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European & Developing Countries
Clinical Trials Partnership

Ethics and regulatory capacities

Type of action	CSA
Call budget	€2.5 M
Maximum funding	€300,000
Funding level	Up to 100% of eligible costs
Open date	3 August 2017, 17:00 CET
Deadline	21 November 2017, 17:00 CET
Call identifier	CSA2017ERC

Description

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; 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⁽¹⁾. National collaborative activities involving NECs and Institutional Review Boards, and/or transnational collaborations involving regional networking activities between NECs or NRAs and other



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partners such as the [African Medicines Regulatory Harmonisation Programme \(AMRH\)](#) are encouraged. Joint NEC and NRA applications are also encouraged. Undergraduate training and Masters 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.

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

At least one legal entity established in a European Participating State**(2)** or a sub-Saharan African country**(3)**. In addition, applications must include at least one legal entity hosting NECs or NRAs in sub-Saharan African countries**(4)**. The requested EDCTP contribution per action shall not exceed €300,000.

Notes:

1. African Regulatory Centres of Excellence (RCOREs) were mandated by the African Medicines Regulatory Harmonization (AMRH) initiative. There are currently 10 RCOREs throughout Africa: <http://www.nepad.org/resource/understanding-role-regional-centres-regulatory-excellence-strengthening-medicines>
2. Legal entities in the following European countries: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom.
3. Legal entities in the following sub-Saharan African countries are eligible to apply: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Republic of Congo, Djibouti, Eritrea, Ethiopia, Gabon, The Gambia, Ghana, Guinea, Guinea-Bissau, Ivory Coast, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, São Tomé & Príncipe, Senegal, Seychelles, Sierra Leone, Somalia, South Sudan, South Africa, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia and Zimbabwe.
4. This additional condition for participation according to RfP Art. 9.5 is required due to the objective of this Coordination & Support Action. It aims to establish and develop robust national medicines regulatory systems and capacities for ethical review of clinical research on and use of medical interventions in humans. It is in line with the activities called for by the EU legislator (EDCTP2 basic act, Annex II, objective 1c) and contributes to the specific objectives of the EDCTP2 programme



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which calls, e.g., for cooperation with sub-Saharan Africa on building their capacity for conducting clinical trials in compliance with fundamental ethical principles, relevant legislations and international standards (EDCTP2 basic act, Annex I, objective 2b).

Procedure and application process

Submission and evaluation procedure

This is a single-stage application procedure. Proposals must be submitted by **21 November 2017** via [EDCTPgrants](#). Evaluation results are expected to be made available by **16 April 2018**.

Evaluation, 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 the EDCTP2 Programme, the EDCTP strategic research agenda and the call topic description
- Importance, relevance/pertinence and clarity of the objectives
- Soundness of the concept and credibility of the proposed approach/methodology
- Clarity, pertinence and importance of the strategic vision
- Soundness of the concept
- Quality of the proposed coordination and/or support measures.

2. Impact

- The extent to which the outputs of the proposed work would contribute, at the European, African and/or International level, to each of the expected impacts listed in the work plan under the relevant topic
- Likelihood to result in major advances in the field
- Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), and to manage research data where relevant
- Sustainability of capacity beyond the end of the grant, where relevant



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- Contribution to networking, where relevant.
3. Quality and efficiency of the implementation
- Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables
 - 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
 - Complementarity of the participants within the consortium, and the extent to which the consortium as whole brings together the necessary expertise
 - Appropriateness of the allocation of tasks and resources, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role
 - Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant
 - Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues
 - 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.

Financial provisions

The call budget is 2.5 million EUR.

The requested EDCTP contribution per project should not exceed 300,000 EUR. The funding level is up to 100% of eligible costs.

Grant agreement

The Coordinator is required to sign a grant agreement with EDCTP (EDCTP2 [mono-beneficiary grant agreement](#) or [multi-beneficiary grant agreement](#)) within three months of receipt of the evaluation outcome letter. Where applicable, all participants in the action must sign a consortium agreement prior to grant agreement signature.

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.

Documents and more information

Documents



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- [Template of application form – Full Application](#) (Word)
- [Call-specific FAQs](#) (PDF)

More information

- For questions related to this call for proposals, please contact: 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 +31 (0) 70 344 08 80
- For guidance on online application procedure, please refer to the [Guidelines for applicants \(PDF\)](#)
- For more information about EDCTP2 procedures, please refer to the [EDCTP2 Grants Manual](#) (PDF) and [EDCTP2 FAQs](#)