

Q&A for Submission of Proposals

General Questions

Question	Answer
What is the proposal process under the Unitaid Operating Model?	 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. Full proposals must be submitted electronically using the Unitaid proposal form by the indicated closing date. 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). 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. Successful applicants receive a formal "go-ahead" for their proposal and will be requested to develop it into a full grant agreement. The full grant agreement is reviewed by the JRC and submitted to the Unitaid Board for funding approval.
	For further details please refer to the Unitaid Proposal Process document that can be found at Microsoft Word - Proposal-process-November 2019 .docx (unitaid.org)

How will Unitaid assess the proposals? What are the evaluation criteria? If there are points or weightings per proposal section, what is the allocation of points per section?

The proposal process is available on the call webpage: Microsoft Word - Proposal-process-November 2019 .docx (unitaid.org). The proposals will be assessed based on the following criteria:

- General fit
- Technical criteria
- Potential feasibility
- Rationale and strategic alignment
- Impact
- Organizational capacity
- Proposal design and alignment
- Budget
- Compliance
- Potential risks

The questions in each of these assessment criteria are scored, however the Joint Review Committee (JRC) makes its recommendations based on the portfolio approach debate looking at the best fit taking into account all of the above criteria.

Can a proposal that includes middle-income countries in scope be submitted?

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.

Across its portfolio of projects, at least 85% of Unitaid funds dedicated to commodity purchase must be spent in low-income 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.

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.

What are eligible organizations for this Call? • A government, government agency/organization? • UN agency? • Research institutions? • Community based	Unitaid interventions are delivered through implementers; that is, Unitaid does not implement interventions directly and has no incountry 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. 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.
organization? 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
What constitutes a consortium?	organization with overall responsibility for project implementation. 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 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. Standard policies, such as limits on overhead, should also be adhered to for consortia members.
Can a consortium lead of an existing Unitaid grant participate as a lead under this call?	There are no restrictions to apply for the existing grantees.
Can an organization respond with more than one proposal in the capacity of lead organization?	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.

What is the total maximum number of members in a consortium?	We encourage well-defined consortia, with clear roles and responsibilities for each consortium member. Consortium structure should be well-tailored to the Call scope and expertise required and the number of consortium members has to be proposed accordingly bearing in mind that Unitaid funds 'lean' proposals.
Can a consortium member, a service provider or a collaborating partner participate in several proposals under the same call for proposals?	Yes, consortium members, service providers and collaborating partners can participate in several proposals under the same call for proposals.
Please confirm that partners from the global North are eligible to be the leadimplementing partner of a consortium.	The call text specifies that Unitaid's objective of progressively engaging an increased number of lead-implementing partners from the global South does not preclude proposals that also include partners from the global North, where their role is deemed complementary and important for the proposal's success.
Can you please define the term 'community' in the context of this call?	Communities in Unitaid's context are defined as follows: people living with and affected by the diseases that are the subject of Unitaid work. More information on community engagement work can be found on Unitaid website: https://unitaid.org/communities-and-civil-society/#en
Does Unitaid support R&D projects for pharmaceuticals and diagnostics?	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.
Can I contact Unitaid for further guidance on proposal development?	Unitaid provides guidance on the application process and the application forms. Questions should be addressed to Grant Applications Manager at proposalsunitaid@who.int 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.
What is the typical timeframe for Unitaid projects?	Unitaid makes catalytic investments. The timeframe is typically 3 to 5 years, including transition and sustainability plan.

