

TERMS OF REFERENCE

Services to support Capacity Assessment of Unitaid's Pre-Grantees (Long-Term Agreement with multiple providers)

PURPOSE OF THESE TERMS OF REFERENCE

These Terms of Reference (TOR) serve as an overall framework for independent professional services to be provided in the context of Unitaid's due diligence (General Capacity Assessment and/or Focused Capacity Assessment on Human Subject Research ("HSR") of organizations seeking Unitaid funding), pursuant to the Request for Proposal (RFP 2025.04).

DESIRED TIMEFRAME

- Anticipated start date: May 2025
- Duration of contract period: May 2028 (initial three years, renewable twice for an additional period of one year each, at Unitaid's discretion and subject to satisfactory performance).

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1. BACKGROUND

Unitaid is seeking to identify multiple independent professional agencies to serve as External Verification Agents ("EVAs"). The selected EVAs will assist, on a rolling assignment basis, in conducting an analysis of the institutional capacity of organizations (hereafter referred to as "pre-Grantees") entering into the Grant Agreement Development ("GAD") process with Unitaid¹. The capacity assessment covers i) the General Capacity Assessment and/or ii) Focused Capacity Assessment on Human Subject Research ("HSR").

For the purpose of this RFP, bidders may submit their bids/proposals corresponding to one of the capacity assessments (General Capacity Assessment or Focused Capacity Assessment on HSR); or for both services for General Capacity Assessment and Focused Capacity Assessment on HSR. Unitaid may award the specific assignment throughout the LTA duration to a single EVA for both General Capacity Assessment and Focused Capacity Assessment on HSR; or award separate contracts to two (2) EVAs for General Capacity Assessment and Focused Capacity Assessment on HSR respectively (based on the relative strength of the proposal for each capacity area and the specific needs of the projects).

¹ Note that in some cases where HSR-focused Capacity Assessment is required, insufficient information will be available at the time of GAD negotiations. If so, it may be that HSR Capacity Assessments will be deferred to take place during grant implementation (during an inception phase after grant signature but prior to launch of HSR work). The reference to 'pre-Grantee' used throughout this TOR should be considered interchangeable with 'Grantee' in that context.

EVA analysis will be performed through a desk review of a General Capacity Assessment questionnaire and/or HSR Capacity Assessment (filled out by the pre-Grantee) and other relevant supporting documents, and phone interviews with relevant stakeholders. It will involve a critical assessment of the pre-Grantee's experience, expertise, applied policies, structures and systems to respond to a defined set of criteria set by Unitaid for its future Grantees, and provision of concrete recommendations and mitigating measures to address identified gaps.

The HSR Capacity Assessment focuses on the assessment of pre-Grantees who have proposed to implement (or oversee the implementation of) research activities involving human subjects. HSR is a critical area that involves ethical, scientific, and regulatory considerations. It is important that HSR activities adhere to international standards on good clinical practices, good laboratory clinical practices as well as ethical principles to protect the dignity, rights and welfare of research participants.

As an international organization hosted by WHO, Unitaid follows WHO guidance relating to HSR². In particular, it should be noted that all Unitaid-funded HSR study protocols must be approved by WHO Ethics Review Committee, prior to implementation. The expert guidance outlined in this TOR serves to ensure Unitaid Grantee compliance with ethical principles, legal frameworks, and best practices, while promoting the integrity and reliability of their research outcomes.

2. OBJECTIVES OF CAPACITY ASSESSMENT

The capacity assessment is a risk-based review led by Unitaid during the GAD process, which takes place before the finalization of the Grant Agreement. The exercise aims to assess the pre-Grantee's capacity (systems, resources, and relevant experience) to successfully implement a Unitaid-funded project in line with WHO/Unitaid's standards and contractual requirements. It provides the opportunity for Unitaid to assess whether the pre-Grantee's experience, systems and policies are well designed and adapted to minimize risk to project goals and objectives during implementation and to put in place relevant mitigating measures in key areas where the Grantee's capacity may be found insufficient.

