

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 include middle-income countries in scope be submitted?</p>	<p>Yes. The ultimate objective of this Call is to enable equitable access to monoclonal antibodies in low- and middle-income countries and proposals should be designed accordingly, especially regarding engaging community-based organizations from relevant low- and middle-income countries.</p> <p>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>Proposals focused on upper-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>
<p>Can a proposal that focuses only on one or two countries be submitted?</p>	<p>As the scope of this Call does not include implementation work in countries, there are no specific requirements for the number of countries included in the proposals.</p> <p>In general, in certain circumstances proposals that focus on a limited number of countries are also eligible. 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.</p>
<p>Who can submit a proposal?</p>	<p>Unitaid interventions are delivered through implementers; that is, Unitaid does not implement interventions directly and has no in-country presence. Proposal submitted should demonstrate that the organization (or consortium) has the capability and capacity to deliver the proposed work.</p>
<p>Are NGOs and civil society organizations eligible to submit a proposal?</p>	<p>Yes. Unitaid can provide grants to NGOs and civil society organizations. All Unitaid implementers must demonstrate their established capacity to manage their project.</p>
<p>Can a consortium submit a proposal?</p>	<p>Yes, a consortium approach is encouraged for the “<i>Establish viable business models for access to monoclonal antibodies in low- and middle-income countries</i>” Call for Proposals. Details on the expectations for consortium partners and skillsets can be found in the Call under Additional Information. However, projects should be as lean as possible. Any consortium approach should have a strong lead organization with overall responsibility for project implementation.</p>
<p>What constitutes a consortium?</p>	<p>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.</p>
<p>Which organization would Unitaid prefer to have in the lead for a consortium project proposal?</p>	<p>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</p>

	<p>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.</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.</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. 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. However, given the scope of the “<i>Establish viable business models for access to monoclonal antibodies in low- and middle-income countries</i>” Call for Proposals, it is expected that projects will be more limited (1 to 2 years).</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. As noted above, given</p>

	the scope of the “ <i>Establish viable business models for access to monoclonal antibodies in low- and middle-income countries</i> ” Call for Proposals, it is expected that projects will be limited in terms of budget.
Do Unitaid grantees automatically benefit from tax exemption for the importation of goods?	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.
What about rights-based projects, like patent law reform?	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.

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</p>

	<p>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 details template (Annex 2) that is available in the Call for Proposals.
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 .
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 4, 5, 6, and 7 need to be completed for all members of consortium?	The Annexes 4, 5, 6, and 7 need to be filled for the lead agency only.

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.
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Responses to Specific Questions Received from Proponents

Question	Answer
Which organizations and countries are eligible to apply?	<p>Please refer to the Call for Proposals where you will find annexes to the Proposal Form with declarations that outline potential conflicts of interest for which an entity would be ineligible.</p> <p>Provided they adhere to these conditions, in general, there are no restrictions on the type of entities that can submit proposals (individuals or organizations, including international, national, community-based, etc.). It is up to the applicant to demonstrate in the application that the entity has the capacity to accomplish what is being proposed.</p> <p>UN agencies can submit proposals, including regional and country offices, except for WHO because there are other procedures for us to work with WHO. WHO staff members could be technical partners as part of a consortium, but are ineligible as the lead entity.</p> <p>Institutions from all countries are eligible to apply, as long as the work will have global impact, particularly benefiting target populations living in LMICs. Institutions based in LMICs are particularly encouraged to apply.</p>
To form a consortium, does Unitaid help identify suitable partners? Or, can partnerships be formalized after the proposal stage?	<p>Unitaid does not typically orchestrate consortium-building at the proposal stage. We would encourage you to reach out to potential partners directly.</p> <p>Applications that do not cover all areas or that plan to engage partners with certain areas of expertise during Grant Agreement Development or project implementation will still be accepted, however they will be assessed against our standard criteria and the other proposals received. We would encourage you to carefully review the Proposal Form which clearly outlines what information from consortia members is required at the proposal stage (in particular section 2.2 and Annex 3).</p>
What is considered a community-based organization?	<p>Unitaid considers community-based organizations to be structures embedded in the communities of people living with or affected by the diseases that are the subject of the work. Please refer to the “expectations for consortium partners” section of the Call for Proposals, which contains further details on the expected representation from across disease areas.</p>
Does the requirement to have impact in multiple countries mean that activities are expected in	<p>Unitaid’s goal is to have global impact. The way to achieve it depends on the topic at hand and is left for proponents to describe in their proposals. We are not prescriptive on what countries are to be involved in the projects, but projects should ultimately have impact beyond the project countries by enabling a better pathway to access for LMICs broadly.</p>

