

Call for Proposals: Improved treatment and clinical management of poverty-related diseases

Type of Action	Research and Innovation Action (RIA)
Call Budget	35 million EUR
Expected number of grants	3-5
Stage 1: open for letters of intent	28 January 2015
Deadline for letters of intent	15 October 2015, 17:00 (CET); 16:00 (GMT)
Stage 2: open for full applications	12 January 2016
Deadline for full applications	15 March 2016, 17:00 (CET); 16:00 (GMT)
Status	Open

Background

Poverty-related diseases (PRDs) represent a major obstacle to the sustainable development of sub-Saharan Africa. Effective, safe, suitable and affordable medical treatments tailored to developing countries' specific circumstances do not exist for most PRDs.

Scope

The purpose of this Call for Proposals is to provide funding to projects that aim to evaluate new or significantly improved drugs or drug regimens in humans or to optimise the efficacy and use of existing therapeutics for any of the PRDs¹, including co-infections of PRDs. Proposals should include one or more clinical trial(s) (phase I to IV) of therapeutics for PRDs to be conducted in sub-Saharan Africa. Applications addressing the following topics are particularly encouraged:

HIV

- Evaluation of new drugs and optimisation of existing drug treatments, particularly for paediatric use.
- Evaluation of new treatment strategies for the prevention of anti-retroviral drug resistance.
- Models of delivery to increase population coverage, retention in care and adherence to treatment.

Tuberculosis

- Evaluation of new drugs, drug regimens and combinations to shorten and simplify treatment.
- Optimisation of treatment of paediatric tuberculosis.
- Evaluation of new drugs and drug regimens to prevent and treat multi-drug resistant tuberculosis (MDR-TB) and extensively multi-drug resistant tuberculosis (XDR-TB).
- Models of delivery to increase population coverage, retention in care and adherence to treatment.

¹ The PRDs targeted through this Call for Proposals are: 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 trematodiasis; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; and yaws, as well as emerging infectious diseases of particular relevance for Africa, such as Ebola.

Malaria

- Evaluation of new drugs, drug regimens and combinations, particularly where there are product development gaps in the global portfolio for treatment of uncomplicated (symptomatic and asymptomatic) and severe *Plasmodium falciparum* malaria.
- Optimisation of treatment and chemo-protection in pregnant women and children.

NIDs

- Evaluation of new drugs, drug regimens and combinations, particularly where there are product development gaps in the global portfolio.
- Large-scale trials to evaluate optimal delivery of existing interventions.

Co-infections

- Improved clinical management of HIV and tuberculosis, with a focus on managing co-infections.
- Phase II-IV trials of clinical management of PRD co-infections.

Proposals for conducting phase II and/or III clinical trials are encouraged.

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 should lead to improvements in public health as a result of policy change at national, regional or global level, through evidence-based formulation and implementation of treatment guidelines and/or lead to the advancement of product candidates through the clinical pipeline or registration or pre-qualification of new products.

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 States² of the EDCTP Association and one of the legal entities must be established in a sub-Saharan African country³. All three legal entities must be independent of each other.

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, 17:00 CET. The evaluation results for the first stage will be available by 12 January 2016.

Second stage: successful applicants in the first stage will be invited to submit a full proposal via [EDCTPgrants](#) by 15 March 2016, 17:00 CET. The evaluation results for the second stage will be available by 7 July 2016.

² To date, 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.

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 individual criteria is 4 and the overall threshold is 8. Successful applicants will be invited to submit a full proposal in the second stage.

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 objectives**
- **Credibility of the proposed approach**
- **Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) 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**

2. Impact

- **Likelihood to result in major advances for 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 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
- **The expected impacts listed in the work plan under the relevant topic:**
 - **Leading to improvements in public health as a result of policy change at national, regional or global level, through evidence-based formulation and implementation of treatment guidelines**
 - **Leading to the advancement of product candidates through the clinical pipeline or registration or pre-qualification of new products**

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).

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. 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 call budget is 35 million EUR.

The requested EDCTP contribution per project should not exceed 15 million EUR, including indirect costs. The funding level is 100% of direct costs (+25% for indirect costs).

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 grant agreement) within three months of receipt of the conditional award letter⁴. 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** and EDCTP work plan carefully before submitting an application

Further information

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

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.



- Dr Montserrat Blázquez-Domingo at blazquez@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.