

Q&A for Submission of Proposals

Specific Questions on Calls for Proposals: “Cost-effective and high impact rollout of lenacapavir for HIV prevention”

| Question | Answer |
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| <p>GEOGRAPHICAL SCOPE - Is the implementation in just one country preferred over multi-country?</p> <p>Is it possible for two countries to apply for this grant jointly?</p> | <p>As stated in the Call for Proposals, proposals that seek to achieve a scale required to demonstrate impact at national or subnational level within a single country are encouraged. Multi-country proposals will also be accepted; however careful consideration should be given to the readiness to implement quickly, the preference for a locally based lead implementer and the scale required for demonstrating impact at the (sub)national level within the project period (ie lenacapavir provided to a sufficient number of individuals at high risk of HIV acquisition to demonstrate measurable epidemic impact).</p> |
| <p>GEOGRAPHICAL SCOPE – What are the priority countries? Should proposals only focus on the list of countries that are qualified as early adopters by Gilead and the Global Fund?</p> | <p>Proposals must be focused on sub-Saharan African countries that plan to introduce lenacapavir as part of national programs as soon as market authorization is granted (or relevant waivers are obtained), with consideration of sub-geographies with highest risk. Beyond this, the geographical scope of Unitaid’s Call for Proposals is not further restricted.</p> |
| <p>GEOGRAPHICAL SCOPE - In a single country, should proponents cover the entire country or select sub-geographies with HIV burden and implement in those areas?</p> | <p>As outlined in the Call for Proposals, proposals should consider sub-geographies with high levels of transmission and have a clear and feasible hypothesis for how the proposed delivery approach will be cost-effective and impactful in the targeted population and sub-geography.</p> |

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| <p>ELIGIBILITY – Is this call restricted to organizations based in the South, and must the prime (lead) applicant be from the Global South? Does this mean organizations must submit funding proposals for the country in which they are headquartered?</p> | <p>Unitaid is seeking projects that are led by local, South-based implementers – i.e. organizations that are headquartered in the sub-Saharan African country of implementation - with extensive technical expertise in implementation of HIV PrEP services and programs and associated implementation research related to cost-effectiveness and impact. To facilitate rapid execution and country transition for sustainability, strong preference will be given to proposals that are led by local sub-Saharan African-based entities. Depending on the proposals received, Unitaid will also consider proposals with consortia including sub-Saharan African-based entities. In such cases, Unitaid will consider the budget proportion allocated to Global South partners, recommending a minimum of 50%.</p> |
| <p>ELIGIBILITY- Who is eligible to apply? E.g. can Ministries apply, are civil society organizations and community-based organizations eligible, and are for-profit organizations also allowed to compete?</p> | <p>Yes. Governments agencies/organizations, UN agencies, international organizations, research institutions, NGOs, and community-based organizations are eligible and may submit proposals. For-profit entities are also eligible to apply or be included as consortium members. Proposal submitted should demonstrate that the organization has the capability and capacity to deliver the proposed work in project countries.</p> |
| <p>ELIGIBILITY – are WHO country and regional offices eligible for this call?</p> | <p>The Call is open to international and UN organizations, with the exception of WHO (including its regional and country offices) as Unitaid has special enabler grants with WHO that are managed through the relevant HQ departments.</p> |
| <p>ELIGIBILITY - Can international organizations or local NGOs without prior experience with Unitaid and with PrEP apply? Will this be a disadvantage?</p> | <p>International organizations and local NGOs are eligible to apply. While prior experience with Unitaid is not required, proposals must be led by organizations with strong technical expertise in implementing HIV PrEP services and programs. This includes experience in integrating these services with other health programs, as well as a proven track record in implementation research. Community-based organizations involved in the project should also demonstrate relevant experience in delivering the required services.</p> |
| <p>ELIGIBILITY – Can organizations already funded by Unitaid apply?</p> | <p>Yes, organizations already funded by Unitaid are eligible to apply.</p> |
| <p>ELIGIBILITY – If there is already a Unitaid-funded project in country, will new partners be considered?</p> | <p>Yes, new partners and proposals are eligible in countries where Unitaid already has funded projects.</p> |
| <p>BUDGET- Can Unitaid choose to fund one or multiple proposals under this call?</p> | <p>Unitaid may choose to fund one or multiple proposals under this call, depending on the proposals received and the scope of work undertaken.</p> |

