



Specific Questions related to the Call

“Catalyzing adoption of an expanded vector control toolbox to fight malaria”

Question	Answer
Could you kindly clarify the following: “New tools must be on track to be considered for a WHO recommendation by 2025/2026”? Does this apply to intervention classes rather than specific products? (e.g. does a product need to be submitted to PQ already and be on track to receive a listing before it is considered for this Call?)	The criteria apply to intervention classes rather than specific products and their PQ listing.
What tools within the 4-year VCAG process will UNITAID prioritize?	Unitaid is not prioritizing specific products. It is up to applicants to make the case for investment in different vector control interventions. As specified in the Call scope, it is most critical that the operational research agenda be based on country priorities.
Will this kind of call be launched by Unitaid periodically (e.g. every 1, 2, 3 years?)	Currently this is the only planned Call for Proposals on this topic.
Which intervention types would be considered? Are you funding more than one intervention? Is an RCT on one or more intervention, individually or in combination an option?	Unitaid hopes to fund several intervention types that align with the target criteria for tools and settings of interest. While RCTs on effectiveness are in scope, the preference is to include operational research with a range of different methodological approaches (e.g. pragmatic trials, quasi-experimental designs, implementation research). Please see the research description under Areas of Work in the Call scope. Research on delivery approaches is critical. The studies should evaluate new tools as they are currently envisaged to be deployed (i.e. either alone or in combination with other tools), leveraging and building on the existing evidence base either from ongoing or completed studies. Studies should aim to assess the incremental or relative cost-effectiveness of new tools compared to or in addition to existing interventions and aim to generate generalizable findings that are transferable to similar settings.

<p>Please define the expected outputs/needs?</p>	<p>By funding interventions targeted to evidence and market conditions, Unitaid hopes to bring <i>measurable change</i> in malaria control that speak to its 2023 – 2025 strategic objectives; notably to optimize deployment of vector control tools for the prevention of malaria, set conditions in place for sustainable and equitable access to these tools, and build partnerships that support a healthy market and deployment in high burden malaria countries and settings where <i>Anopheles stephensi</i> is a growing threat. Please see the “Impact we are seeking” section of the Call scope.</p>
<p>Please confirm if genomic surveillance tools are in scope.</p>	<p>The primary focus of the Call is on vector control products, rather than surveillance tools. The intervention classes under review by the WHO Vector Control Advisory Group can help better clarify what is in and out of scope (https://apps.who.int/iris/bitstream/handle/10665/274451/WHO-CDS-VCAG-2018.03-eng.pdf). We welcome the use of surveillance data to inform the selection of interventions to be evaluated through operational research.</p>
<p>Is it allowable to work on a new vector control tool that is not yet undergoing review by VCAG?</p>	<p>Under this Call for Proposals, we are aiming to support intervention classes that are currently undergoing review by VCAG. Please see the “Tools” section of the Call scope. The operational research aims to support the identification and refinement for effective delivery strategies for products that may be recommended by WHO on a 2025/2026 timeline.</p>
<p>Do you accept proposals for the control of residual malaria transmission in pre-elimination countries?</p>	<p>For this Call for Proposals, we are less focused on pre-elimination settings. Our target settings of interest are high malaria burden countries and countries where the invasion of <i>Anopheles stephensi</i> is a threat.</p>
<p>Are multi-country consortium (e.g. South-South partnerships) eligible?</p>	<p>Yes, multi-country consortia are eligible and South-South partnerships are encouraged. Unitaid sees value in proposals from South-based implementors with experience in leading the implementation of large-scale multi-country projects that support access to health products.</p>
<p>Which countries are eligible?</p>	<p>Work funded by Unitaid can target / benefit LIC, LMIC, UMICs as defined by World Bank. For this funding Call, the target geographies are those highlighted under “settings of interest,” namely countries with a high burden of malaria and/or countries where <i>Anopheles stephensi</i> is a growing threat.</p>
<p>What are eligible organizations for this Call?</p> <ul style="list-style-type: none"> • A government, government agency/organization? • UN agency? • Research institutions? <p>Community based organization?</p>	<p>All these organizations are eligible and can submit proposals. There are no restrictions on the type of entities that can submit proposals or participate in proposals. UN agencies can submit proposals, except for WHO in most cases, including regional and country offices. We have special enabler grants with WHO that are channeled through the corresponding departments in HQ. Please reach out to us with specific queries on WHO eligibility at proposalsunitaid@who.int.</p>

