390	112,230	425,441	817,831
Oti	9	31,775	113,761	32,442	122,981	236,742
Upper East	15	53,789	192,575	54,865	207,982	400,558
Volta	18	79,779	285,625	80,657	305,755	591,379
total	93	396,637	1,420,040	404,951	1,535,088	2,955,128



Ghana introduced the malaria vaccine into routine immunization in selected regions on 1st May 2019. Forty-two of the 76 districts in Brong Ahafo region (now divided as Bono, Bono East and Ahafo), Central, Volta (now split into Volta and Oti), and Upper East regions were involved in the implementation.

The selection of the districts was based on high malaria burden (\geq 20%); high immunization coverage; and a high number of age-eligible children to receive the vaccine.

The objective of this upcoming phase is the continuation of MVIP activities beyond December 2023 in the 7 regions that piloted the RTS,S, including current vaccinating districts (42) plus the comparator districts (51). Donation doses from the MVIP are available for the country to expand vaccination to the comparator areas through to December 2023.

One of the regions, Upper East, was not entirely covered by the pilot, with 2 MVIP districts and 2 comparators under the phase IV trial covered, out of a total of 15 districts.

The country plans to expand RTS,S to all districts in the Upper East region. There is moderate to high malaria transmission across the Upper East region¹ and the region has been included in all MVIP-related activities including training, monitoring, and performance review meetings, hence little additional investment is needed to roll out to the entire region. It will also be operationally cost-effective and feasible to deploy the vaccine across all the 15 districts compared to only 4 districts which may incur similar logistical and administrative costs. Additionally, the remaining districts and communities are expectant o be included in the prioritize district alongside the formal comparator district.

Region	number of districts	target population (<1 year) 2024	total vaccines required for 1 year (doses) 2024	target population (<1 year) 2025	total vaccines required for 1 year (doses) 2025	total vaccines required for 2 years
Upper East MVIP and comparators	4	11,730	41,996	11,965	45,357	87,353
Upper East non-MVIP	11	42,059	150,580	42,900	162,625	313,205
Total	15	53,789	192,575	54,865	207,982	400,558

Forecasted needs for Upper East region are detailed in the table below:

Malaria epidemiological profile of the 15 districts in Upper East Region (including the 11 non-MVIP districts) is presented below. It should be noted that while malaria is endemic and

¹ Ghana NITAG recommendation (minutes attached to this submission)

perennial in all parts of Ghana, varying transmission intensity and seasonal variations are more pronounced in the regions in the north, including Upper East.

DISTRICTS	map4_pfpr_2018	u5mr	MVIP
BAWKU MUNICIPAL	10.0	57.0	
BAWKU WEST	10.9	55.5	
BINDURI	11.2	50.8	
BOLGA EAST	11.3	47.3	
BOLGATANGA MUNICIPAL	10.4	48.8	
BONGO	9.4	52.6	
BUILSA NORTH	11.5	51.3	MVIP Comparison
BUILSA SOUTH	12.4	54.0	MVIP Comparison
GARU	15.3	52.1	
KASENA NANKANA EAST	8.8	53.2	MVIP
KASENA NANKANA WEST	10.0	54.0	MVIP
NABDAM	10.6	50.6	
PUSIGA	12.7	58.0	
TALENSI	11.2	51.9	
TEMPANE	13.5	53.5	

Are there **plans to expand the implementation** of the vaccine beyond the current areas covered under MVIP (implementation and comparator areas)?

The present application is for **the continuation** of the malaria vaccine in MVIP and comparator districts beyond December 2023. Ghana intends to apply in January 2023 for support to **scale up** the malaria vaccine to the remaining 168 districts or areas of greatest need, in a phased manner based on the malaria burden and epidemiology outside the pilot areas from January 2024, depending on the global availability of vaccines

B. Expansion of malaria vaccination into additional geographic areas and/or population groups not covered by MVIP (implementation and comparator areas)

Does the country want to include into this request an expansion of malaria vaccination beyond geographic areas / populations covered in MVIP, noting such expansion will be guided by the Framework for the allocation of limited malaria vaccine.

If yes, please provide detailed information on the areas and requested doses.

Year	Vaccine / presentation	Wastage	Target age	Population in target age cohort	Target population to be vaccinated according to coverage target
2024					
2025					

PART 2: SUPPORTING INFORMATION

Below should heavily draw from available MVIP documentation. You may choose to refer to existing documentation or reports; please be as specific as possible in below responses where relevant information can be found (e.g. document name and page numbers); and attach the relevant documents.