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| BUDGET - In a partnership of two or more organizations, should all partners submit the audited statements and other key documents or is it only the lead organization that submits such documents? | Audit reports are only required from the lead organization. |
| BUDGET - Is there a maximum grant amount that can be requested in the proposal? | 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. The total approximate funding for all projects selected from this Call for Proposals will depend on the proposals received and the scope of work undertaken, but may be up to US\$ 25 million overall at this time. Please note that budget is one of the important criteria for selection of a proposal. Submitting proposals for the maximum budget envelope may be a disadvantage in a highly competitive selection process. |
| BUDGET - Should the proponents include cost for drugs in the proposal budget? What price will implementers have for lenacapavir? On the budget guidelines, does the 2% cap on commodity expenses also include the lenacapavir? | Given the current uncertainties about the supply arrangements and access price for lenacapavir for low- and middle-income countries, and as indicated in the proposal template, the budget for procurement of lenacapavir should be kept separate from the rest of the project budget and will be considered a placeholder. The unit price and total cost estimate in this placeholder budget is not mandatory, but it should include the quantification of lenacapavir supply that would be required for the project. Other drugs that applicants propose to procure should be included in the budget. |
| BUDGET - Given that the total budget ceiling is indicated as up to USD 25 million, is there an indicative or approximate country-level allocation for a specific country? Will Unitaid fund more than one award per country? | There are no pre-determined country-level funding envelopes or allocations. Similarly, there is no pre-determined number of grants per country or budget ceiling per project. Funding for all projects selected from this Call for Proposals will depend on the proposals received and the scope of work undertaken. |
| BUDGET - Can an organization apply and further sub-contract during the implementation process? | Consortium partners should be included in the budget and their role should be explained in the proposal. Certain activities may be further subcontracted to other organizations under the responsibility of the lead implementer or consortium partners. |
| BUDGET - are there any limitations applicable to staff salary? | Salaries budget must be in line with applicant's internal policies. Also, please refer to page 30 of Unitaid's financial guidelines (attached to the Call for Proposal documents). |

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| BUDGET - Is there an applicable exchange rate US\$/local currency for budgeting? | As per article 16 of Unitaaid financial guidelines that are attached to the Call for Proposal documents, <i>“the budget should be converted using a 6-monthly average rate from a trusted source (e.g. Central Bank or Oanda)”</i> . |
| BUDGET - Can project audits be used, or should they be the organization's audits? | Organization's audit reports are expected to be submitted as part of the Call. |
| TIMEFRAME - Should applicants determine both the project duration and the proposed start date? | Yes, applicants determine the project duration, as well as the project start date. Strong preference will be given to proposals that demonstrate readiness to implement alongside national introduction of lenacapavir, anticipated in Q1 2026. Applicants propose the timeframe required for their project, however as stated in the Call for Proposals, implementation of delivery approaches for lenacapavir should demonstrate impact at national or subnational level within a project period of approximately three years. |
| CONSORTIUM AND PARTNERS - Are consortium arrangements encouraged or permitted, and if so, what are the expectations regarding the roles, responsibilities, and budget share between consortium members? | A consortium approach may be considered for the project implementation purposes. Projects should be as lean as possible. Any consortium approach should have a strong lead organization with overall responsibility for project 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 Unitaaid. 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. |
| CONSORTIUM AND PARTNERS - How many applications can one organisation participate in, and how many applications can one organisation be the prime on? | Provided the entity can demonstrate the capacity to deliver on each proposal submitted, there is no limit to the number of applications an organization can submit. Consortium members, service providers, and collaborating partners may also participate in multiple proposals under the same call provided they have the capacity to deliver on each one. Each proposal must include a strong justification for the proposed consortium structure, clearly outlining the roles and responsibilities of all members and how they contribute to achieving the proposal’s objectives. |