3. WORK TO BE PERFORMED

A. General Capacity Assessment

Component steps of the **General Capacity Assessment** process:

- i. Pre-Grantee completes the General Capacity Assessment Questionnaire (self-assessment) and submits it with relevant supporting documentation, to the Unitaid focal point.
- ii. Unitaid focal point meets with the EVA (the selected EVA for the specific assignment) for a briefing on the context of the assignment and shares

² <https://www.who.int/teams/health-ethics-governance/governance/research>

the Capacity Assessment Questionnaire and supporting documents submitted by the pre-Grantee.

- iii. The EVA checks pre-Grantee submissions for completeness and commences desk review and interactive discussions with pre-Grantee and proposed consortium partners if relevant, and Unitaid focal point as needed, with the ultimate objective of providing a final report for Unitaid to inform grant-making negotiations.

The scope of the assessment is detailed in the questionnaire and usually covers the following main areas:

- **Organizational Governance/ Legal** – i.e.,
 - Pre-Grantee's status as a properly registered legal entity with the full capacity to enter into a Grant Agreement with Unitaid, and having an appropriate and functioning governance structure.
 - Pre-Grantee's capacity to contract effectively with third parties and obtain all necessary approvals and authorisations from project countries for the successful implementation of the project in compliance with applicable regulations and laws.
- **Operations / Project management** – i.e., Pre-Grantee's capacity to deliver the activities and outputs listed in the Unitaid grant agreement documents.
- **Finance and fiduciary management** – i.e., Pre-Grantee's capacity to use project funds effectively and efficiently for the intended purpose while minimizing the risk of financial misconduct and having robust risk management strategic measures.
- **Monitoring & Evaluation** – Pre-Grantee's capacity to collect, analyse, measure, and report project results.
- **Procurement and Supply Management** – i.e., Pre-Grantee's capacity to manage the Procurement and Supply Chain Management (PSM) system, including establishment of forecasting methodology, supply planning.
- **Other issues relevant to the particular Project** – for example
 - **Intellectual property (IP)** – Pre-Grantee's ownership of the IP rights in relation to relevant product(s), and capacity to manage any relevant licencing and/or searches as relevant to the project.
 - **Market access** – Pre-Grantee's capacity to secure appropriate/adequate commitments with the aim of securing equitable access to products in relevant low-and-middle-income countries, in accordance with Unitaid's market access objectives.
 - **Data sharing** – Pre-Grantee's capacity to manage and appropriately share data generated by the project during the project term with key stakeholders, and the public health community generally, in order to ensure fulfilment of project objectives.

- **Climate & Health** - Pre-Grantee's capacity to provide relevant strategies and programs of work related to its efforts at the intersection of climate and health (for example, carbon footprint assessment, climate action plan aimed at reducing carbon emissions, etc).

B. Focused Capacity Assessment on HSR

Component steps of the **HSR Capacity Assessment** process:

- iv. Pre-Grantee completes the HSR Capacity -Assessment Questionnaire and submits it, with relevant supporting documentation, to the Unitaid focal point.
 - v. Unitaid focal point meets with the EVA for a briefing on the context of the assignment and shares the Capacity Assessment Questionnaire and supporting documents submitted by the pre-Grantee.
 - vi. The EVA checks pre-Grantee submissions for completeness and commences desk review and interactive discussions with pre-Grantee and proposed consortium partners if relevant, and Unitaid focal point as needed, with the ultimate objective of providing a final report for Unitaid to inform grant-making negotiations.
- a. Any risks associated with the pre-Grantee's ability to ensure adherence to International Conference on Harmonization (ICH) Harmonised Tripartite Guidelines, Good Clinical Practices (GCP) / Good Clinical Laboratory Practice (GCLP), national regulatory requirements for clinical development, and other relevant guidelines (Declaration of Helsinki, WHO, etc), with particular attention to the
 - Defined approach to the operational requirements of GCP/GLCP;
 - Defined approach to the ethical requirements to ensure full compliance with national health research ethical clearance procedures in countries where the research is conducted;
 - Clinical research study management experience and relevant expertise in Regulatory Affairs including but not exhaustive:
 - Knowledge of regulatory frameworks,
 - Systems for marketing authorization and post-marketing surveillance,
 - Dossier Preparation,
 - Chemistry, Manufacturing and Controls,
 - Labelling and Product information.