1. Please describe strategies and plans that are in place to ensure the **use of the malaria vaccine** will continue, as was the case during the MVIP, **as a complementary intervention** that does not replace the package of existing malaria prevention and case management tools nor does it weaken routine immunisation systems.

The RTS,S malaria vaccine continuation will leverage existing malaria control policies, infrastructure, human resources, and strategies for routine immunisation. The strategic plan for the vaccination continuation in Ghana focuses on coordination mechanisms and critical partnerships for the expansion, opportunities for improving routine immunisation programmes, and health system strengthening

a) Implementation of malaria control tools:

The current interventions implemented for malaria control include: a) Use of Long-Lasting Insecticide Nets (LLINs) b) Indoor Residual Spraying (IRS) c) Limited larviciding d) RTS,S malaria vaccine e) Intermittent Preventive Treatment in pregnancy (IPTp) f) Seasonal Malaria Chemoprevention (SMC) g) Case management (Diagnosis and Treatment).

	Coverage (scope and scale)/districts				
Strategic interventions	NSP 2014-2020	NSP 2021-2025			
ITN distribution: routine	260 (nationwide)	261* (nationwide)			
ITN distribution: mass	235 districts (except IRS	217 districts (except IRS			
campaign	districts)	districts)			
IRS	25 (all districts in UWR,	43 (all districts in UWR,			
	Obuasi, 3 districts in UER	Obuasi, 3 districts in UER and			
	and 4 districts in NR, 5	4 districts in NR, 5 districts in			
	districts in NER)	NER, 18 new districts added)			
Larval source management	105	105			
IPTp	260 (nationwide)	261* (nationwide)			
SMC	55 (NR, NER, SR, UER,	68 (NR, NER, SR, UER, UWR,			
	UWR)	Oti, BER 5 districts)			
Case management	260 (nationwide)	261* (nationwide)			
RTS S vaccine	Currently implemented in	42 districts from May 2019			

The results from the national stratification exercise in 2019 supported the sub-national tailoring of interventions to maximize impact. The intervention mix is shown below:

*One new district has been created since 2021 bringing the total number of districts to 261

The comparison of the package of malaria prevention tools implemented by MVIP and non-MVIP districts does not show any difference, confirming that RTS,S is integrated as a complementary intervention and does not affect or replace the implementation of other malaria control tools. All MVIP (vaccinating and comparator) districts implemented malaria case management, similar to non-MVIP districts. Out of 260 districts in the country only 25 implemented IRS. All districts are implementing IPTp.

There has been improvement in uptake of malaria control activities in MVIP districts in general, but it is difficult to attribute the increase to RTS'S introduction. For example, results from MICS conducted in 2019 (Data collection: September - November) indicates improvement in ITNs use among children

to 54% from 52% in 2014. [BAR- 65 to 69, CR-61 to 56, VR- 53% to 68%]. Parasite prevalence among children 6-59 months decreased to 14% from 21% in 2014 [BAR - 22% to 17%, CR - 30% to 18%, VR -28% to 20%]. However, there was also a decline in health seeking behavior for fevers from 72% in 2014 to 69% [BAR - 76% to 64%, CR - 70% to 61%, VR -79% to 80%] in 2019.

Reaching the unreached: it has been observed during the first phase of MVIP that RTS, S increased equity in access to malaria prevention. Data from the pilot programme showed that more than two-thirds of children who were not sleeping under an insecticide-treated net benefited from the RTS,S vaccine. Layering the tool results, over 90% of children benefited from at least one preventive intervention (insecticide-treated nets or the malaria vaccine).

EPI performance: comparison of Penta 3 and MR coverage between MVIP and other districts

The proportion of districts with Penta 3 coverages of >=95% between currently implementing and continuation districts did not show any statistical difference.

Overall, 19/42 (45.2%) districts that are currently implementing MVIP achieved a coverage of 95% or more between May -December 2019. Also, 22 /51(43.1%) continuation districts achieved coverage levels of 95% or more within the same period. Refer to attached excel file "Penta3_MR_2019_2022_Coverage"

b) EPI / NMCP coordination and country-led mechanisms:

Coordination with the NMCP is especially critical since the vaccines complement other interventions. The RTS,S malaria vaccine continuation will leverage existing malaria control policies, infrastructure, human resources, and strategies for routine immunisation. The strategic plan for the malaria vaccination in Ghana focuses on coordination mechanisms and critical partnerships, opportunities for improving routine immunisation programmes and health system strengthening.

