** Unitaid Proposal Cover Page**

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| **Title of proposal:** |  |
|  |  |
| **Lead Organization legal name:** |  |
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| **Consortium organization(s) legal name(s), if any:***If more than one partner, list on separate lines* |  |
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| **Primary contact person for the proposal:** |  |
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| **Primary contact postal address:** |  |
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| **Primary contact e-mail address:** |  |
|  |  |
| **Primary contact telephone number:**  |  |
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| **Total budget including co-funding (in USD):***As per section 2.3* *Round to the nearest 100 USD* |  |
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| **Budget to be funded by Unitaid (in USD):***As per section 2.3**Round to the nearest 100 USD* |  |
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| **Target countries:***Please note: Unitaid does not normally consider single country proposals…….* |  |
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| **Proposal timeframe:***Total number of months* |  |

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| Signature of duly authorized party to validate submission of proposal | *Enter full name, date and signature*  |

**Glossary of Key Terms Used**

***Access barriers:*** *Unitaid investments are designed to overcome access barriers, so that markets become effective, i.e. there is:*

* ***Innovation and availability****: There is a robust pipeline of new products, regimens or formulations intended to improve clinical efficacy, reduce cost, or better meet the needs of end users, providers or supply chain managers. It means that new and/or superior, evidence supported, adapted products are commercially available and ready for rapid introduction in low income countries and lower-middle income countries.*
* ***Quality****: The medicine or technology is quality-assured, and there is reliable information on the quality of the product.*
* ***Affordability****: The medicine or technology is offered at the lowest sustainable price and does not impose an unreasonable financial burden on governments, donors, individuals, or other payers, with a view to increasing access for the underserved.*
* ***Demand and adoption****: Countries, programs, providers (e.g., healthcare providers, retailers), and end users rapidly introduce and adopt the most cost-effective products within their local context.*
* ***Supply and delivery****: Supply chain systems, including quantification, procurement, storage, and distribution, function effectively to ensure that products reach end users in a reliable and timely way. Adequate and sustainable supply exists to meet global needs.*

***Carbon footprint:*** *carbon footprint refers to**the emissions of CO2 (and other green house gases) that result from the implementation of the project; these include scope 1 (direct emissions), scope 2 (emissions from energy use) and scope 3 (principally from the procurement of products and services); Unitaid encourages its grant implementers to measure their carbon footprint and pursue carbon emission reduction strategies, in a way that is compatible with other project objectives; Unitaid does not prescribe a specific approach at this stage; a modest and reasonable portion of the grant budget may be allocated to support such efforts; the eligibility of such costs will be assessed and validated by Unitaid during grant development.*

***Climate and environmental co-benefits****: Unitaid defines climate and environmental co-benefits as longer-term catalytic impact in the field of climate and / or the environment beyond the direct project scope; this may include climate mitigation impact (eg, reducing the current and future carbon footprint of a health product), climate adaptation impact (eg, introducing innovative products or approaches that increase the resilience of health systems with respect to climate risks), and environmental impact (eg, reducing waste from the disposal of products); proponents are encouraged to identify opportunities to deliver such co-benefits and build evidence around them, and to estimate any additional associated costs; it is not expected that every project will have such co-benefits, and the pursuit of such co-benefits should be done within the context of the call for proposals and in synergy with the main public health objectives of the project.*

**Community and Civil Society Engagement** – *Unitaid Working Definitions*



*Note: The definitions above are intended to provide a general classification of typical entities with whom Unitaid expects to work. They are not intended to provide a complete description of engagement, or all actors and stakeholders in the sphere of Communities and Civil Society.*

Unitaid considers working with communities a critical part of generate demand and strongly encourages adopting inclusive approaches, and the engagement of communities towards improving the lives and health of the most vulnerable people. Engagement with affected communities can be key determinant for project success. The role of affected communities and planned collaborations with other relevant groups including grassroots community organizations and Civil Society Organizations and meaningful engagement with these important groups at all stages of a project/programme is essential.

