Call for Proposals

EDCTP Regional Networks

Type of Action:	Coordination & Support actions (CSA)
Call budget:	€ 12,000,000
Funding threshold:	€ 3,000,000 per network
Funding Level:	100% of eligible costs
Expected number of grants:	4
Open date:	5 November 2015 00:00
Deadline:	18 February 2016 17:00 (CET); 16:00 (GMT)
Status:	Open

Background

There are significant clinical research disparities and a very heterogeneous clinical research landscape for conducting clinical trials in sub-Saharan Africa across African researchers, institutions, countries and sub-regions. Fostering research collaborations is a means of addressing this challenge through investing in a joint pathway towards a stronger and sustainable sub-Saharan African clinical research landscape.

Scope

The purpose of this Call for Proposals is to provide funding for actions that aim to support regional networking in sub-Saharan Africa and with Europe in order to build and strengthen regional, national, institutional and individual capacities to conduct clinical trials in line with the International Conference on Harmonization guidelines for Good Clinical Practice (ICH-GCP). The networks should contribute to overcoming the lack of capacity, critical mass and adequate infrastructures that prevent many African institutions from engaging in high quality clinical research activities. The networks should build on results from former EDCTP-funded regional networking actions with the aim of strengthening the scientific and clinical research environment for conducting clinical trials to prevent and treat poverty-related diseases in sub-Saharan Africa.

EDCTP may fund up to four regional networks, defined geographically as Southern[1], Eastern[2], Western[3], and Central Africa[4].

The specific objectives of the networks should include:

1. To strengthen collaboration and optimise the use of resources and infrastructures within the network. This could include the establishment of shared facilities such as clinical laboratories or data management centres, and setting rules and guidelines for sharing and accessing these.

2. To offer training and mentorship aimed at promoting professional development and scientific leadership in clinical trials. This would require the establishment of a formal

[1] Southern Africa: Botswana, Lesotho, Madagascar, Malawi, Mozambique, Namibia, South Africa, Swaziland, Zambia, and Zimbabwe.
[2] Eastern Africa: Burundi, Comoros, Djibouti, Eritrea, Ethiopia, Kenya, Mauritius, Rwanda, Seychelles, Somalia, South Sudan, Sudan, Tanzania, and Uganda.
[3] Western Africa: Benin, Burkina Faso, Cape Verde, Gambia, Ghana, Guinea, Guinea-Bissau, Ivory Coast, Liberia, Mali, Mauritania, Niger, Nigeria, Senegal, Sierra Leone, and Togo.
[4] Central Africa: Angola, Cameroon, the Central African Republic, Chad, the Republic of the Congo, the Democratic Republic of the Congo, Equatorial Guinea, Gabon, and São Tomé and Príncipe.

training programme and platform for exchange of expertise in key skills such as design of clinical trials, monitoring, data management, pharmacokinetics, laboratory techniques, biostatistics, clinical epidemiology, pharmacovigilance, as well as financial management, administration, and quality assurance.

3. To strengthen South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established institutions in building capacity for conducting high quality clinical research.

4. To encourage and promote networking and dialogue between researchers, communities and policy makers to maximise the impact of clinical research in Africa.

The proposed networks should have a clear governance structure, an independent advisory structure and a transparent process for acquiring new network participants and for excluding non-performing network participants. The networks should also have a clear strategy for succession in leadership, and a detailed business plan for becoming self-sustainable by the end of the award period. The overall responsibility for the scientific management and direction of the network should be firmly based in sub-Saharan Africa. The proposed networks should propose activities that address all four objectives listed above and cover the poverty-related diseases (HIV/AIDS, tuberculosis, malaria), and selected neglected infectious diseases and emerging ones of relevance to Africa and within the scope of the EDCTP2 programme[5]. The proposed networks should present the proposed management of Intellectual Property Rights (IPR) and measures to communicate the project, to increase competitiveness, to reduce research capacity inequalities, and, where relevant, to manage research data. The proposed networks should also present their arrangements to encourage career development within the network. The proposed networks should comprise sufficient participants to address all objectives, but should not be too large to function and communicate effectively.

The grant is strictly limited to 36 months, whereupon successful networks that demonstrate satisfactory progress may be given an opportunity to apply for an additional 5 year grant.

Successful networks should achieve the following deliverables during the 36-month project period:

Partnership:

- Publish at least three peer reviewed scientific or policy publications as a demonstration of active collaboration and coordination.
- Organise at least one annual meeting, provide regular consortia communication (e.g. documented teleconferences), and develop annual work plans aimed at increased harmonisation of study methods, and sharing infrastructures.