The following coordination mechanisms have been established in Ghana:

- In 2009, a malaria vaccine Technical Working Group (TWG) was established as a subcommittee to the National Malaria Control Programme (NMCP) to compile and evaluate evidence on use of a malaria vaccine in Ghana.
- The TWG prepared RTS,S/AS01 malaria vaccine technical brief summarizing the data and information to support informed decision-making to participate in the RTS,S pilot implementation programme
- The TWG provided advisory oversight to the MVIP (and other malaria vaccine trials/activities in the country), includes membership of researchers and evaluation partners.
- Please describe how this application for vaccine funding support will contribute to increasing vaccine coverage. Specifically, please describe strategies and plans (including the use of digital health innovations) put in place to enhance the coverage of the 4th dose and reduce the drop-out between the 3rd and 4th dose observed during the MVIP.

Coverage rate:

• Generally, the coverage rates have been fairly good for a new vaccine with an average of 68% of all districts achieving at least 60% coverage

- The drop-out rate also improved with dose 1/3 at less than 10% (few challenges with negative drop-out rates in some districts)
- However, there is relatively high drop-out rate for the 4th dose (28% as of May 2022 and as high as 50% in some districts)

Table 1: Coverage of RTS,S doses

	May - Dec 19	2020	2021	Jan - May 22	Intro - May 22
RTS,S 1	66%	71%	76%	74%	72%
RTS,S 2	62%	67%	73%	71%	69%
RTS,S 3	51%	66%	74%	72%	67%
RTS,S 4	-	22%	47%	46%	42%
Drop-out 1/2	6%	5%	4%	4%	4%
Drop-out 1/3	7%	6%	2%	2%	6%
Drop-out 3/4*		35%	24%	28%	28%

The following strategies are in place to improve vaccine coverage:

- Malaria vaccine is integrated with **other child health interventions**: Vitamin A supplementation, LLIN distribution, integrated supportive supervision
- Districts are supported to periodically conduct **mop-up vaccinations**
- Defaulter tracing registers were developed to document and trace eligible children
- Use of volunteers for community mobilization and identification of missed children
- Use of Community Information Centres (CICs) to provide education and reminders to caregivers
- Support provided to hard-to-reach districts to sustain and extend outreach services
- Integration with mass public health interventions (vaccine campaigns, SMC, deworming, etc.)
- The country plans to align the 4th dose of RTS,S to 2nd Year of Life (2YL) interventions i.e., Measles-Rubella (MR2), Men A, and LLIN.

Table 2: Alignment of RTS,S with routine immunization schedule:

Child Age Vaccine	Birth	6 wks.	10 wks.	14 wks.	5 mo.	6 mo.	7 mo.	9 mo.	12 mo.	15 mo.	18 mo.	22 mo.	24 mo.
BCG	0												
Oral polio	0	0	2	3									
DTP-HepB-Hib (penta)		0	2	3									
Pneumococcal conj.		0	2	3									
Rotavirus		0	2	3									
Inactivated Polio				0									
Meningococcal A c.											0		
Measles-Rubella								0			2		
Yellow Fever								0					
RTS,S in Ghana						0	9	8			4		•
Vitamin A						0		•	2		6		4

RTS,S schedule has been aligned with routine immunization to decrease the number of required additional visits.

The first dose at 6 months allows starting protection at the age when children start being at risk, with protection from mother waning. Dose 3 at 9 months is timed with yellow fever and MR1.

The main challenge with RTS,S is drop out between dose 3 and dose 4, as dose 4 at 24 months falls beyond the "2YL (second year of life)" platform. The country has therefore decided to schedule **dose 4 at 18 months** for the continuation phase, to coincide with Men A and MR2.

Other strategies to improve the uptake of the 4th dose will include provision of LLIN at month 18 for caregivers and children when they complete the 4-dose schedule. Also, there will be the engagement of CBOs/CSOs to support defaulter tracing and soliciting the involvement of religious leaders and key community stakeholders to lead the advocacy and public education on the benefits of completing the vaccination schedule.

Please describe strategies and plans that are in place (or will be developed) to create/ sustain strong community engagement to ensure vaccine acceptance and resilient demand.

The EPI Programme will continue to collaborate with the Ghana Coalition of NGOs in Health (GCNH) and other partners in creating demand and educating the public on the importance of vaccination in general and the RTS,S vaccine in particular.

1) Community involvement in the malaria control

Generally, community involvement happens through existing structures: sub-districts and districts through to region and national stakeholders' engagements. Specifically for campaigns, ITNs mass distribution and SMC, regions and national teams participate at the community and subdistrict engagements for pre, during and post campaign social mobilizations. Malaria NGOs assigned to several communities to improve the uptake of interventions interact with communities and get feedback to the programme. Beyond the household surveys which solicit feedback from the community on malaria interventions, operational research is conducted periodically to get the community involved in strategies (such as targeting) for implementation of interventions.

