



Call for Proposals: Ethics and Regulatory Capacities

Type of Action:	Coordination & Support Action (CSA)
Call budget:	1.5 million EUR
Funding threshold:	300,000 EUR per application
Expected number of grants:	5-10
Open date:	15 October 2015, 00:00
Deadline:	21 January 2016, 17:00 (CET); 16:00 (GMT)
Status:	Open

Background

Many African countries lack sound ethical review mechanisms and some even lack medicines regulatory bodies. There is a pressing need to develop and strengthen the national ethics and medicines regulatory frameworks in sub-Saharan Africa in order to strike a balance between the public health interest, the interests of the pharmaceutical industry, and ethical values.

Scope

The purpose of this Call for Proposals is to provide funding to actions that aim to support sub-Saharan African countries to establish and develop robust national medicines regulatory systems and capacities for ethical review of clinical research and use of medicinal products and technologies for use in humans. This scheme targets both National Ethics Committees (NECs) and National Regulatory Authorities (NRAs).

The objectives of this Call are:

1. To support NECs' development of institutional and personnel capacities to enable them to perform their national ethical oversight function over the Institutional Review Boards (IRBs); efficiently review clinical trial applications; and to provide ethical oversight for clinical trials and health research in general
2. To support NRAs' development of institutional and personnel capacities to enable improved regulatory pathway activities directly related to clinical trials and registration of new medicinal products. This may also include strengthening pharmacovigilance systems.

Proposals may include support for training, networking and promotion of good practices through improved recognition and accreditation of the relevant bodies. This may include relevant long-term training of regulatory staff, in particular through regulatory curricula provided by Regional Centres of Regulatory Excellence in Africa. National collaborative activities involving NECs and IRBs, and/or transnational collaborations involving regional networking activities between NECs or NRAs and other partners from any EU country or country associated with Horizon 2020 are encouraged. Joint NEC and NRA applications are also encouraged. Undergraduate training, as well as Master's and PhD studies that are not directly relevant and applicable to the daily activities of NECs and IRBs will not be supported under this scheme.



EDCTP considers that proposals for actions of between 24 and 36 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for actions of a different duration.

The Calouste Gulbenkian Foundation will support the EDCTP2 programme with a total cash contribution of up to €200,000 to this Call for Proposals. This cash contribution is restricted in use by the EDCTP Association for funding participants in actions resulting from this Call for Proposals, which are legally established in Portuguese-speaking sub-Saharan African countries. The call, evaluation and grant management is centrally managed by the EDCTP Association in line with the Rules for Participation of Horizon 2020.

Expected impact

Actions funded under this Call for Proposals should strengthen the functionality, recognition and performance of NECs and NRAs in sub-Saharan African countries. They will also contribute towards development of sustainable strategies for both NECs and NRAs.

Eligibility

Applications must include at least one legal entity hosting NECs or NRAs in sub-Saharan African countries. The requested EDCTP contribution per action shall not exceed €300,000.

Submission and evaluation procedure

This is a single-stage application procedure. A full proposal must be submitted via [EDCTPgrants](#) by 21 January 2016 at 17:00 (CET) (16:00 GMT).

The evaluation results will be available by 26 May 2016.

Evaluation criteria, scoring and thresholds

This call follows a single-stage application procedure. Following an admissibility and eligibility check, full proposals are evaluated by external, independent experts. Proposals are evaluated according to the criteria *Excellence*, *Impact* and *Implementation*. Each criterion is scored between 0 and 5. The threshold for individual criteria is 3 and the overall threshold for the sum of the three individual scores is 10. Applicants have the opportunity to submit a written response to the expert reviewers' comments prior to an expert review committee meeting convened by EDCTP to finalise the funding recommendations.

The following aspects are considered under the evaluation criteria:

1. Excellence

- Fit with the scope and objectives of EDCTP2 and the call topic description
- Importance, relevance and clarity of the objectives
- Credibility of the proposed approach
- Clarity, pertinence and importance of the strategic vision
- Soundness of the concept
- Quality of the proposed coordination and/or support measures.

2. Impact

- The expected impacts listed in the work plan under the relevant topic
- Likelihood to result in major advances for the field
- Effectiveness of the proposed measures to exploit and disseminate the project results
- Sustainability of capacity beyond the end of the grant, where relevant
- Contribution to networking, where relevant.

3. Quality and efficiency of the implementation

- Coherence and effectiveness of the proposed work, including appropriateness of the allocation of tasks and resources
- Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant
- Appropriateness of the management structures and procedures, including risk and innovation management, and how responsibilities for research data quality and sharing, and security will be met
- Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues
- Complementarity of the participants within the consortium and gender balance among consortium members (when relevant)
- Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s)
- Quality of the leadership and a clear and effective governance structure
- Support from and relationships with the host institutions.

Financial provisions

The indicative call budget is 1.5 million EUR.

The total requested EDCTP contribution (direct + indirect costs) shall not exceed 300,000 EUR. Indirect costs may constitute up to 25% of direct costs. EDCTP may fund 100% of eligible project costs.

EDCTP considers that proposals of between 24 and 36 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for actions of a different duration.

Grant agreement

The Coordinator is required to sign a grant agreement with EDCTP (EDCTP2 [mono-beneficiary](#) or [multi-beneficiary](#) agreement) within three months of receipt of the conditional award letter. All participants in the project must sign a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

Application process

- The application must be submitted online via [EDCTPgrants](#)
- Only registered users of EDCTPgrants system can apply for grants and therefore you are advised to register on the system as soon as possible
- Please read carefully the guidance in the online application form before submitting your proposal.

Further information



For questions related to this Call for Proposals, please contact:

- Ms Nuraan Fakier at fakier@edctp.org

For questions and issues about EDCTPgrants and the online application submission please contact EDCTP via EDCTPgrants@edctp.org or +27 21 938 0690.

For more information about EDCTP2 procedures, refer to the [EDCTP2 Grants Manual](#).