**Community-led approaches**: Approaches where communities take the lead in choosing, designing, planning, implementing, and evaluating activities and programmes i.e., community advisory boards (CABs), community-led monitoring, community-led service delivery, and community-led research such as assessing the values and preferences of communities regarding tools and products.

***Consortium Member****: Consortium members are 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. The lead implementer is ultimately responsible for all project outputs implemented under the project by the consortium.*

*Entities or individuals providing services to the project on a commercial basis are service providers and not Consortium Members.*

*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 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.*

***Equity:*** *Unitaid aims, through its interventions, to reduce inequities in access to health products; specifically, Unitaid’s interventions are designed to benefit (i) people living in developing countries, with particular attention to Low income, and Lower middle-income countries; (ii) underserved groups, which are to be defined based on the specific disease context.*

***Impact:*** *Unitaid defines impact as both public health and economic impact, and both direct impact from any intervention, as well as indirect, longer term impact (typically 5 years after the end of a project). Because of the catalytic nature of Unitaid’s investments, indirect impact tends to be much larger than direct impact. Public health impact may include: the additional lives saved, infections averted, Disability Adjusted Life Years (DALYs) averted. The economic impact may include health budget savings or health systems efficiencies resulting from the introduction of new products or approaches.*

***Unitaid’s Mission*** *as defined in the Unitaid’s* [*Strategy 2023-2027*](https://unitaid.org/assets/Unitaid_Strategy_2023-2027.pdf)*: Unitaid’s mission is to design and invest in innovative approaches to make quality health products available and affordable in low- and middle-income countries. Unitaid inspires and promotes collective efforts with partners, countries, and communities, unlocking access to the tools, services and care that can deliver the best results, improve health and address global health priorities.*

***Scalability:*** *Scalability refers to creating the conditions for scale-up, so better health products reach all people who need them. Unitaid, along with grantees and partners, works on ensuring the right conditions are in place for an innovation to be taken to scale. Planning for scalability is an integral part of Unitaid projects from conception, and scalability is a key dimension along which projects are assessed throughout implementation. Please refer to Unitaid’s Scalability Framework for more detail.*

***Scale-up:*** *Scale-up is the wide adoption and use of a product by the people who need it. Unitaid considers a project successful if the health product/ approach supported (if proven relevant) is afterwards used at scale within the countries of the Unitaid project as well as in other countries. While Unitaid and grantees are key contributors to creating the conditions for scale-up, scale-up itself is typically funded by other organizations (other donor agencies, countries) after Unitaid projects end.*

***Transition:*** *Transition refers to sustaining the achievements of the Unitaid-funded project after the Unitaid financial support for the project ends (this includes, but is not limited to, ensuring the ethical responsibility is upheld to keep the patients on essential treatment and/or continue essential services, etc.). While it is important that Unitaid-funded work be transitioned (to country programs, other donors), Unitaid views this as a steppingstone on the way to scale-up, not an end goal in and of itself.*

***Value for Money****: Unitaid defines Value for Money as maximizing the impact of every dollar spent by Unitaid. At a strategic level, Value for Money is evaluated by comparing the expected impact (both direct and indirect, with consideration for equity) of a Unitaid project, relative to the expected costs of delivering this impact (i.e. both by Unitaid and other funders over the long-term). At the operational level, Value for Money is linked to the efficiency and effectiveness of a project design and implementation.*

***Instructions for completing this form:***

***The number of characters in each text box is limited to match the physical size of each text box*** ***that cannot be expanded. To create a new line in the text box, please press CTRL+ENTER. Please ensure that your input is fully visible in the designated space.***

***Please note that the Sections 2.2 a) and d); 2.3 c) and d) and the Section 4 allow you to adjust and expand the tables (The font type in those sections should be Arial and minimum font is size 10).***

***No additional sheets or annexes should be submitted beyond the application form and the annexes listed in the application package. The only exception is the list of* *abbreviations (especially those used for your organization internally).***