Based on the outcome of 2019 survey response on RTS,S vaccine; 90% of women stated they would allow their children to be vaccinated against malaria. It can be interpreted that the successful SBCC during the RTS,S roll out will impact on community mobilization against malaria.

2) Lessons learned from the MVIP

Stakeholder engagement on sub-national introduction included the following key activities:

- Early stakeholder mapping and engagement: National House of Chiefs and Queen mothers, Professional Health Associations, Media, Parliament, National Academy of Arts and Sciences
- Media engagement: meeting with senior editors
- Training of key spokespersons
- Community engagement strategies developed at all levels
- **Communication messages** emphasized the phased introduction and continuous use of existing malaria control interventions

Main successes:

- Engagements facilitated high level and community support for the vaccine despite the initial anti-vaccination campaign and rumours
- Trained spokespersons adequately addressed public concerns following the social media campaign against the vaccine

Challenges:

- Funding to sustain community engagements and education
- Initial communication gaps by healthcare workers with regards to the concept of phased introduction and asking for "consent"

Community acceptance of RTS,S in Ghana is high because the population is aware of malaria and its impact. However, the findings from the PIE indicate the need to strengthen community engagement and advocacy, particularly around the uptake of the fourth dose (the PIE showed that more than half of the caregivers interviewed did not know about the 4-dose schedule).

3) Community engagement strategy for the next phase:

The communication strategy for the next phase will build on best practices to engage communities, through durbars, workshops, and information service/delivery vans and will include:

- Community education on the continuous use of other malaria interventions
- Healthcare worker job aids to reduce missed opportunities
- SMS reminders to parents and caregivers of vaccinated children to remind them of the date for the next visit for immunisation services, including RTS,S vaccines.
- Videos on eligibility criteria
- Quizzes
- Information sheets

Critical audiences for community engagement within the MVIP districts include groups who decide whether to bring eligible children for vaccination (parents and other caregivers). Other primary audiences include those who have the potential to inform vaccination decisions (including health care

workers, community health workers, caregivers, religious and traditional leaders, traditional healers, local government administrators, media, CSOs, and non-governmental organizations representatives).

Health workers will receive training on how to communicate effectively with caregivers. They will be provided information to accurately relay information on the benefits and risks of vaccination with the RTS,S vaccine through engagement meetings, briefings and dialogue sessions.

Communication activities will address **information gaps** related to the RTS,S malaria vaccine and increase understanding of the MVIP. Simple, evidence-based messages will be developed in the local languages to cover all MVIP districts within the seven regions. These will include an explanation of the target population for vaccination and why that group, the potential health benefits of the vaccine; the possible side effects; how to manage AEFI; how the vaccine works; what it does; and its role in the overall malaria control strategy. Messages will emphasize the vaccine's effectiveness (specifically, that vaccinated children will have fewer and less severe episodes of malaria) and the need to continue to use malaria preventive measures and seek care promptly for fever.

The Ghana Health Service will leverage on the **risk communication strategy**, deployed for COVID-19 vaccination for the RTS,S Malaria vaccine. The Service has a misinformation taskforce that has the capacity to track, detect, analyze and respond to misinformation by using the Talkwalker platform. Biweekly meetings are held to analyze and propose remedies that are shared with the multi-sectoral misinformation task force.

4. Please describe steps the country has taken to strengthen the pharmacovigilance system to enable **continued pharmacovigilance** of the malaria vaccine.

The Food and Drugs Authority (FDA) is mandated by the Public Health Act 2012, Act 851, to ensure only safe and efficacious vaccines are available to Ghanaians. Detailed guidelines for surveillance of AEFI have been published in 2014. There was also improved coordination between the NMCP, FDA and EPI with the formation of the Joint Malaria Vaccine Safety Committee.

The country has met the reporting threshold of at least 10 AEFIs per 100,000 surviving infants from 2018 to 2021. In 2021, the country reported 9,223 AEFI cases (majority [8,694] from the enhanced surveillance for COVID-19 vaccination, 379 from the malaria vaccine safety surveillance with routine immunisation and Yellow Fever vaccination campaign recording 147 and 3 cases respectively). Serious AEFIs constituted less than 1% (229 cases) of all the reported cases.