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| CONSORTIUM AND PARTNERS - is formal partnership with local government or health authorities required at the time of application, or can such collaboration be formalized during the implementation phase? | Proposals must submit letters of support from government stakeholders that confirm the country's intention to introduce lenacapavir as part of national programs as soon as market authorization is granted (or relevant waivers are obtained), with clear justification in case such a supporting letter is not available. |
| PROJECT DEFINITION- Can the proposal include other PrEP options to LEN? Will we be allowed to switch participants and to which products (e.g., oral PrEP, CAB LA?) | Yes, proposals are encouraged to integrate lenacapavir as part of a comprehensive PrEP program alongside other relevant tools, such as oral PrEP. |
| PROJECT DEFINITION - Is there scope within this call to integrate HIV prevention with broader sexual and reproductive health and rights or other services? | Yes, implementation of delivery approaches can integrate lenacapavir alongside other services for same target group. |
| PROJECT DEFINITION – Do you support differentiated service delivery models that are community-led or peer-driven, particularly for adolescent girls and young women, and other hard-to-reach populations? | Yes, proposals should complement facility-based implementation with community-based and other decentralized and tailored services to reach high-risk populations in areas with high levels of transmission that may face barriers to accessing existing HIV prevention services |
| PROJECT DEFINITION - Are innovative or digital strategies for HIV prevention—such as telehealth, mobile outreach, or social media campaigns—eligible or encouraged under this funding opportunity? | Yes, this call is seeking implementation of innovative delivery approaches, which may include leveraging existing platforms currently not in use or under-utilized for HIV PrEP services, supported by innovative demand generation approaches. |
| PROJECT DEFINITION- Is it appropriate to apply for funds to strengthen/expand an ongoing grant on a complementary topic? | Yes, proponents are encouraged to indicate potential, or secured, sources of co-funding for the program or for complementary activities. |
| PROJECT DEFINITION - Are there opportunities to include subnational governments in this study for sustainability? | Yes, government and government agencies are eligible (see Eligibility section above). |

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| <p>PROJECT DEFINITION - Can proposals focus on only one of the three areas of work or can they address a combination? Do you have a formula as to how much should be allocated to each work area?</p> | <p>Proposals should be very targeted to, and comprehensive of, the three areas of work outlined in the call: 1) implementation of delivery approaches for rolling out lenacapavir; 2) evidence generation of cost-effectiveness and health impact; and 3) stakeholder engagement with countries and communities. In other words, proposals should include all three areas of work and should not seek to include other areas beyond this scope. There is no formula for the budget or level of effort that should be allocated to each area – this is for applicants to define in their proposals.</p> |
| <p>PROJECT DEFINITION - To what extent should proposals demonstrate structured engagement with affected communities? What role is envisioned for civil society organizations?</p> | <p>Unitaid considers working with affected communities, including grassroots groups, and civil society organizations, to be critical and strongly encourages adopting inclusive approaches. This includes considering and adequately funding and resourcing their meaningful and continued engagement and participation in decision-making throughout all stages of the design, planning, implementation, and evaluation of activities.</p> |
| <p>PROJECT DEFINITION - What is the minimum scale (estimated minimum number of participants targeted) of implementation of the proposed study?</p> | <p>Proposals should seek to achieve impact in the affected area within the project period (i.e. small pilot/demonstration projects are excluded) compared to existing approaches for the same population, thereby requiring projects to have sufficient size to demonstrate the yield and impact of the selected approaches. Proposals should clearly indicate and justify the number of individuals they intend to reach to meet such objectives.</p> |
| <p>PROJECT DEFINITION – What is expected in terms of measuring the cost-effectiveness of lenacapavir? What assumptions should be used about price?</p> | <p>This Call for Proposals is not focused on the cost-effectiveness of lenacapavir as a PrEP commodity, for which there are several existing modelling studies across different countries. Rather, this call is seeking to determine cost-effectiveness of the delivery approach and how it minimizes programmatic costs for the targeted population(s) and sub-geographies as compared to other approaches for reaching the same population(s). Applicants are asked to provide a clear and feasible hypothesis and a proposed way to collect the required evidence.</p> |
| <p>PROJECT DEFINITION – Will research require WHO ethics approval?</p> | <p>Yes, Unitaid-funded human subject research is required to obtain approval from the WHO Ethics Review Committee.</p> |

