



**EDCTP**

European & Developing Countries  
Clinical Trials Partnership

## Targeting control and elimination of NIDs through clinical trials

Type of action	RIA
Call budget	€18.8 M
Expected number of grants	4-6
Funding level	Up to 100% of eligible costs
Opening date	4 July 2017, 17:00 CET
Deadline	31 October 2017 2017, 17:00 CET
Call identifier	RIA2017NCT

### Description

#### Background

Neglected Infectious Diseases (NIDs, also known as Neglected Tropical Diseases) are a diverse group of diseases that affect an estimated 1.2 billion people worldwide. These diseases disproportionately affect the world's poor, causing significant mortality and morbidity. Global investment into research and development of new products for NIDs is limited and there is an urgent need to develop new or improved products and to optimise the use of existing products in order to achieve disease elimination.

#### Scope

The objective of this Call for Proposals is to provide funding for clinical trials to accelerate the development of new or improved therapeutics for NIDs(1) in sub-Saharan Africa. Proposals that are in line with [EDCTP's strategic research agenda](#) are encouraged.

Proposals must include one or more clinical trial(s) (phases I to III) conducted in sub-Saharan Africa to evaluate the safety and efficacy of new or improved drugs, drug regimens and formulations, including for prevention and post-exposure prophylaxis. Proposals should clearly describe the desired target product profile for the drug candidate(s) and describe how it contributes to the global product development pipeline for the disease. Full details of the product development milestones, including specific go/no-go criteria for the implementation of the proposed clinical trial(s) must be included, as well as specific plans for the subsequent regulatory approval process, which should aim at obtaining relevant market authorization, and an access strategy that will allow patients in low-resource settings to access the final product.

Proposals focused exclusively on implementation of mass drug administration programmes or health systems strengthening are outside the scope of this Call.

EDCTP considers that proposals for activities of between 36 and 60 months duration and requesting funding of up to € 5 million would allow the specific challenges to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting another duration and/or funding.

## **Expected impact**

Projects funded under this Call for Proposals shall contribute towards the achievement of the United Nations' Sustainable Development Goal 3 (SDG3: 'Ensure healthy lives and promote well-being for all at all ages'). Projects should lead to the advancement of candidate products along the product development pipeline.

## **Eligibility**

Consortia comprising a minimum of three independent legal entities are eligible to apply. Two of the legal entities must be established in two different European Participating States**(2)** of the EDCTP Association and one of the legal entities must be established in a sub-Saharan African country**(3)**. All three legal entities shall be independent of each other.

'Sole participants' formed by several legal entities (e.g. European Research Infrastructure Consortia, European Groupings of Territorial Cooperation, central purchasing bodies) are eligible if the above-mentioned minimum conditions are satisfied by the legal entities forming together the sole participant.

## **Notes:**

1. For the purpose of this call, NIDs include: Buruli ulcer, cysticercosis/taeniasis, dengue, dracunculiasis, echinococcosis, foodborne trematodiases, leprosy (Hansen disease), human African trypanosomiasis, leishmaniasis, lymphatic filariasis, mycetoma, onchocerciasis, rabies, schistosomiasis, soil-transmitted helminthiases, trachoma, yaws.
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: 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.

## **Procedure and application process**

### **Submission and evaluation procedure**

This is a single-stage application procedure. Proposals must be submitted by **31 October 2017** via [EDCTPgrants](#). Evaluation results are expected to be made available by **14 March 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 (rebuttal) to the expert reviewers' comments prior to the expert review committee meeting.

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.
- Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) or research study now.
- Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial.
- Extent that the proposed trial will advance the field. In particular, how it differs from or complements any relevant planned, ongoing or recently completed trials internationally.
- Appropriate consideration of interdisciplinary approaches, and where relevant, use of stakeholder knowledge

## 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.
- Advancing the clinical development of new and improved products.
- Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results.
- Contribution to improved disease management and prevention through changes in policy, with the ultimate goal of improving public health.
- Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials.
- Effectiveness and quality of the proposed measures to exploit and disseminate the project results (including management of IPR) to communicate the project activities to different target audiences, and to manage research data

## 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).
- Competence of the participants and their investigators in conducting trials according to international standards of Good Clinical Practice (ICH-GCP).

- Involvement of sub-Saharan African researchers in the scientific leadership of the clinical trial.
- Arrangements and plans to take forward clinical development of the products under evaluation (where applicable).

### **Financial provisions**

The call budget is € 18.8 million.

The funding level is up to 100% of eligible costs.

### **Grant agreement**

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

- [Template of application form – Full Application](#) (Word)
- [Template for essential information to be provided for proposals including clinical trials](#) (Word)
- [Call-specific FAQs](#) (PDF)

### **More information**

- For questions related to this call for proposals, please contact: Dr Michelle Helinski at [helinski@edctp.org](mailto:helinski@edctp.org)
- For questions and issues about [EDCTPgrants](#) and the online application submission please contact EDCTP via [edctpgrants@edctp.org](mailto:edctpgrants@edctp.org) or +31 (0) 70 344 08 80
- For guidance on online application procedure, please refer to the [Guidelines for applicants](#)
- For more information about EDCTP2 procedures, please refer to the [EDCTP2 Grants Manual](#) and [EDCTP2 FAQs](#)