Results from the MVIP - PIE showed that AEFI and AESI forms were available in 55.6% of the facilities. Majority (92.6%) of staff interviewed knew the correct definition for AEFI. From May 2019 to September 2021, a total of 2,423 AEFIs and nine AESIs were reported. The majority of reported AEFIs (72.1%) and AESIs (77.8%) were for RTS,S, due to enhanced safety surveillance. The top five AEFI were fever, headache, cough, abdominal pain, and enteritis; and for AESI the top five were abscess, intussusception, thrombocytopenia, meningoencephalitis, and viral encephalitis. AESI and serious AEFI were investigated, and patients were treated or referred depending on case management capacity of the reporting facility. Public education was embarked upon to assure vaccine safety.

Areas for improvement

Although the majority of the staff knew the definition for AEFI and reporting forms were available, only 22.2% (12/54) of the facilities had reported at least one AEFI since RTS,S was introduced.

Recommendation

- Districts to conduct frequent on-site coaching visits and send periodic reminders to facilities on AEFI and AESI reporting.
- Setting up sentinel surveillance sites for AESI instead of current nation-wide spread which is not yielding desired results.

To build on these recommendations, the safety monitoring methods to be employed during the continuation phase are:

- Enhanced spontaneous reporting: this will monitor the RTS,S vaccine safety in all the 93 districts in the seven regions.
- Active surveillance for (AESIs): active surveillance system will be employed using sentinel hospitals in the 3 ecological zones of the country, namely, the northern, middle, and southern zones with Bolgatanga Regional Hospital, Bono Regional Hospital, and Winneba Trauma and Specialist Hospital to be used in each ecological zone respectively.

The Safety Sub-committee will collaborate with the Training Sub-committee to include vaccine safetyrelated information in the training manual and plan for training of Focal Persons for adverse events following immunisation (AEFI). The training will focus on the identification, reporting, investigation, and management of AEFIs to ensure the safety of the vaccine recipients and obtain accurate data for decision making. Targeted training will be provided for focal points at the sentinel sites responsible for AESI surveillance, with resources to enable focal persons to carry out this activity effectively.

The EPI/FDA will print tools, job aids and the updated guidelines for AEFI and AESI. AEFI monitoring guidelines and tools will be disseminated.

AEFI reporting will be through service delivery points to the FDA. Healthcare providers who administer vaccines maintain permanent vaccination records and are required to report occurrences of all AEFIs immediately to the next level as soon as they become aware. AEFI reporting by parents or guardians will be encouraged. Existing reporting tools and/channels, namely; the Call Centre, Med Safety App and Online reporting will be available to parents and guardians.

AEFI surveillance and reporting will be a collaborative effort between the EPI and FDA to ensure that all serious AEFIs are reported and investigated. Vaccine safety-related events will be managed with the Communication and Social Mobilization sub-committee. The existing system for addressing rumours will be enhanced at all levels to maintain and improve confidence in immunisation services.

All serious AEFIs/AESIs, AEFI clusters, and AEFIs of Community concern will be investigated by the Regional AEFI Investigation Team. Technical Advisory Committee on Safety of Vaccines, and Biological Products will then carryout causality assessment and provide feedback to stakeholders and the community to dispel rumours and maintain confidence in the RTS,S vaccine. The EPI will work with FDA to integrate the planned safety surveillance activities with ongoing routine vaccine safety monitoring activities in the Phase 2 (comparator) districts.

5. Please describe how the routine immunisation programme and health system will be strengthened so as to accommodate the additional work the malaria vaccine will create, including the need to provide the malaria vaccine at touch points (time points) not currently used in routine immunisation.

The pilot programme provided an opportunity to improve communication around immunisation and improved the capacity of health care workers in providing quality immunisation services, managing data, cold chain and transport, managing waste and monitoring safety through additional training and supervision.

The malaria vaccine schedule has been tailored to minimize the additional visits outside the existing routine immunization schedule (table 2).

The RTS,S vaccine roll-out in the comparator districts will be delivered through the **existing routine strategies** employed during the pilot phase:

- Daily immunisation sessions at hospitals, polyclinics, health centres, clinics and Communitybased Health Planning and Services (CHPS)
- Outreach services using the network of health facilities for widely dispersed populations falling within catchment areas of fixed health facilities
- Periodic Intensification of Routine Immunisation (PIRI) activities
- Mop-up vaccination for areas with low vaccination coverage based on administrative data
- Camp out in hard-to-reach communities and vaccinate all eligible children as and when necessary

To better equip front-line health workers for the next phase of the extension to comparator districts, the Training and Service Delivery Sub-committee is reviewing the existing **training modules** relevant to the various levels of the service. The modules include:

- the rationale for the expansion of the RTS, S vaccination
- vaccination schedule and co-administration of RTS, S with other EPI antigens
- lessons learned from the pilot implementation
- injection site and technique with special focus on multiple injections at the same immunisation session
- injection safety and waste management
- vaccine safety, AEFI and AESI surveillance and reporting
- vaccine storage and management
- cold chain maintenance
- advocacy, communication, and social mobilization
- monitoring, supervision, recording and reporting
- defaulter identification and tracing
- strategies to improve the uptake of RTS,S dose-4

Implementing the **2YL and urban immunisation programmes** has significantly improved vaccines' uptake beyond the first year of life and other child health services. These include growth monitoring, catch-up vaccinations, distribution of LLINs, deworming, and vitamin A supplementation in the pilot regions and districts. Existing 2YL tools include:

- Communication flip charts
- Decision Algorithm
- Vaccination Referral cards
- Catch-up App

The existing 2YL strategies will be adapted to generate the necessary demand for the 4th dose of the RTS,S malaria vaccine, with the objectives to (1) scale up the current 2YL interventions to all MVIP districts, (2) generate demand for the 4th dose of the RTS,S malaria vaccine, (3) provide an opportunity to offer catch-up vaccinations to eligible children, and (4) enhance the uptake of the other child health interventions beyond the first year of life.

Specifically, strategies for health care workers will aim at:

- sensitizing and educating them through coaching, supportive supervision, and development of appropriate job aids
- staff in implementing districts to compile a register of eligible children before the due month.
- developing reminders for caregivers presenting for Men A, MR2, and Vitamin A in the MVIP areas.
- including RTS,S malaria vaccine in the Catch-up App and making it available in pilot areas.
- intensification and/or expansion of outreach services.
- strengthening defaulter identification and tracking systems
- including RTS,S malaria vaccine in the decision algorithm tool (see below)



Cold Chain Availability

The **national** cold room has benefitted from partner-support (COVAX, VODACOM and others) to replace the four existing overaged Walk-In-Cold-Rooms (WICRs). The support further provides for installation of six additional WICRs. These replacements will provide adequate space to cover the targeted regions, with possibility to stagger the receipt of RTS,S vaccines to accommodate the expansion taking cognizance of routine, campaign and COVID-19 vaccines, should the need arise.

New cold chain support from partners will increase the capacity of **regions** to accommodate the additional volume of vaccines because of the RTS,S expansion:

• The three (3) **new regions**, i.e., Oti, Ahafo and Bono East, that do not have adequate cold chain capacity, have been allocated 40m³ Split WICRs through partner support. However, these regions will require the construction of superstructures to accommodate the WICRs to store the extra volumes of vaccine that may be coming in for the MVIP comparison areas.

The four old regions (Central, Volta, Bono, and Upper East regions) included in the RTS,S expansion programme are also being considered for cold chain equipment support. The central region will receive a combined WICR/WIFR of 40m³. UNICEF has provided support for the superstructure and the other equipment. The regional WICR for the Bono region is functioning relatively well, but will be provided with WIFR and a standby generator to support other routine vaccines. The Upper East region will also be provided with 40m³ WICR and 20m³ WIFR. Volta Region will receive a 40m³ capacity WICR.

The continuation of RTS,S vaccination will cover 93 **districts**. The current cold chain capacity at the district level has seen significant improvement from 2020 with support from the Cold Chain Equipment Optimization Platform (CCEOP) and COVAX. There are however cold chain gaps in some of the comparator districts earmarked for the introduction of RTS,S malaria vaccine, that will receive additional partner support.

		ССЕОР	equipment	COVAX equipment	Vodaco	n equipment
Region	Number of districts	Total equipment received	Districts provided with equipment (Vestfrost 1451)	Number of equipment (Vestfrost 1451)	No. of freezers	No. of districts benefiting from ice-lined fridges
Ahafo	6	44	5	1	6	6
Bono	12	80	9	1	12	10
Bono East	11	55	7	12	11	8
Central	22	219	16	2	22	15
Oti	9	95	8	0	9	8
Upper East	15	92	13	1	15	10
Volta	18	240	17	2	18	14
Total	93	825	75	9	93	71

Distribution of Cold Chain Equipment by Region and source of equipment

Waste management:

The introduction of the RTS,S vaccine will increase injection waste significantly in the comparator districts. Using a two-dose vial presentation of RTS,S vaccine means that two mixing syringes and 4 Auto-Destruct (AD) injection syringes are needed for each child to be fully vaccinated. This is estimated to increase the injection waste of the EPI Programme by approximately 25%. The final disposal of used syringes and sharps is done by incineration. Seven new incinerators will be constructed in the comparator districts to improve the waste management system in four MVIP pilot regions.