**Executive Summary**

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| **Please provide a summary of the proposal.***Include the following – Background and problem statement, proposed approach, expected impact, how inequities in access are proposed to be addressed, innovation, articulation with the broader response, implementation arrangements, transition and scale up.*  |
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| * 1. **Background**

Clearly articulate the challenge (both in terms of broad public health challenges, as well as specific issues) your project aims to address, including the scope, history of previous efforts to address the problem and your analysis of the root cause(s) with reference to supporting evidence. Your project should address one or more elements of the problem stated in the call for proposal. Below is a summary of the areas of work in the call for proposals for your reference*.* 1. **Analysis of demand:**
	* Targeted market size for specific products, based on overall need and consideration for potential constraints on demand such as funding availability.
	* Potential overall market size for mAbs in LMICs across products, including considerations for different disease profiles (i.e., mAbs for diseases primarily in LMICs, mAbs for diseases with a dual market but a higher prevalence in LMICs, and mAbs for emerging infectious diseases and pandemic threats)[[1]](#footnote-1).
2. **Analysis of supply models and pilots to demonstrate manufacturability proof of concept:**
	* Manufacturing capacity requirements to achieve sufficient scale of production to meet LMICs’ health needs and attain economies of scale.
	* Opportunities that could lower the cost of producing and the cost of delivering mAbs and pilots to demonstrate their effectiveness.
	* Opportunities to ensure that manufacturers leverage optimized technologies and/or processes to lower costs.
	* Pilots to demonstrate the potential role of regional manufacturing and technology transfer, as needed.
3. **Define the products for which viable use cases can be established:**
	* Viable use cases need to be conducive to product launch, sustainable demand and scaled use in LMICs, including in the context of other tools that may be available or emerging for the same disease indication. This must take into account the supply and demand analysis outlined above, including the opportunities to simplify and lower costs of production and delivery.
	* Consideration must be given to implications for health budgets based on potential price scenarios and patient populations.
4. **Engage with community-based organizations from relevant LMIC regions to ensure their input in analysis of demand, supply, and viable use cases:**
	* Community-based organizations need to be engaged at all stages of the work. This should include meaningfully contributing to the depth of knowledge that is required to scope and size market potential, the most promising use cases and formulations, and the business models required to render fit for purpose products equitably accessible.
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| * 1. **Project Approach (Theory of Change)**

Using the template below, describe how your project will address the problem(s) outlined in Question 1.1. 1) In the Problem section, describe the following:  **a)** **Public health need** – what is the public health problem or need the project intends to address?  **b) Access barriers** – What are the access-specific impediments related to the identified public health issue? Identify and frame the problem along the critical access barriers (as defined by Unitaid) that the project aims to overcome/address.2) Describe the conceptual pathway from outputs through to outcomes and impact, and how each of these address the problem(s) identified in Question 1.1. 3) In the Key Risks and Assumptions section, document the top 3 risks that could impede the success of the project and 1-2 assumptions (conditions that are expected to hold true/be in place) for achieving the intended impact.Please refer to the Results Framework guidance for more detail on Unitaid’s expectations of the Theory of Change. |
| **Problem**  |  |
| **Outputs** | *.* **Outcomes** |  **Goal** |
| *The outputs are the direct project related deliverables that are directly attributed to the budgeted activities in the project.**The outputs answer the question, “What are the immediate results that our activities have delivered?* *Example: beneficiaries reached with goods or services in the project.* | *The outcome is a short-term or intermediate result achieved by the project at the population level: it should be directly but not wholly attributable to project outputs as it relies on other external factors.* *In the context of Unitaid projects, the outcome should typically reflect a change in access to health products at a population level, along the five dimensions of access defined in the Glossary (innovation and availability, quality, affordability, demand and adoption, supply and delivery)* *The outcomes answer the question, "What difference does this intervention make, i.e. what change do you expect to see as a result of the outputs?”**Example: countries adapting policies following evidence generated from project.* | *This reflects the overarching public health aim of the intervention and captures the long-term effect or end result of the project: it reflects the changes in health status in target populations as well as changes in health systems. It should be directly (but not wholly) attributable to the expected outcome from the implementation of the project.* *In the context of Unitaid, goals can be achieved during the project’s life time but more often will be realized after project closure following further scale up of an intervention by other stakeholders. It should typically reflect impact on public health (in project countries and beyond, if relevant), and/or economic impact (savings and efficiencies achieved by health systems).**The goal answers the question "What impact do you expect this project to have?”*  |
| **Key Risks and Assumptions** |