The scope of the assessment is detailed in the questionnaire and usually covers the following main areas:

- **Project Governance / Legal** – i.e.,
 - Pre-Grantee's insurance procurement policies and methods
 - Pre-Grantee's quality assurance infrastructure to sufficiently govern and monitor HSR progress and success.
 - Sufficient legal capacity to manage HSR activity as captured in terms of conditions.

- **Operations/Project management** – i.e., pre-Grantee’s capacity to deliver the HSR activities and outputs listed in the Unitaid grant agreement document.
- **Finance and fiduciary management** – i.e., pre-Grantee’s capacity to use the project funds effectively and efficiently for the intended HSR purposes while minimizing the risk of financial misconduct and having robust risk management strategic measures.
- **Monitoring & Evaluation** – pre-Grantee’s capacity to collect, analyse, measure and report on HSR activities. Non-exclusively including routine and ‘for cause’ audit functions, as well as clinical and non-clinical monitoring processes, and report project results.
- **Risk Mitigation** - Any risks associated with the pre-Grantee’s ability to ensure study adherence to International Conference on Harmonization (ICH) Harmonised Tripartite Guidelines, Good Clinical Practices (GCP) / Good Clinical Laboratory Practice (GCLP), national regulatory requirements for clinical development, and other relevant guidelines (Declaration of Helsinki, WHO, etc), with particular attention to:
 - Defined approach to the operational requirements of GCP/GLCP;
 - Defined approach to the ethical requirements to ensure full compliance with national health research ethical clearance procedures in countries where the research is conducted
- **Other issues relevant to the Project** – for example:
 - **Market access** – pre-Grantee’s capacity to assess and/or navigate the landscape for market authorization or equitable access to products in relevant low-and-middle-income countries, insofar as it affects the design of HSR activities.
 - **Data sharing** – pre-Grantee’s capacity to manage and appropriately share data generated by the HSR activities during the Project term with key stakeholders, and with the public health community generally, to ensure fulfilment of the Project’s objectives.
 - **Analysis and Publication** – pre-Grantee’s capacity to effectively analyse and distribute the HSR data in line with local and international regulatory and ethical guidelines, and in line with Unitaid’s objectives.

When the need for services arises (for the General Capacity Assessment and/or Focused Capacity Assessment on HSR), Unitaid will contact the selected EVA (Unitaid may conduct a mini tender/quotation amongst the LTA holders) as early as possible (normally no less than 1-3 weeks in advance) for the specific assignment/engagement. The assignment-specific TOR (i.e., an amended version of this TOR reflecting any changes that might be relevant to specific project/pre-Grantee context) will be shared with the EVAs. As capacity assessments are usually subject to time constraints, the EVAs are therefor expected to ensure rapid turnaround to confirm the availability of the relevant experts and proposed assignment-specific level of effort and its budget, for Unitaid’s consideration and approval.

4. DELIVERABLES

Deliverables may vary depending on the scope of the capacity assessment and will be defined and communicated at the time of EVA engagement for each specific assignment. They may include, but are not limited to the following:

- Inception Report comprised of:
 - Executive Summary Report (Word format) outlining EVA key findings and recommendations (SMART), presented with priority ranking, and
 - Supporting annexes including:
 - Detailed narrative description of key findings (Word format),
 - EVA scoring, by capacity assessment tool criteria and sub-criteria - presented as comparative input against pre-Grantee self-assessed scoring, with comments provided in all cases where EVA and pre-Grantee scores differ (Excel format),
- Summary version of Inception Report (PowerPoint format).
- Final Report (format as per DRAFT Report, as stated above, also accommodating any requested changes per Unitaid Project Team feedback).

5. METHODOLOGY, PLACE OF WORK AND FREQUENCY OF INTERACTION

The Capacity Assessments usually involve a combination of document reviews and interviews with the relevant stakeholders.

The EVA will be expected to undertake a review of a variety of assignment-specific documents such as:

- General Capacity Assessment Questionnaire and/or HSR Capacity Assessment Questionnaire (self-assessment) completed by the pre-Grantee.
- Supporting documents submitted by the pre-Grantee in relation to the self-assessment (e.g. draft protocol for HSR focused).
- Unitaid Area for Intervention and Call for Proposal documents.
- Pre-Grantee proposal.