6. Please describe strategies or plans that are in place to enhance **monitoring**, **evaluation and learning** (MEL) and leverage on the learnings from the MVIP, including as relevant to inform the broader scale up.

At the start of the MVIP, data recording and monitoring tools were updated, and new tools such as defaulter tracing registers were first introduced into the immunisation service delivery which has improved defaulter listing and tracking.



Availability of reporting and recording tool in health facilities

EPI has been tasked to mobilize additional resources to print adequate reporting and recording forms for distribution to the facility level in all (93) MVIP districts.

Data collection, management and monitoring:

At the national level, the Data Management, Monitoring and Evaluation Sub-committee will coordinate and oversee all data management activities, and monitor and evaluate the extension to comparator districts. The committee will develop indicators, a data dictionary, tools for data capture and update or review the existing database (DHIS2, EPI e-tracker) to manage RTS,S data.

In collaboration with the Family Health Division of the Ghana Health Service, the current Maternal and Child Health Record Book (MCHRB) will be revised to have RTS,S added to the vaccines and RTS,S sticker printed at the back of the MCHRB and made available to the 93 districts. RTS, S data element on the reporting tools in both DHIS-2 platform (DHIMS) and e-Tracker will be activated for the seven MVIP regions. These platforms and reporting tools will be available to the 93 districts for data management.

The **EPI tracker for data capture, management and reporting** will be piloted in seven selected districts across the seven MVIP regions during the second phase of the vaccine rollout. The EPI team will collaborate with the Centre for Health Information Management (CHIM) to support the deployment and training of the selected districts on the **EPI e-tracker**.

The Child Welfare Clinic register, EPI monitoring charts, EPI tally book, and monthly vaccination report will be revised to include columns for RTS, S and printed for comparator and implementing districts. These will be distributed to all levels to manage the information system where relevant. An inventory assessment will be conducted at the facility level to ascertain the number of tablets available at the MVIP facilities using a template.

The role of enhanced supervision:

• Regular performance review is done and feedback provided to districts to guide in the development of improvement plans and using data for action

- To standardize and expand the scope of supportive supervision, the country employed electronic supervisory tools (ODK). This allowed for prompt analyses of key indicators to guide support to MVIP districts
- Immunisation data triangulating meetings will be conducted at the regional and district levels to triangulate data from various sources such as DHIMS2 (i.e., Immunisation service data, stock data, malaria morbidities, mortalities and GhiLMIS data). The meetings will comprise regional and district teams
- 7. Please explain how past implementation challenges and lessons learned are being taken into account for this request e.g., how challenges and lessons learnt from the MVIP will be leveraged to inform the continuation of malaria immunisation in the MVIP areas and/or introduction of the malaria vaccine in areas outside of the MVIP areas.

First challenge: vaccination schedule

The difficulty of health workers in interpreting the eligibility criteria for the 1st dose and the timing of the 3rd dose for late reporters

Interventions:

- Eligibility criteria job aid has been developed and provided to health care workers
- Developed simplified messaging: the first dose up to 1 year and maintaining at least 4 weeks between 2 doses
- Videos on eligibility criteria and schedule
- Updated algorithm for decision making (see above)

Lessons learned:

- Need simplified and clear messaging on the vaccination schedule
- Develop various scenarios during healthcare worker training
- Strengthen supervision at the lower-level support supervision
- Adjustments to eligibility for scale-up:
 - Country will maintain the 6, 7, and 9 months (1st dose 6 11 months)
 - 4th dose schedule to be aligned with MR2 and Men A at 18 months
 - Upper age limit for 4th dose aligned with other antigens on EPI schedule (up to 5 years vs. 3years during the initial phase of pilot implementation)

Second challenge: the sub-optimal coverage rate (<80%) and the high dropout rate from dose 3 to dose 4.

Strategies:

- PIRI activities, guided by data analysis, led by districts, and implemented at the community level
- Targeted supportive supervision to health facilities
- Defaulter tracing registers to guide home visits and outreach services
- Support for hard-to-reach areas (camp out in hard-to-reach communities and provide all vaccines to eligible children)
- Periodic review meetings and feedback to MVIP districts
- Community education on vaccination schedule
- Integration with school health (early childhood centres), Vit A supplementation, LLIN distribution etc.
- Catch-up campaigns may be necessary to optimize the uptake of the 4th dose, including leveraging on the second year of life (2YL) strategies

Third challenge: misinformation was a major concern for low vaccine uptake

Lessons learned: the advent and proliferation of smartphones and social media in Ghana facilitated spread of disinformation ahead of the launch of the vaccine.