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| * 1. **Expected Impact**

Based on the goal defined in the previous section, please detail the expected impact (qualitative and quantitative) of your proposal on no more than one page. This section should address the following questions: 1. What would happen in the absence of this project? (defining the counterfactual)
2. What is the incremental impact of the project in terms of public health and economic impact?
3. What are the key drivers of public health impact? *(e.g., increased coverage, improved effectiveness of a treatment or diagnostic)*
4. What are the key drivers of economic impact? *(e.g., What is the cost of the innovation during grant implementation and during scale-up? Is it more/less expensive than the current standard of care or counterfactual? Are price reductions expected? Will this innovation result in averted cases/infections leading to averted health care costs to treat these cases?)*
5. Will the scale-up of this innovation result in a net added cost or cost saving to the health system?
6. What are the key strategic benefits / positive externalities of the project? What impact will the project have on equity (e.g., benefiting underserved populations, promoting equitable access)?
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| NB – please refer to the Unitaid Guidance on Impact Assessment for Proposal Development and Grant Agreement Development as well as the Results Framework guidance document for more details.  |

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| * 1. **Equity**

Please summarize how your project will help address inequities in access, with particular emphasis on *(i) people living in developing countries, with particular attention to Low income, and Lower middle-income countries; (ii) underserved groups, which are to be defined based on the specific disease context.* |
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| * 1. **Innovation**

Please describe what makes your project innovative relative to past, existing and planned efforts from other partners (including Unitaid projects) |
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| * 1. **Community engagement**

Please describe how you have engaged communities to develop and conceptualise this project. Please also detail how communities (local and international) will be engaged throughout the project lifecycle and include any specific milestones and activities that are community driven, or community led. Include any community-led activities or approaches that will support the success of the project.  |
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| * 1. **Climate and environmental co-benefits**

If relevant, please describe how the project may deliver climate and/or environmental co-benefits |
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| * 1. **Articulation with others in the global health response**
1. Please describe how your project complements existing and planned efforts of other stakeholders (including Unitaid projects)
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| 1. Using the table below, describe the existing and planned efforts by other partners (including Unitaid projects), which your project seeks to complement.
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| **Organization Name** | **Programme Name** | **Brief description of the programme.** |
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| 1. List the key strength(s) that make the lead organization (and consortium if relevant) uniquely positioned to successfully implement the approach outlined in section 1.2
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| **Key strength(s)***(1-5 strengths)* | **Supportive evidence** |
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| **2.1 Project Design**1. Please describe the proposal design, outlining the activities, assumptions and dependencies to achieve the outputs stated in section 1.2.
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| 1. Using the GANTT chart (Annex 1), indicate a clear timeline for project implementation, activities, who is responsible for which activity, and the key milestones to measure progress.
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| 1. Please explain the selection of project implementation countries.
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| Please explain which criteria have been used as a basis for country selection, and why |
| Please provide the list of countries selected for inclusion in the project and the rationale for their selection based on the criteria described above; for each country, describe the engagement process during proposal design and development of national level stakeholders including relevant government agencies/institutions and civil society and the outcomes of this engagement. |
| Please detail the extent to which the proposed project includes local partners as co-implementers and/or sub-implementers. Also detail the costed activities proposed to be implemented by these partners and any associated budget that may be required to sustainably build the capacity of such entities, as needed and relevant, during the proposed project duration. |