What is the budget? Unitaid does not specify minimum or maximum grant sizes. The And how many awards does Unitaid Board considers funding size in light of Unitaid's strategy and Unitaid expect to make? existing portfolio of projects, which are described on our website. Is the budget the same Proponents are advised to consult these documents to understand how regardless of whether an their ideas for an intervention may fit with Unitaid's funding model and applicant submits for one strategy. project or up to three projects? As a general principle, Unitaid aims to fund projects that are 'lean' – Is Unitaid looking to fund one that is, scoped at the minimum size required to achieve the desired lead proposal, or are they market impact and public health effects while demonstrating value for considering funding multiple money. Our calls for proposals involve a competitive selection process, proposals that fit specific with the budget being one of the assessment criteria. Therefore, subsets of the CfP's aims (e.g., submitting large budgets may work to the disadvantage of your diagnostics-focused, malaria proposal. treatments-focused, and PPH Unitaid retains the right to select one or several proposals as required to and HIV treatments-focused)? achieve the objectives of the call. Do Unitaid grantees Unitaid encourages the grantees to take all measures to secure tax and automatically benefit from customs duty exemptions for all expenses incurred, especially tax exemption for the regarding purchase of commodities with delivery to project countries. It should be noted that many of our grantees are successful in importation of goods? securing such exemptions. Products must comply with Conditions on procurement within Unitaid grants may vary according Unitaid Quality Assurance to the commodity purchased, and detailed procurement conditions are Policy to be eligible for typically finalized during grant development. Regarding quality procurement. Are there any assurance, as a general rule, Unitaid has harmonized its policy with other conditions to be met? 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 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-healthproducts August2014.pdf A high-burden country makes Unitaid welcomes efforts to improve access to better, quality-assured treatment. Unitaid requires that any product procured with its funds and buys its own local medicine, which is not WHOconform with the Unitaid Quality Assurance guidelines as stated in https://unitaid.org/assets/UNITAID OA-of-healthprequalified or registered by products August2014.pdf - i.e., that products are WHO-prequalified or a recognized stringent approved by a recognized SRA. In addition, in funding activities not regulatory authority (SRA). Would Unitaid require that directly related to product procurement, Unitaid still emphasizes the any project work it funds be importance of quality assurance to 1) ensure that people in need used to increase demand only receive appropriate, quality-assured medicines and diagnostics and 2) for product that is WHOcontribute to improving market health and stability for quality- assured prequalified or SRAhealth products. registered? What about rights-based While Unitaid considers rights-based approaches important, Unitaid projects, like patent law works through a market-based approach. The two approaches are not reform? 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.

Is Unitaid aware of all	We do not share the lists of applicants and it is fully up to proponents
potential applicants for	to find potential partners.
this opportunity? If so,	
could you share a list of	
expected applicants?	

Questions Related to Submission of Proposals

Question	Answer
Does Unitaid provide samples of proposal	No; however, the submission form provides a useful guidance on how proponents should approach each section of the proposal form.
Explanation on theory of change (set of interventions, outcomes, impact, the monitoring and evaluation framework etc.)	Additional guidance can be found in the following documents that are available on the call webpage: • Guidance on Impact Assessment [PDF: 160 KB] • Financial Guidelines for Unitaid Grantees [PDF: 1,2 MB] • Unitaid Results Framework [PDF: 1.3 MB] • Unitaid Scalability Framework [PDF: 466 KB]
Do we have word limits for the proposal or for each section of the application form?	We use a restricted form to ensure equal treatment of all proponents and fair treatment of our reviewers. The text boxes in the form cannot be expanded, and there is a limit on the character input in each text box, except 2.2 a) and d); 2.3 c) and Section 4, where you can expand the table or graph. This character limit is now indicated in the proposal form. All sections should be Arial, and the minimum font is size 10.
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?	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: - 2% on commodity expenses; - 13% on other project expenses. 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. There is no differentiation in the funding approach based on the type of entity.
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?	Co-funding is not a mandatory requirement; however, proponents are encouraged to include this information in the proposal.
at which level.	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.
	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.
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 prepopulated 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? Are audited financial statements required from only the Lead Organization?	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. Yes, the financial statements are required from the lead only. The same applies for the annexes - those have to be completed by the lead entity 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.
Will the Unitaid confirmation of receipt be sent within one working day following the deadline even if we have submitted our proposal two to three days in advance of the deadline?	We are trying to confirm the receipt of proposals as soon as they are received in the proposals inbox, however due to large number of submissions this confirmation may be sent within one working day following the deadline.
Does Unitaid provide feedback on the JRC deliberations at the end of the proposal review	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.

Technical Questions related to RMEA Call for Proposals

Question	Answer
What kind of coalitions is UNITAID looking for?	Consortia should include technical support organizations, non-government organizations (NGOs), market-shaping organizations, academic and research institutions with demonstrated competencies in upstream product development and manufacturing, and downstream activities, including in-country product access. Proponents can submit one proposal (with different sections) focusing on one or multiple disease areas (and related product categories) and interventions
Wish to know if products are not CE or ISO13485 complaint at this moment are we eligible?	All manufacturers are encouraged to apply regardless of the regulatory status of their products.