Strategy:

- Social media is a very powerful tool for message amplification and should be harnessed to generate demand especially for new vaccines.
- The Ghana Health Service will leverage the risk communication strategy deployed for COVID-19 vaccination for the RTS,S Malaria vaccine. The Service has a misinformation taskforce that has the capacity to track, detect, analyse, and respond to misinformation by using the Talkwalker platform. Bi-weekly meetings are held to analyse and propose remedies that are shared with the multi-sectoral misinformation task force.
- 8. Please describe **technical assistance** (if any) that the country would need to enable continuation of malaria immunisation in the MVIP areas (implementation and comparator areas) or expansion into additional areas, and whether sources for this TA have already been identified.

TA and operational funding for implementation in the 51 continuation and 42 currently implementing districts is provided by PATH and WHO. The country will need TA for data management and PIE for the continuation in comparator districts.

9. Other comments/recommendations (optional): Provide any additional contextual information relevant to this request (any explanations that further clarify any possible linkages, routine monitoring, any considerations or data that informed this request)

PART 3: GOVERNMENT SIGNATURE FORM

The Government of Ghana would like to expand the existing partnership with Gavi for the improvement of the immunisation programme of the country, and specifically hereby requests Gavi support for:

Continuation of malaria vaccine implementation in the MVIP areas (implementation and comparator areas) beyond December 2023

The Government of Ghana commits itself to developing national immunisation services on a sustainable basis in accordance with the national health and immunisation strategic plans. The Government requests that Gavi and its partners contribute financial and technical assistance to support immunisation of children as outlined in this application.

Please note that Gavi will not review this application without the signatures of both the Minister of Health and Minister of Finance or their delegated authority.

We, the undersigned, affirm that the objectives and activities in this request are fully aligned with the national health and immunisation strategic plans (or equivalent), and that funds for implementing all activities, including domestic funds and any needed vaccine co-financing² will be included in the annual budget of the Ministry of Health.

We, the undersigned, further affirm that the requested funding for salaries, salary topups/allowances, per diems and incentives does not duplicate funding from other sources (e.g., from other donors).

We, the undersigned, further affirm that the terms and conditions of the Partnership Framework Agreement between Gavi and the Country remain in full effect and shall apply to any and all Gavi support made pursuant to this application.³

Minister of Health (or delegated authority)	Minister of Finance (or delegated authority)
Name	Name
Date	Date
Signature	Signature

² Applications will not need to be accompanied by a pre-determined co-financing commitment. Countries whose applications are recommended for approval by the IRC will have an opportunity to review the new co-financing policy in early 2023 and consider the co-financial implications of their application for Gavi support.

³ In the event the country has not yet executed a Partnership Framework Agreement, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.

PART 4: ATTACHMENTS & SUPPORTING DOCUMENTS

I. Mandatory supporting documents:

Please ensure the following documents are provided together with this form to support your request:

- Clear calculation supporting the number of malaria vaccine doses requested
- Confirmation of country decision to continue with malaria immunisation in the MVIP areas beyond December 2023 e.g., Minister of Health sign off, NITAG meeting minutes, Immunization Inter-Agency Coordination Committee (ICC) minutes, or other documented evidence

In the case that an expansion to areas not included in the MVIP is requested, you will need to also provide:

- Documentation of country decision to expand into additional areas
- Information on these additional areas and rational to include them, in line with the <u>Framework for the allocation of limited malaria vaccine</u> elements and a detailed calculation on the additional number of malaria vaccine doses requested
- A detailed plan for the introduction of the vaccine (new vaccine introduction plan)
- As applicable, a budget for a vaccine introduction grant (using the <u>Gavi Budgeting &</u> <u>Reporting Template</u>) for the introduction of the malaria vaccine in areas outside the MVIP areas.

II. Other supporting documents (not mandatory):

To support your request, you are encouraged to provide the following documents:

- If available, an updated **National Malaria Strategy** (or an addendum to it) that describes the country's plans to use the malaria vaccine within a comprehensive malaria control strategy as a complementary intervention that does not replace the package of existing malaria prevention and case management tools
- If available, an updated **National Immunisation Strategy** (or an addendum to it) that describes the country's plans to roll out the malaria vaccine within a comprehensive immunisation strategy such that the vaccine introduction or continuation of immunisation does not weaken routine immunisation systems