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| * 1. **Organization, roles and responsibilities**
1. Using an organogram (example below), describe the implementation arrangements for the project, indicating the organizational relationships between the lead organization, consortium members and others involved, including their role, activities and budget. (Please refer to glossary for definition of consortium members).
 |
| **Co-Funder****Lead**BudgetRoleActivitiesBudget**Consortium Member****Consortium Member**RoleActivitiesBudgetRoleActivitiesBudget |

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| 1. Provide a brief description of the lead organization (and other consortium members as appropriate).
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| **Lead Organization** |  |
| Mission | *Please describe the mission of the organization in a maximum of two sentences.* |
| Structure | *Please describe organizational & governance structure e.g. HQ in Country X, Regional offices in A, B & C and country offices (total = Y)*  |
| Current Operations | *Please describe the overall number and size of existing grants. Indicate the portfolio budget managed per year during the last three years.* |
| In-Country Presence | *Please describe in which countries the organization intervenes, and relative size between countries, Indicate field presence if applicable.*  |
| Staffing Levels | *Please indicate number of staff in lead organization and proportion that would be allocated to the project*   |
| Funding Levels | *Please attach the latest audited financial statements for the last three years including audit reports (please give a reason, if not provided).**Please list the historical funding sources for the past 3 years (donor, public, private, other), including breakdown by key source and whether funding was restricted or unrestricted.* *Please indicate the forecast of known funding sources (donor, public, private, other) for the current year and the duration of the project, whenever available, including breakdown by key funding source and whether the forecasted funding is restricted or unrestricted and secured vs anticipated.* |
| Legal status of the organization  |  |
| **Consortium Members** | *Please provide a brief description of the consortium member(s) in case applicable.* |
| 1. Describe the previous experience of the lead organization in developing, implementing and managing projects in the geographical and technical areas proposed including measures of success and lessons learned.
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| 1. Indicate, for the lead organization only, the key team members proposed for implementing the project. (Please add rows as appropriate; CVs of key team members should be included as Annex 3).
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| Name | Title | Role | % full time equivalent |
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| **2.3 Budget and co-funding** *(Please use this section and the Annex 2 – Proposal Budget and Co-funding, to provide information on the proposal budget)*a) Budget by output and consortium members |
| *Please provide below a brief narrative supporting the budget breakdown by consortium member/output as captured in the Annex 2- Proposal Budget and Co-funding table and articulating key budget considerations in terms of the respective output contributions and roles of the different consortium partners.*  |
| b) Budget by output and expense group |
| *Please provide below a succinct narrative supporting the budget breakdown by output and expense group as captured in the Annex 2- Proposal Budget and Co-funding, covering key budget lines. More specifically, describe what the key budget assumptions and cost drivers are as well as what the main sources of budgetary information are.**This can include :* * *For commodity: avg. unit price per year and total quantities to be purchased, etc.*
* *For travel: estimated number of travel, average cost per type of travel, etc.*
* *For external professional services: type of services, brief description of the top 5 elements, budgeting source, etc.*
* *For equipment: type of equipment, estimated value by type of equipment*
* *For project staff: total FTE per consortium member, fully loaded vs take home pay information, etc.*
* *For financial audit: avg. audit cost per year, etc.*
* *For general administrative expenses: recovery method (itemised or based on fixed %), recovery % if applicable*

*Please also refer to the Annex 2- Proposal Budget and Co-funding for additional instructions and ensure the information provided in this section and in the Annex 2 is consistent with the information outlined in the Log frame.* |

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| c) Please indicate if other organizations (including your own) will/are co-funding the project |
| *Please provide an overview of the project funding including co-funding (this should include your own funding contribution) using the below table (add row as appropriate). Please also refer to the Annex 2- Proposal Budget and Co-funding for additional instructions.*