<p>Does UNITAID consider the combination of interventions to include non-vector control interventions? (e.g would dual AI nets and PMC be seen as a combination worth investigating or should the scope be limited to combinations of vector control interventions).</p>	<p>We envisioned the Call for Proposals as focusing on vector control combination interventions, but if there is a compelling reason to include a non-vector control intervention, you are welcome to make that case, particularly if it aligns with the priorities of national malaria control programs, communities, and civil society stakeholders.</p>
<p>Is it allowable to work on a new vector control tool that is not yet undergoing review by VCAG?</p>	<p>No, we have a criterion that tools must “belong to the intervention classes and prototype/products under WHO Vector Control Advisory Group (VCAG) review for assessment of public health value.” Please refer to the “Tool” section of the Call scope for information on eligibility.</p>
<p>Would a proposal focused on a product that is on track to submit evidence from a third RCT to VCAG late 2025/early 2026?</p>	<p>We specify that tools must “be on track to be considered for a WHO recommendation by 2025/2026.” Yes, based on the information you provided, this appears to fit the criteria. Please refer to the “Tool” section of the Call scope for information on eligibility.</p>
<p>Will proposals for a clinical trial as final piece of public health impact evidence for WHO-VCAG also be considered?</p>	<p>The research we envision funding is more focused on operational deployment considerations. Rather than funding the epidemiological trials aimed at assessing public value, the research we intended to fund may begin in parallel to those trials and inform “deployment and integration of new vector control tools within the wider malaria control toolbox, focusing on cost-effectiveness, and operational deployment strategies in specific settings.”</p>
<p>Can junior researcher be considered to lead the grant if their ideas meet the scope of the call?</p>	<p>We do not have requirements related to the seniority of researchers leading grants. We specify the following in the proposal requirements section: “The consortium should clearly demonstrate strong expertise in the different technical and market intervention areas needed to undertake the project, including the implementation of large-scale multi-country projects of this nature as well as research activities that cover both pragmatic trials and economic evaluations in LMICs. This should include evidence of strong skills in design and analysis of quasi-experimental studies, a specialized approach likely to be needed in this project.”</p>

<p>We are excited to see guidance from Unitaid acknowledge that “Strong stakeholder engagement will be critical throughout research design and implementation, including with national policymakers and implementers, civil society, and communities.” Does this imply that there will be time to allow the co-creating of research and learning agendas before the development of study protocols? This could increase the lead-times required.</p>	<p>You are welcome to propose a co-creation period for the research and learning agenda and make the case for its value, including considering the trade-offs due to increased lead time.</p>
<p>Does Unitaid expect to make a significant market intervention (copayment, subsidy, volume guarantee, or other supply-side mechanisms), or is the opportunity more narrowly focused on evidence generation.</p>	<p>The Call scope has two Areas of Work: (1) operational research, (2) market readiness. Please refer to the section of the Call scope on “Market readiness to support a sustainable market for an expanding vector control toolbox.” Applicants are welcome to make the case for specific market interventions as relevant. As described in the proposal requirements section, “the operational research component is the main focus, and this should be reflected in the consortium leadership structure and budget.”</p>
<p>Is there a preference for one multi-component, consortium-led grant designed to address each key question, or a desire for multiple, smaller awards that focus on the individual key issues addressed in the CFP (Resistance, Residual transmission, An. stephensi, Challenging contexts and specific high-risk populations)?</p>	<p>We do not have a pre-determined preference. We anticipate funding 1-3 projects. Please refer to the text in the proposal requirements section, where the following is stated: “it is expected that a consortium of partners will be required to undertake the full complement of activities described (Areas of work, as above). Applicants may choose to focus their proposals on one or both settings of interest.”</p>