Does the call consider developing a sustainable manufacturing infrastructure, e.g., for injectables, which does not currently exist outside of RSA? Or is it preferable to leverage existing factory facilities?	The scope of the call is for technical partners that support manufacturers at the various stages of their journey. The scope of the EOI is open to pharmaceutical manufacturers, contract development and manufacturing organizations (CDMOs), and Clinical Research Organizations (CROs) established and working in Africa
We do not provide technical assistance on the manufacturing process itself; we support policy measures that foster sustainable manufacturing capacity, aiming for health equity, sovereignty, and self-reliance for the African continent. We are inquiring whether our profile aligns with the scope of the call	This Call for Proposals aims to develop a manageable number of project(s) that will design and implement bespoke packages of interventions targeted at interested, eligible, and competitively selected manufacturers in Africa. Proponents can submit one proposal (with different sections) focusing on one or multiple disease areas (and related product categories), as detailed in the Table. However, strong preference will be <a #en"="" evaluations="" href="given to proposals that are comprehensive enough to deliver expected results across one or multiple disease areas and work packages.</td></tr><tr><td>Can we apply to manufacture and implement smart-software-based technologies to be used for malaria diagnosis?</td><td>Manufacturers of Invitro diagnostics (IVDs) are currently not in scope. An EOI for IVD manufacturers was published in November 2023. IVD manufacturers can submit their expression of interest here: Expression of interest: strengthening the regional supply of in vitro diagnostics in LMICs.</td></tr><tr><td>What are some of the most valuable lessons learned from past projects that Unitaid believes are crucial for new implementing partners to understand?</td><td>Kindly find a link to previous evaluations and what we look out for : https://unitaid.org/evaluations/#en to get valuable insights from past projects.
We are in the process to build up a consortium to develop paper based RDT to detect malaria from saliva and I would like to understand and we have already partnered with leading paper and pulp companies and with an integrator. What are the requirements for the consortium?	Manufacturers of Invitro diagnostics (IVDs) are currently not in scope. An EOI for IVD manufacturers was published in November 2023. IVD manufacturers can submit their expression of interest here: Expression of interest: strengthening the regional supply of in vitro diagnostics in LMICs. The consortium is only for implementing partners (or a consortium of partners) that can design and implement technical and market-shaping interventions to support manufacturers in achieving sustainable manufacturing and market entry of cost-competitive, quality-assured products within Unitaid's current portfolio.

Has the manufacturer's EOI dropped? Are there any general prioritization criteria we should know for our technical proposal? Are malaria RDTs priority?	Further details of the EOI can be found here: Call for Expression of Interest (EOI): Strengthening sustainable regional manufacturing of therapeutics for Maternal health, Malaria, and HIV programmatic priorities in Africa — Unitaid. The summary of target products outlines the programmatic priorities and support for rapid diagnostic tests(RDT) manufacturing, including malaria, which is a priority. Specifically, self-tests are identified as a priority investment given their potential public health impact and market readiness.
Is there an expectation that there is more than 1 manufacturer per product?	There may be more than one manufacturer per product, and one manufacturer may work on more than one product.
Since we don't know the companies we will be paired with to support, should be costing out hypothetical support packages we can provide to manufacturers to put in the proposal?	The cost of the packages will be tentative and can be based on previous experience working with African–based manufacturers and/or manufacturers of generic medicines and IVDs in LMICs. Furthermore, proposals are expected to be targeted in the budget, with intervention duration ranging (indicative) from 2 – 4 years, with clear milestones and deliverables over time. The selected technical partner will not be paired with manufacturers to support. The project will entail the process of selecting manufacturers from the pool that respond to the EOI.
In the manufacturer EOI, the HIV section doesn't specify which activities will be supported. However, the antimalaria section states the following "This support may include formulation development, technology transfer support, active pharmaceutical ingredient (API) cost optimization, quality assurance through WHO Prequalification or qualification by a WHO-Listed Regulatory Authority, and market-shaping initiatives for accelerated market entry and scale-up." Are these the types of support that would be expected for HIV or is it broader?	The support for all manufacturers of HIV, Malaria, and postpartum hemorrhage (PPH) commodities may include formulation development, technology transfer support, active pharmaceutical ingredient (API) cost optimization, quality assurance through WHO Prequalification or qualification by a WHO-Listed Regulatory Authority, and market-shaping initiatives for accelerated market entry and scale-up. It is also important to note that these interventions will be associated with requisite contractual access commitments by the manufacturing partners. The interventions are tied to the manufacturer's needs and can be broader than the listed support.