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| TEMPLATES – Can you share the template that we are supposed to use at this stage? | Proposal templates are available on the Call for Proposals webpage. Please note that each template is specific to its corresponding call, and proponents are strongly encouraged to strictly adhere to the template format and word limits. |
| TEMPLATES – Will the expedited proposal timeline be similarly reflected in the review timeline and Grant Agreement Development timeline? Why is the proposal form different from previous calls? | Yes, Unitaid is aiming to expedite its standard processes for the call (include proposal submission, review, and grant agreement development) in order for projects to start implementing as countries introduce lenacapavir, which is anticipated for Q1 2026. The proposal template has been adapted to be closely aligned with the final grant documents in order to facilitate the expedited grant agreement development process. |
| TEMPLATES - Which organizational details should applicants include in Annex 4? | Annex 4 must contain a brief high-level presentation of the organization (similar to what one would include on organization's webpage under "About" section) as well as the CV of key team members. There is no specific template provided. |
| TEMPLATES -Is it possible to apply in a language other than English? | No, only applications in English will be reviewed. |
| USE OF AI TOOLS - Does Unitaid have any guidelines or restrictions regarding the use of Artificial Intelligence (AI) tools during the proposal development? | Each proponent remains responsible for the content of their proposal (including without limitation for any copyright infringement, biases, inaccuracies) and should comply with the applicable laws and their own policies while inputting data into AI tools and using the output. |

General Questions

| Question | Answer |
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| What is the proposal process under the Unitaid Operating Model? | <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. |

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| <p>Can a proposal that includes middle-income countries in scope be submitted?</p> | <p>Generally speaking for Unitaids Calls for Proposals, yes. While the primary focus of Unitaids investments is in low-income countries, proposals that include middle-income countries in scope are eligible. In principle, Unitaids 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>For this particular call, proposals must be focused on sub-Saharan African countries that plan to introduce lenacapavir as part of national programs as soon as market authorization is granted (or relevant waivers are obtained), with consideration of sub-geographies with highest risk.</p> <p>Across its portfolio of projects, at least 85% of Unitaids funds dedicated to commodity purchase must be spent in low-income countries. Middle-income countries are also eligible for inclusion in Unitaids-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> |
| <p>Can I contact Unitaids 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, Unitaids 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 Unitaids website or through webinars announced in the call text.</p> |
| <p>Do Unitaids 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> |

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| Products must comply with Unitaid Quality Assurance Policy to be eligible for procurement. Are there any other conditions to be met? | 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 reviewed and permitted for use by the Expert Review Panel (ERP) as described in the Unitaid Quality Assurance guidelines. |
| 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 funds be used to increase demand only for product that is WHO- prequalified or SRA- registered? | 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 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. |
| 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. |
| Do you fund construction under scalability and sustainability approaches? | Unitaid does not fund health system strengthening activities beyond those required to introduce new and underused commodities and interventions - such as health worker training. Unitaid does not generally fund health infrastructure - such as construction of hospitals or purchase of ambulances. |

Questions Related to Submission of Proposals

| Question | Answer |
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| 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. |

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| 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 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> |
| 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. |

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| 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> |
| Can more than 5 risks be listed in 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. |