Call for Proposals: Strategic actions supporting large-scale clinical trials

Type of Action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	2-5
Stage 1: open for letters of intent	28 January 2015
Deadline for letters of intent	Extended to 15 October 2015, 17:00 (CET), 16:00 (GMT)
Status	Open

Background

There are multiple research opportunities arising continuously, some of which are of utmost strategic importance to advance clinical research in poverty-related diseases (PRDs). These research opportunities are often complex and resource-intensive, requiring financial investments that a single funder cannot bear alone. Extended international cooperation with other funders is vital to harness synergies and to ensure that the impact of research is maximised and resources and investments are leveraged.

Scope

The purpose of this Call for Proposals is to support distinct strategic actions (clinical research activities) which are part of a large-scale clinical trial that has the potential to achieve rapid advances in the clinical development of new or improved medical interventions against PRDs. Such large-scale clinical trials are often expensive and may require clinical research in different countries or on different continents, including outside of Europe and Africa. Applications for a strategic action should focus on clinical trials on PRDs in sub-Saharan Africa, and may address any disease within the scope of the EDCTP2 programme[1]. Proposals that include phase III trials are encouraged.

Proposals must present the large-scale clinical trial in its entirety, clearly indicate for which part of the trial EDCTP2-funding is requested and how the financing of the other parts of the trial is ensured, and present its relevance to reaching the objectives of the EDCTP2 programme. The ambition and design of the proposed large-scale clinical trial as well as the relevance of the proposed strategic action for the large-scale clinical trial must be presented clearly. Supporting information on the composition and scale, as well as on the management structures and procedures of the large-scale clinical trial, must be present to enable assessment of their appropriateness.

EDCTP considers that proposals for activities 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 for activities of a different duration.

The large-scale clinical trial must be of a sufficient scale and ambition to justify EDCTP support in combination with financial support from other funders (i.e. from EDCTP2 Participating States and/or third parties). EDCTP considers that at least half of the costs of the large-scale clinical trial should be supported by other funders (i.e. from EDCTP2

[1] All stages of clinical trials can be supported, from phase I to IV, including implementation research on optimisation of health services. For the purpose of this Call for Proposals, PRDs include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); Leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; and yaws, as well as emerging infectious diseases of particular relevance for Africa such as Ebola.

Participating States and/or third parties) and that the foreseen total costs of the large-scale clinical trial should not be less than €3.0 million to provide this specific challenge with a strategic dimension.

Expected impact

Actions funded under this Call for Proposals should contribute to increased international cooperation among researchers and funders; catalyse research synergies; leverage resources and investments; and maximise the impact of global research in 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. The requested EDCTP2 contribution should be leveraged by at least the same amount of funding from other funders (i.e. from EDCTP2 Participating States and/or third parties). Proposals that clearly demonstrate major support from other funders at the level of the large-scale clinical trial will be considered to have a higher impact.

Eligibility

Consortia comprising a minimum of three different 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 must be independent of each other.

In addition to these standard criteria, the following apply to this call for proposals:

1. The requested EDCTP contribution per action shall not exceed €10.0 million.

Submission and evaluation procedure

This is a two-stage application procedure comprising the following steps:

First stage: a letter of intent must be submitted via **EDCTPgrants** by 15 October 2015. The evaluation results for the first stage will be available by [TBC].

Second stage: successful applicants in the first stage will be invited to submit a full proposal via **EDCTPgrants** (timelines to be confirmed).

Evaluation criteria, 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. The threshold for each individual criterion is 4 and the

[2] So far, the following 14 European Participating States have joined the EDCTP Association as members: 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, Equatorial Guinea, 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

overall threshold is 8.

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 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 objective**s
   - **Credibility of the proposed approach**
   - **Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) now**
   - **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**
   - **Ambition and design of the proposed large-scale clinical trial**
   - **Relevance of the proposed strategic action for the large-scale clinical trial**
   - Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial.

2. **Impact**
   - **The expected impacts listed in the work plan under the relevant topic:**
     - **Contribution to an increased international cooperation among research groups, public and private funders**
     - **Catalysing research synergies;**
     - **Leveraging resources and investments; and**
     - **Maximising the impact of global research in PRDs**.
   - **Likelihood to result in major advances for the field**
   - **Advancing the clinical development of new and improved products**
   - **Contribution to improved disease management and prevention through changes in policy, with the ultimate goal of improving public health**
   - **Potential of the large-scale clinical trial to achieve maximum impact in the field of PRDs and to make a significant contribution to the objectives of the EDCTP2 programme**
   - **Clear demonstration of major support by other funders, with at least half of the costs of the large-scale clinical trial supported by other funders**
   - Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results
   - Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials
   - Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant
   - Contribution to extended international cooperation with other funders
   - Contribution to improved North-North, North-South and South-South networking and collaboration.

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)
- 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)
- Contribution to the scale and composition of the large-scale clinical trial
- Contribution to the management structures and procedures of the large-scale clinical trial.

Please note that:
- For the evaluation of letters of intent only the criteria '*Excellence*' and '*Impact*' will be evaluated. Within these criteria, only the aspects highlighted above **in bold** will be considered at the letters of intent stage.
- For all applications involving human participants, and/or human tissues, cells or personal data, the evaluation process will include an assessment of ethical issues.

Financial provisions

The requested EDCTP contribution per action shall neither exceed 50% of the total cost of the activity nor exceed €10.0 million. EDCTP considers that the foreseen total costs of the action should not be less than €3.0 million. EDCTP considers that at least half of the costs of the action should be supported by other funders (i.e. from EDCTP2 Participating States and/or third parties).

EDCTP considers that proposals 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 of a different duration.

Grant agreement

The Coordinator is required to sign a grant agreement with EDCTP (EDCTP2 multi-beneficiary agreement) within three months of receipt of the conditional award letter[4]. 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 the **Guide for Applicants** before submitting an application

[4] Grant awarding by EDCTP will depend on the final approval of the EDCTP2 work plan and associated budget for 2015 by the European Commission and the EDCTP Association.

Further information

For questions related to this call for proposals, please contact:

- Mr Jean Marie Vianney Habarugira, habarugira@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.