In the manufacturer EOI, on Page 5, Footnote 7 said that 'APIs in scope will be limited to the products covered within this document'. I assume this referring only to API manufacture, but fill/finish manufacture of other APIs is in scope? Please confirm.	Yes, API in this context refers to API manufacturing or process improvement interventions. Furthermore, API's outside of the programmatic priorities listed in the call for proposals are not in scope.
What funding will be provided to manufacturers?	The current open EOI aims to provide critical information to inform Unitaid's future investments and efforts to accelerate and strengthen regional manufacturing in Africa. This EOI may result in future funding opportunities, in which case a targeted Requests for Proposals (RFP) will be sent to the eligible and relevant EOI respondents. The specific funding provided will be based on the manufacturers' proposals and the technical partner's recommendations.
In the separate EOI can manufacturers use that funding for infrastructure upgrades (e.g., develop ARV manufacturing; move from vaccine fill-finish to ARV fill-finish)? In the separate EOI can manufacturers use that funding for bioequivalence or effectiveness studies?	Yes, manufacturers can express interest in leveraging existing production capacities to include Unitaid-related programmatic priorities. Furthermore, manufacturers may be supported to undertake bioequivalence or studies as a step towards a quality-assured product.
Would formulation development for an oral solid dosage form for TXA be within scope of this RFA?	No, the only formulation of TXA in scope of this call for proposals or the EOI is the injectable formulation.
Is this focused on pharmaceutical manufactures purely?	No, The scope of the EOI is for therapeutics and PPH-related medical devices. An existing EOI for IVD's can be found here Expression of interest: strengthening the regional supply of in vitro diagnostics in LMICs.

- 1. Can an organization submit as a sub for multiple proposals that are focused on different areas (e.g., diagnostics and commodities)? 2. Is Unitaid looking to fund one lead proposal, or are they considering funding multiple proposals that fit specific subsets of the CfP's aims (e.g., diagnosticsfocused, malaria treatmentsfocused, and PPH and HIV treatments-focused)? 3. Are Unitaid intending to select manufacturers with which to engage under a separate CfP to this one and link the workplans and outcomes from the 2(+)grants or will supplier selection be part of this CfP? When will the second CfP be released? (currently states June 2024)
- 1. Yes, an organization can submit as a sub for multiple proposals focused on different areas. The proponent's intervention can address a partial scope of a comprehensive intervention package; however, preference will be given to proponents that can offer end-to-end support.
- 2. The Call for Proposals is aimed at developing a manageable <u>number of initial project(s) (e.g., up to three)</u> that will design and implement bespoke packages of interventions targeted at interested, eligible, and competitively selected manufacturers in Africa.
- 3. The current EOI to manufacturers will provide critical information to inform Unitaid's future investments and efforts to accelerate and strengthen regional manufacturing in Africa. This EOI may result in future funding opportunities, in which case a targeted Requests for Proposals (RFP) will be sent to the eligible and relevant EOI respondents. The targeted RFP will be developed jointly with the selected implementing partner. The EOI to the industry is currently open and can be found here: Call for Expression of Interest (EOI): Strengthening sustainable regional manufacturing of therapeutics for Maternal health, Malaria and HIV programmatic priorities in Africa Unitaid

To what extent is the importance of having global south organizations prime or be included in project teams/consortia?

Unitaid sees value in proposals from South-based lead implementers with experience in leading the implementation of large-scale multi-country projects that support access to health products in LMICs. We also support the meaningful inclusion of South-based sub-implementers, where feasible and relevant, in proposed project implementation consortia.