Expertise:

- Initiate at least one ICH-GCP-compliant clinical trial in PRDs funded from other grants, conducted and managed by appropriately qualified individuals within the network.
- Train or otherwise acquire at least five clinical research associates (CRAs) that are certified to monitor clinical trials and can be contracted by EDCTP, other funders or clinical trial sponsors to monitor the progress and quality of clinical trials.

Training:

[5] In the EDCTP2 programme, "poverty-related diseases (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); echinococcosise; foodborne trematodiases; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola.

- Develop a comprehensive training and mentorship plan to support the career development of talented individuals through dedicated courses, short term staff exchange programs, and active rotation process among sites for mentors/trainers and trainees.

Infrastructure:

- Incorporate at least one fully functional clinical laboratory, accredited to GLP to perform clinical trials research, which can be used by the network or contracted by an external clinical trial sponsor to support clinical trials
- Develop a functioning data management service, which can be used by the network or contracted by an external clinical trial sponsor to support clinical trials

Organisation:

- Develop a robust strategic business plan with demonstrated commitment and support from its constituent organisations; a transparent, fully-functional management and governance structure; a long-term strategy to ensure the viability, sustainability and progression of the network after the end of the EDCTP funding
- Develop a communication strategy, including a regularly updated website and policies for dissemination data, results and other relevant information

Expected impact

Networks funded under this Call for Proposals should contribute to measurable increase in collaborative research (south-south and north-south collaborations), competences and capacity to conduct clinical trials. By the end of the award period, the networks should collectively be able to conduct clinical trials to ICH-GCP standard. Additionally, each network should have published at least three peer reviewed scientific or policy publications and been able to competitively attract additional funding from local and/or international global health R&D funders.

Eligibility

- The network must comprise a minimum of six legal entities from at least three different sub-Saharan African countries and a minimum of two legal entities from two different European PSs[6]
- The requested EDCTP contribution per network must not exceed € 3.0 million
- The maximum project duration must be 36 months

Submission and evaluation procedure:

This is a single-stage evaluation procedure. A full proposal must be submitted by 18 February 2016 at 17:00:00 CET. Evaluation results will be available by 7 July 2016.

Evaluation criteria, scoring and thresholds

Following an admissibility and eligibility check, full proposals will be 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

[6] The 14 European members of the Association or Participating States are: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom

expert review committee meeting convened by EDCTP to finalise the funding recommendations.

The following aspects are considered under the evaluation criteria:

Excellence

- Fit with the scope and objectives of EDCTP2 and the call topic description
- Importance, relevance and clarity of the objectives
- Credibility of the proposed approach
- Clarity, pertinence and importance of the strategic vision
- Soundness of the concept
- Quality of the proposed coordination and/or support measures.

Impact

- The expected impacts listed in the work plan under the relevant topic
- Likelihood to result in major advances for the field
- Effectiveness of the proposed measures to exploit and disseminate the project results
- Sustainability of capacity beyond the end of the grant, where relevant
- Contribution to networking, where relevant.

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).
- Quality of the leadership and a clear and effective governance structure.
- Support from and relationships with the host institutions.

For all full 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 network shall not exceed € 3.0 million including indirect costs. The funding level is 100% of direct costs (+25% for indirect costs).

The grant is strictly limited to 36 months. Successful networks that demonstrate satisfactory progress by the end of 36 months may be given an opportunity to apply for an additional 5 year grant.

Grant agreement

A grant agreement with EDCTP (general EDCTP2 multi-beneficiary grant agreement) should be signed within three months of receipt of the conditional award letter. All participants in the

network must sign a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

EDCTP will only sign grant agreements with organisations (legal entities) that are registered in the Beneficiary Register for Horizon 2020 and that have a validated Participant Identification Code (PIC). For more information, see the H2020 participant portal.

Application process

- The application must be submitted online via **EDCTPgrants** (http://www.edctpgrants.org).
- Please note that only registered users of the EDCTPgrants system can apply for grants
- Please read carefully the guidance in the online application form before submitting your proposal
- For more information about EDCTP2 procedures, refer to the EDCTP2 Grants Manual.

For further information

For questions related to this funding scheme, please contact:

- Ms Michelle Nderu at nderu@edctp.org

For questions and issues about EDCTPgrants and the online application submission please contact EDCTP via EDCTPgrants@edctp.org or +27 21 938 0690.