Q&A for Submission of Proposals

General Questions

Question	Answer
<p>What is the proposal process under the Unitaid Operating Model?</p>	<ol style="list-style-type: none"> 1) Once a Call is issued, applicants are invited to attend a webinar on a date specified in the call for proposals text. The webinar presents the call scope, content, and process and answers questions submitted ahead of time using the online webinar registration form. Webinar attendance is not a mandatory requirement, however is strongly encouraged as it allows proponents to obtain further information and ask questions. A webinar recording is posted on the call for proposals web-page for all those unable to attend real time. 2) Full proposals must be submitted electronically using the Unitaid proposal form by the indicated closing date. 3) Proposals received are then assessed and eventually submitted to the Joint Review Committee (JRC), composed of representatives of the Unitaid Secretariat and the Proposal Review Committee (PRC). 4) The recommendations of the JRC must be endorsed by the Unitaid Board for a “go-ahead” to start developing a grant agreement. This endorsement does not mean and should not be perceived as involving any obligation on the part of Unitaid to fund the project. 5) Successful applicants receive a formal “go-ahead” for their proposal and will be requested to develop it into a full grant agreement. 6) The full grant agreement is reviewed by the JRC and submitted to the Unitaid Board for funding approval. <p>For further details please refer to the Unitaid Proposal Process document that can be found at http://unitaid.org/calls</p>
<p>Can a proposal that includes middle-income countries in scope be submitted?</p>	<p>Yes. While the primary focus of Unitaid investments is in low-income countries, proposals that include middle-income countries in scope are eligible. In principle, Unitaid looks for proposals that accrue benefit to those most in need (e.g., those in low-income countries, vulnerable populations). To this end, proposals should clearly demonstrate the use of innovative and sustainable approaches and are expected to outline a concrete and clear pathway to results and impact. Applicants should also demonstrate that their proposal is feasible and that they have the capacity to implement it.</p> <p>Across its portfolio of projects, at least 85% of Unitaid funds dedicated to commodity purchase must be spent in low-income</p>

	<p>countries. Middle-income countries are also eligible for inclusion in Unitaid-funded projects, however for any proposed project that includes a greater than 15% proportion of funding for commodity purchases in middle-income countries, the justification should be clearly stated, in line with the objectives of the Call for Proposals. Wherever possible, funding in middle-income countries should be used to increase access to commodities for vulnerable groups. Proposals focused on middle income countries will need to explain how low and lower-middle income countries will benefit from the interventions, at least indirectly, and what efforts will be made to ensure these indirect benefits materialize.</p>
Can a proposal that focuses only on one or two countries be submitted?	Yes, in certain circumstances. Unitaid works through market-based interventions to have global market and public health impact. This may require work in more than one or two countries. However, an intervention in a single country (or in a very limited number of countries) can be supported when the proponent can make the case, with clear supporting evidence, that such an intervention could have global impact or when the problem addressed is regional in nature.
Who can submit a proposal?	Unitaid interventions are delivered through implementers; that is, Unitaid does not implement interventions directly and has no in-country presence. For proposals that include country implementation, proposal submitted should demonstrate that the organization has the capability and capacity to deliver the proposed work in project countries and that the intervention will have a global/regional effect.
Are NGOs and civil society organizations eligible to submit a proposal?	Yes. Unitaid can provide grants to NGOs and civil society organizations. All Unitaid implementers must demonstrate their established capacity to manage their project.
Can a consortium submit a proposal?	Yes, a consortium approach may be considered for the project implementation purposes. However, projects should be as lean as possible. Any consortium approach should have a strong lead organization with overall responsibility for project implementation.
What constitutes a consortium?	A Consortium is a group of partners who have agreed to implement the project together on the basis of clearly defined agreements, which set out the basis on which all but the lead implementer is a sub-grantee with no direct legal relationship to Unitaid. Entities or individuals providing services to the project on a commercial basis are service providers and not Consortium Members. Partners collaborating on the implementation of the project but that are not active part of the project design and execution are not to be considered members of the consortium but will be identified as collaborating partners.
Which organization would Unitaid prefer to have in the lead for a consortium project proposal?	Should the establishment of a consortium for the project implementation purposes be necessary and substantiated, the selection of the lead agency/ organization in a consortium application is at the discretion of the consortium members. It should be noted that the lead of a consortium has overall responsibility for project implementation, including coordination of consortium members and communications with/reporting to Unitaid. They are also often the main route of funding. In determining the most suitable lead, consideration should be given to each of these factors to identify