multiple countries during the project?	
What is the expected start date.	By end of Q2 2024, proponents will be notified of the outcome of the proposal review and successful proponents will move into Grant Agreement Development, so the start of the project could be by Q4 2024 depending on the length of the agreement development process.
What is the maximum funding available and how many grants will be awarded?	<p>As explained above, Unitaid does not specify minimum or maximum grant sizes. Given the scope of this specific Call for Proposals, it is expected that projects will be limited in terms of budget. The overall amount we are expecting to spend now in this area is approximately USD 12 million. However please note that this full funding envelope will not necessarily be spent only on the activities outlined in the Call for Proposals.</p> <p>The number of grants awarded will depend on the proposals received, but given the integrated nature of the areas of work outlined in the Call for Proposals, we would hope to support one or a small number of comprehensive grants than multiple grants targeted siloed pieces of work.</p>
What is expected for final deliverables?	We expect proponents to propose what is feasible within the parameters of the available funding. Activities that can already be taken to demonstrate feasibility of business models and proof of concept of manufacturability, including opportunities to simplify and lower the cost of production and delivery of mAbs, are strongly encouraged. Final deliverables are expected to outline concrete next steps that could build upon and/or complement initial pieces of work.
Does “cost of delivering mAbs” refer to bringing them to market or actual in-country adoption?	We are interested in potential ways to decrease the in-country administration/delivery mAbs (e.g. administration route, dosing requirements, etc.). However, a broader analysis of the supply side, including cost of entrance in the market, is expected as well.
Can we submit proposals for long-term plans to reduce costs to monoclonal antibodies?	The focus of this Call for Proposals is on solutions that can be available in the near term. In other words, we are seeking solutions that could be relevant for the infectious disease mAbs that are approved or in advanced stages of the pipeline and may play a role in the global health response in the next few years.
What is the disease scope? Is there a list of products Unitaid would like to see included?	<p>Proposals are expected to take a comprehensive view of the potential mAbs market in LMICs, with a priority focus on enabling access to mAbs for infectious diseases. So, Unitaid is not prescriptive in which mAbs need to be included in proposals, but rather it is up to the proponent to make the case for how the mAbs included will establish proof of concept of business models that can enable an affordable and sustainable supply of mAbs, including for infectious diseases, in LMICs.</p> <p>Further details on Unitaid’s programmatic priorities can be found in our Strategy.</p>

<p>Should regional and community perspectives inform which products have viable use cases?</p>	<p>Yes, please refer to the Areas of Work in the Call for Proposals. Regional and community perspectives should be reflected in all stages of the work, including the identification of viable use cases.</p>
<p>How early in research and development of mAbs or biosimilars is in scope?</p>	<p>Early research is out of scope for this Call for Proposals. The focus of the Call for Proposals is business models that can enable equitable access to mAbs more generally, whether originator or biosimilars.</p> <p>Late-stage optimization to demonstrate proof of concept in the short-term for simplified production and/or delivery of mAbs could be considered.</p>
<p>Does Unitaid plan to launch other Calls for Proposals on this topic?</p>	<p>We do not expect to run additional Calls for Proposals on this topic in the short term. Potential further interventions will be informed by this initial phase of work as well as by the evolution of the clinical pipeline of mAbs for infectious diseases.</p> <p>As noted in the Call for Proposals, Unitaid also expects to undertake separate and complementary work related to regulatory pathways and intellectual property for mAbs. It is expected that any successful proponent of this Call for Proposals would work collaboratively with partners in Unitaid's portfolio as relevant.</p>
<p>We are pursuing complementary pieces of work (e.g. engaging with regulators). Should this be outlined in the proposal and can we assume the success of such efforts as they relate to our proposal?</p>	<p>Yes, please do outline relevant complementary work you are undertaking and indicate any assumptions and/or dependencies on which your proposal is based.</p>
<p>Does the IP arising from the project remain the property of the implementer?</p>	<p>In general, yes, however please note that terms to ensure that final products fulfil access objectives are tailored during Grant Agreement Development and included in final agreements.</p>