Call for Proposals: Strategic projects with major cofunding

Type of Action	Research & Innovation Action (RIA)
Funding level	50% 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 3 September 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 among research groups and public and private funders is vital in order to harness synergies and to leverage resources and investments in order to achieve maximum impact.

Scope

The purpose of this Call for Proposals is to provide cofunding to strategically important, large-scale research projects with the potential to achieve rapid advances in the field of PRDs and to make a significant contribution to the objectives of EDCTP2. Applications for a strategic project should focus on clinical trials, related clinical research and/or capacity building efforts on PRDs in sub-Saharan Africa, and may address any area of research within the scope of EDCTP2[1]. Projects that include phase III trials and/or address research areas not covered by other open or forthcoming EDCTP2 Calls for Proposals in 2015 are encouraged. Applications must demonstrate financial commitment from other funders (i.e. EDCTP2 Participating States and/or third parties) and be of a sufficient scale and ambition to require EDCTP cofunding. Proposals should clearly indicate their relevance to reaching the objectives of EDCTP2.

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.

Expected impact

Projects funded under this Call for Proposals will contribute to increased international cooperation among research groups and public and private funders; catalyse research synergies; leverage resources and investments; and maximise the impact of global research in PRDs.

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

[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.

[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

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 shall neither exceed 50% of the total cost of the activity nor €10.0 million.
2. The total cost of the activity shall not be less than €3.0 million.
3. Letters of intent should provide evidence of financial commitments from other funders.

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 3 September 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 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.**
   - Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial.

2. **Impact**

[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

- **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 to achieve rapid advances in the field of PRDs and to make a significant contribution to the objectives of EDCTP2**
- **Availability of guaranteed funds from 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 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).
- Sufficient scale and composition to achieve rapid advances in the field of PRDs and to make a significant contribution to the objectives of EDCTP2.

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 shall neither exceed 50% of the total cost of the activity nor €10.0 million, and the total cost of the activity shall not be less than €3.0 million.

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

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.

[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.