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| --- | --- | --- | --- | --- |
|  | **US$ amount** | **% funded** | **Confirmed\*** | **Anticipated\*** |
| **Unitaid** |  | % |[ ] [ ]
| **Co-funding** |  | % |[ ] [ ]
| Organization name 1 |  |  |[ ] [ ]
| Organization name 2 |  |  |[ ] [ ]
| Organization name 3 |  |  |[ ] [ ]
| Organization name 4 |  |  |[ ] [ ]
| … |  |  |[ ] [ ]
| **Total** |  | **100%** |  |  |

*\*Add “X” where relevant* |

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| d) Please provide an overview of your organization’s commitments to carbon emission reductions, as well as specific strategies that will be pursued to minimize the carbon footprint of this project |
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| **3. Scalability**Unitaid considers a project successful if the health product/ approach supported (if proven relevant) is adopted and used widely within the countries of the Unitaid project as well as in other countries. This includes (but is not limited to) managing transition of project activities, i.e. ensuring the ethical responsibility is upheld to keep the patients on essential treatment and/or continue essential services etc.). While scale-up may begin during the lifetime of a project, it is expected to occur to a large extent after the project has ended. |
| Within the context of this project, describe:* What conditions need to be in place to achieve successful scale-up;
* How the project will create scalability at a) the global and b) country levels;

Please structure this section along the dimensions outlined in *Unitaid’s Scalability Framework.* Please note that not all conditions or dimensions may be relevant to every project. |
| Describe the potential funders and key stakeholders (governments, communities, civil society, etc.) that will be engaged to ensure successful scale-up, indicating what their role would be and how and when they will be engaged.(Please attach any letters of support/commitment, where relevant). *Please also see separate Communities and Civil Society Engagement section below.* |

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| A key component of Unitaid’s work and the *Scalability Framework* is Community and Civil Society Engagement (CCSE). 1. What is your project’s overall strategy for engaging both communities and civil society and why are these engagement approaches important for this project? Who are the community and civil society partners that are or will be engaged and how are they expected to contribute to the project’s scalability? Highlight use of established mechanisms, partnerships, or networks. Where available, list global and national partners.
2. What are the proposed engagement activities for the project for each group (communities and civil society)? How will they work both separately and together in order to achieve the project outcomes? List the expected outcomes, potential risks and challenges of this work. Include community representation in proposed project groups (i.e. project inception communities, programme advisory committees etc.).

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| **4. Please articulate the risks that could inhibit success of the project and the strategies your organization will use to mitigate the risks.***(Please describe up to five key risks)* |
| Type of risk | Risk description | Mitigation strategy |
| Strategic risks *(What key assumptions could change and put at stake the relevance of the project to Unitaid?)* | *e.g. Changing market assumption affecting relevance of identified market problem or solution* |  |
| *e.g. Duplication of intervention with other stakeholder* |  |
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| Implementation risks*(What key assumptions related to the project delivery and/or external environment could change and put at stake the successful implementation of the project?)* | *e.g. Delays or shortage of supply for procurement* |  |
| *e.g. Delays due to technical failure* |  |
| *e.g. Political instability* |  |
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| Sustainability/Scalability risks*(What key assumptions related to the sustainability of the proposed approach could change and put at stake the transition & scale-up?)* | *e.g. Non-identification of transition partner* |  |
| *e.g. Lack of funding for scale up* |  |
| *e.g. weak evidence (e.g., clinical, operational, cost effectiveness) to justify the wider roll-out and use of a health product or approach.*  |  |
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1. See *Novel business models for accessible mAbs for infectious disease in LMICs: recommendations from a multistakeholder meeting convened by IAVI, Unitaid, the Medicines Patent Pool and Wellcome* for more details, available [here](https://unitaid.org/assets/Novel-business-models-for-accessible-monoclonal-antibodies-for-infectious-diseases-in-low-and-middle-income-countries.pdf). [↑](#footnote-ref-1)