	<p>which organization is best suited to deliver on each of them and assume overall responsibility for project activities. The capacity of the lead organization to manage the consortium and to report will be key at all stages of the project implementation.</p>
<p>Can an organization respond with more than one proposal in the capacity of lead organization?</p>	<p>Yes. Organizations can certainly respond with more than one proposal as lead organization. However, the organization must have the capability to deliver on any proposal they submit. Organizations must provide robust justification for the configuration of any consortium proposed, including the relative roles and responsibilities of members in achieving the goals detailed in each proposal.</p>
<p>Can a consortium member, a service provider or a collaborating partner participate in several proposals under the same call for proposals?</p>	<p>Yes, consortium members, service providers and collaborating partners can participate in several proposals under the same call for proposals.</p>
<p>Does Unitaid support R&D projects for pharmaceuticals and diagnostics?</p>	<p>Subject to call scope, Unitaid can support some late-stage R&D activities. Unitaid interventions typically focus on formulation or final product field validation where a product is about to reach the market. However, Unitaid carefully monitors the pipeline for innovative new products that may be “game changers” in the market in order to support entry, enable future scale-up and have public health impact. Note: Late-stage R&D activities are not within the call scope of this current call for proposals.</p>
<p>Can I contact Unitaid for further guidance on proposal development?</p>	<p>Unitaid provides guidance on the application process and the application forms. Questions should be addressed to Grant Applications Manager at proposalsunitaid@who.int</p> <p>In the interest of fairness and transparency, Unitaid does not provide guidance to individual organizations on substantive issues for responding to each particular call beyond what is available in the call text, associated documents published on the Unitaid website or through webinars announced in the call text.</p>
<p>What is the typical timeframe for Unitaid projects?</p>	<p>Unitaid makes catalytic investments. The timeframe is typically 3 to 5 years, including transition and sustainability plan.</p>
<p>Is there a limited grant size?</p>	<p>Unitaid considers funding size in light of Unitaid's strategy, available funds, investment required for impact, and existing portfolio of projects. As a general principle, Unitaid aims to fund projects that are targeted and ‘lean’ – that is, scoped at the minimum size required to achieve the desired market impact and public health effects and demonstrate value for money.</p>
<p>Do Unitaid grantees automatically benefit from tax exemption for the importation of goods?</p>	<p>Unitaid encourages the grantees to take all measures to secure tax and customs duty exemptions for all expenses incurred, especially regarding purchase of commodities with delivery to project countries. It should be noted that many of our grantees are successful in securing such exemptions.</p>
<p>Products must comply with Unitaid Quality Assurance Policy to be eligible for procurement. Are there any other conditions to be met?</p>	<p>Conditions on procurement within Unitaid grants may vary according to the commodity purchased, and detailed procurement conditions are typically finalized during grant development. Regarding quality assurance, as a general rule, Unitaid has harmonized its policy with those of other major partners, such as the Global Fund or PEPFAR. As a result, Unitaid typically requires that product be WHO Prequalified, authorized for use by a Stringent Regulatory Authority (SRA), or</p>

	<p>reviewed and permitted for use by the Expert Review Panel (ERP) as described in the Unitaid Quality Assurance guidelines https://unitaid.org/assets/UNITAID_QA-of-health-products_August2014.pdf</p>
<p>A high-burden country makes and buys its own local medicine, which is not WHO-prequalified or registered by a recognized stringent regulatory authority (SRA). Would Unitaid require that any project work it funds be used to increase demand only for product that is WHO-prequalified or SRA-registered?</p>	<p>Unitaid welcomes efforts to improve access to better, quality-assured treatment. Unitaid requires that any product procured with its funds conform with the Unitaid Quality Assurance guidelines as stated in https://unitaid.org/assets/UNITAID_QA-of-health-products_August2014.pdf - i.e., that products are WHO-prequalified or approved by a recognized SRA. In addition, in funding activities not directly related to product procurement, Unitaid still emphasizes the importance of quality assurance to 1) ensure that people in need receive appropriate, quality-assured medicines and diagnostics and 2) contribute to improving market health and stability for quality-assured health products.</p>
<p>What about rights-based projects, like patent law reform?</p>	<p>While Unitaid considers rights-based approaches important, Unitaid works through a market-based approach. The two approaches are not mutually exclusive, but the language used to present the issues, and the way to estimate and articulate impact can be considerably different. Nevertheless, one may wish to consider including elements related, for example, to the use of intellectual property flexibilities to bring down prices in quantifying impact.</p>

