



**E D C T P**

European & Developing Countries  
Clinical Trials Partnership

## Strategic actions supporting large-scale clinical trials

Type of action	RIA
Call budget	€43 M
Funding level	Up to 100% of eligible costs
Expect number of grants	2-4
Stage 1 Opening date	3 July 2017, 17:00 CET
Stage 1 Deadline	19 September 2017, 17:00 CET
Stage 2 Opening date	15 December 2017, 17:00 CET
Stage 2 Deadline	14 March 2017, 17:00 CET
Call identifier	RIA2017S

### Description

#### Background

There is an urgent need for new or improved products for tackling poverty-related diseases (PRDs). Late phase clinical trials find themselves at the critical juncture between clinical development and market authorisation by the regulators. These trials, which provide evidence to support the product approval process and/or influence policy and practice, are often large in scale, complex and expensive, beyond the resources of a single funder. Coordination and collaboration between partners and funders is essential to leverage the expertise, resources and investments needed that in turn accelerate the development of new or improved products for PRDs and maximise the impact of research funding investments.

#### Scope

The purpose of this Call for Proposals is to support strategic actions (clinical research activities) that are part of a large-scale clinical trial with the potential to achieve rapid advances in the clinical development of new or improved medical interventions (drugs, diagnostics, vaccines, microbicides) for PRDs. Proposals for a strategic action should focus on phase III study(ies) on PRDs within the remit of the EDCTP2 programme. The proposed EDCTP-funded study(ies) should be conducted in sub-Saharan Africa but may form part of a larger trial that is conducted globally. The clinical trial must be supported by an appropriate regulatory approval and access strategy and/or include plans for uptake into policy and practice at national or international level.

Proposals for a strategic action must also present the broader large-scale clinical trial in its entirety, including details of the component(s) of the trial for which EDCTP funding is requested and the component(s) that are to be financed from other sources. Proposals should make a clear distinction between the broader context (i.e. the large scale clinical trial) as opposed to the proposed action itself (i.e. the specific part of the clinical trial to be funded as a strategic action by the EDCTP Association). The clinical trial must be of a sufficient scale and ambition to justify EDCTP support in combination with financial support from other funders, such as EDCTP2 Participating States and/or third parties.

The total cost of the large-scale clinical trial should not be less than € 10 million and ideally at least half the cost of the large-scale clinical trial should be supported by funders other than the EDCTP Association. EDCTP considers that proposals for a strategic action of between 36 and 60 months

duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals with different total costs and/or a different duration. Proposals for strategic actions that address the priorities outlined in the [EDCTP Strategic Research Agenda](#) and that address topics not covered in the scope of the other EDCTP2 calls for proposals launched in 2017 are particularly encouraged.

### **Expected impact**

Actions funded under this Call for Proposals should contribute to increased international cooperation among researchers and funders; catalyse research synergies, and leverage resources and investments in order to achieve rapid advances in the development of new or improved products for PRDs. The large-scale clinical trial supported by the action should have the potential to achieve maximum impact in the field of PRDs and to make a significant contribution to the objectives of the EDCTP2 programme. Proposals that leverage major support from other funders, in particular financial contributions, at the level of the large-scale clinical trial will be considered to have a higher impact.

### **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. 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.
2. 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 two-stage application procedure. For the first stage, a letter of intent must be submitted by **19 September** via [EDCTPgrants](#). Applicants will be notified of the first-stage outcome by **15 December 2017**. Successful applicants in the first stage will be invited to submit a full proposal. The indicative deadline for submission of full proposals is **14 March 2018**. Evaluation results are expected to be made available by 28 July 2018.

## Evaluation, scoring and thresholds

Following an admissibility and eligibility check, letters of intent and 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.

### Stage 1: Letters of Intent

For the evaluation of the first stage (Letters of Intent), only the criteria Excellence and Impact are evaluated. Within these criteria, only the aspects **in bold** will be considered. The threshold for both individual criteria will be 4. The overall threshold, applying to the sum of the two individual scores, will be set at the level such that the total requested budget of proposals admitted to stage 2 is as close as possible to three times the available budget, and in any case, not less than two and a half times the available budget. The actual level will therefore depend on the volume of proposals and funding request per proposal received. The threshold is expected to normally be set at 8 or 8.5. For the evaluation of first-stage proposals under a two-stage submission procedure, an arithmetic average (mean value) or median of the individual scores may be taken as the consensus score.

### Stage 2: Full proposals

For the evaluation of the second stage (Full Proposals), evaluation scores will be awarded for 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 €43 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 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**

- [Template of application form – Letter of Intent](#) (Word)
- [Template of application form – Full Application](#) (Word)

- [Template for essential information to be provided for proposals including clinical trials](#)  
(Word)

**More information**

- For questions related to this call for proposals, please contact: Dr Montserrat Blázquez-Domingo at [blazquez@edctp.org](mailto:blazquez@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](#)