The EVA will usually work remotely but may be requested to travel to the pre-Grantee's office location, depending on the specific assignment. The EVA may also be required to meet with the Unitaid Project Team in Geneva for initial briefing, and/or Inception Report review discussions, and/or presentation of findings/recommendations when deemed necessary. The Unitaid focal point for the engagement will coordinate closely with the EVA via emails, phone, or teleconference.

6. QUALIFICATION AND SKILLS

The EVAs (**both firm and team members**) shall have prior experience and expertise in the following:

Essential:

Demonstrated extensive experience in conducting similar capacity assessments for implementers of donor-funded projects in **all areas** listed in scope, within “Section 3: WORK TO BE PERFORMED” – refer the specific experience requirements for the respective General Capacity Assessment and/or Focused Capacity Assessment on HSR, depending on the area(s) of services that bidders will be participating in this RFP.

Desirable:

- Experience in conducting similar capacity assessments for Unitaid-funded projects.
- Additional areas as defined in the context of each specific assignment.

Specifically for HSR-focused capacity assessment, **additional** criteria will include:

- Demonstrated expertise in Human Subject Research (clinical trials) and/or operational research.
- Proven ability in Clinical study design and management.
- Medical ethics relating to research involving human subjects.
- Conducting due diligence on global health projects with elements of clinical and/or operational research.

Proficiency in English is required. Additional language skills may be required, which will be noted in the assignment-specific TOR as necessary. Please indicate in the proposal, the language proficiencies in other languages.

The list below illustrates the type of experts/roles that are potentially required:

- Programmatic expert
- Finance/Accounting expert
- Procurement & supply chain expert
- Monitoring & evaluation expert
- Legal/IP expert
- Expertise as relevant to Unitaid’s Programmatic Priorities³ (HIV and co-infections, TB, malaria, women’s and children’s health, global health emergencies)
- Analyst/Consultant
- Junior analyst/consultant

Whenever approached for a new assignment, the EVA is required to submit the following documents to Unitaid for review and approval before commencement of activities.

- Brief Executive Summary, highlighting the relevant experience concerning the specific assignment and how the EVA’s expertise could contribute to the successful capacity assessment;
- Confirmation on the team’s availability during the requested assignment period;

³ https://unitaid.org/uploads/Unitaid_Strategy_2023-2027.pdf

- The proposed detailed timeline, aligning with Unitaid's expectation;
- Updated CVs of the proposed team member(s), with clear descriptions of relevant skills and past experience aligned with the specific assignment. The following elements shall be demonstrated:
 - Relevant expertise and qualification of the proposed EVA team;
 - Appropriate team composition (e.g. mix of seniority, expertise, language skills, etc);
 - Appropriate level of effort (number of days allocated for each expert).
- Completed declaration of interest form; and
- Proposed budget (Financial Offer).

7. PAYMENT TERMS AND SCHEDULE

Payments will be made based on satisfactory completion of each assignment in accordance with the agreed TOR and budget (aligned with LTA's daily rates), submission of satisfactory deliverables, and the submission of corresponding detailed invoices indicating the actual number of days worked per team member and deliverables, along with necessary supporting documents.

For travel costs (if requested by Unitaid), payment will be made in accordance with WHO rates and upon submission of invoices indicating actual travel costs with proof of payment. The EVA is responsible to organize all logistics of travel, including hotel booking and local transportation. All travels must be arranged in the most economical way, in line with Unitaid's effort in reducing carbon footprints related to the procurement activities.

8. CONFLICT OF INTEREST

To avoid any real or perceived bias in the assessments provided by the EVAs, Unitaid will examine any potential conflict of interest in a systematic manner. The Authorized Representatives of the business entity, under the long-term agreement, will be expected to sign the Memorandum of Understanding on Confidentiality, and a Declaration of Interest form, upon contract initiation. Thereafter, the lead staff responsible for the EVA will be required to facilitate the same (confidentiality and DOI statements) for each individual staff/consultant engaged in relation to each specific assignment.