Questions Related to Submission of Proposals

Question	Answer
Does Unitaid provide samples of proposal submissions?	No; however, the submission form provides a useful guidance on how proponents should approach each section of the proposal form.
Does GANTT chart need to include monthly planning for the full duration of the project?	At the proposal stage proponents are requested to provide quarterly planning and monthly planning only for the first year of the project. The monthly planning can be indicative at this stage and if the proposal receives “Go-Ahead” decision, a more detailed planning will need to be done during the grant agreement development process.
What level of detail should the budget contain?	At the stage of submission of a proposal an indicative but realistic budget estimate will have to be prepared using the budget template that can be found at http://unitaid.org/calls
What are the rules regarding the, indirect or overhead costs?	<p>Unitaid agrees to fund a fair share of general administrative expenses linked to the general running of the head office administration of the different consortium members. Such expenses should primarily include expenses associated to head office corporate functions which support the entire operations (e.g. general management, human resources, finance, accounting, legal, internal audit, risk management) as well as expenses linked to the general running of headquarter infrastructures (e.g. facility, information systems). Unitaid has established the following maximum levels:</p> <ul style="list-style-type: none"> - 2% on commodity expenses; - 13% on other project expenses.

	<p>Any expenses linked to fundraising and lobbying activities are excluded from such general administrative expenses and are not funded by Unitaid. When projects are implemented through a consortium of organizations, Unitaid only accepts general administrative expenses of either the lead grantee or the sub-grantee and does not support overlapping layers of general administrative expenses.</p> <p>There is no differentiation in the funding approach based on the type of entity.</p>
Is there a list of cost category allowable/non-allowable for inclusion in the proposal budget?	Yes, Unitaid uses a standard expense classification. It can be found in the proposal budget form (Annex 3) that is available on Unitaid website (http://unitaid.org/calls).
Should budget be segregated by sub-grants?	Budgets of sub-awards to partners should be detailed using the proposal budget form (section 1, table Budget by organization).
Is there an audit requirement (do we have to plan some budget for audit or evaluation that would be contractually requested)?	Unitaid requires the grantees to engage with an audit firm to carry out annual financial audits during the project implementation and until the end of the project. The lead applicant should therefore include financial audit costs in the annual budgets. Such financial audit would normally include reasonable assurance engagements and agreed-upon procedures on specific areas. The estimated value of audit costs should be based on prevailing market rates.
Is co-funding, required or recommended and if yes, at which level?	<p>Co-funding is not a mandatory requirement; however, proponents are encouraged to include this information in the proposal.</p> <p>Please note that Unitaid defines co-funding as funding secured from other funding sources in addition to the Unitaid project funding to accomplish the Unitaid project outputs. Other funding source that will be used to finance activities which will support but not directly contribute to the achievement of the outputs should not be treated, and therefore not included, as co-funding.</p> <p>Please note that the budget form asks you to indicate the co-funding source (Section 2 of the form), if applicable, and if the co-funding is confirmed or anticipated.</p>
What analysis on impact and value for money needs to be included in the proposal?	The proposal must plausibly demonstrate a clear analysis of the expected market and public health impacts and how the proposal would contribute to goals and targets set in respective disease strategies by WHO and other partner organizations. A more detailed guidance on impact assessment can be found at http://unitaid.org/calls
The goal and outcome in the log-frame template (Annex 1) is already pre-populated with a standard goal. Can this be changed?	Yes, proponents are free to change the goals and outcomes. The pre-populated goals and outcomes are only included to be a guide for the level and type of statements Unitaid is expecting.

Can more than 5 risks be listed under the Section 4 of the application form?	Unitaid would like to encourage proponents to identify the most critical risks for the implementation of the project instead of presenting a large list of potential risks.
Do Annexes 5, 6, 7 and 8 need to be completed for all members of consortium?	The Annexes 5, 6, 7 and 8 need to be filled for the lead agency only.
What type of governmental bodies can sign the “Country engagement support letters”?	These letters can be signed by any relevant government body based on the proposed work and target countries.
Does Unitaid provide feedback on the JRC deliberations at the end of the proposal review process?	Unitaid proposal processes do not include the process of appeal. Letters are sent to inform each proponent of the result of the review and indicate decisions and rationale. In some cases, Unitaid may provide additional feedback at its discretion.