



E D C T P

European & Developing Countries
Clinical Trials Partnership

Treatment innovations for poverty-related diseases

Type of action	RIA
Call budget	€ 30M
Funding level	Up to 100% of eligible costs
Expected number of grants	3-5
Stage 1 Opening date	3 July 2017, 17:00 CET
Stage 1 Deadline	19 September 2017, 17:00 CET
Stage 2 Opening date	22 December 2017, 17:00 CET
Stage 2 Deadline	14 March 2018, 17:00 CET
Call identifier	RIA2017T

Description

Background

Poverty-related diseases (PRDs) represent a major obstacle to the sustainable development of sub-Saharan Africa. There is limited availability of effective, safe, suitable and affordable products to diagnose and treat PRDs in sub-Saharan Africa, and the number of new chemical entities that are registered remains very low. There is therefore an urgent need to accelerate the development of new and improved products through the clinical development pipeline.

Scope

The purpose of this Call for Proposals is to provide funding for the clinical evaluation and development of new and innovative drug candidates for HIV/AIDS, malaria, tuberculosis, diarrhoeal infections or lower respiratory infections, including co-infections.

Proposals should include at least one clinical trial (phase I-III) in sub-Saharan Africa to evaluate the safety, dosage, pharmacokinetics, pharmacodynamics, and/or efficacy of a new candidate drug product. The candidate drug should consist of active substance(s) or biologicals that have not previously been authorised anywhere in a medicinal product. However, combination therapies are within the scope of this call insofar they contain at least one new active substance. Furthermore, re-purposed drugs and novel combinations thereof are also within the scope of this call, provided these have not previously been authorised for use against an infectious disease anywhere in the world.

The proposed clinical trial(s) must be conducted to ICH-GCP regulatory and ethical standards. The proposal should include a product development plan including clear go/no-go criteria as well as specific plans for the regulatory approval process, which should aim at obtaining a relevant market authorisation. Proposals must further outline the target product profile of the investigational product and describe how it fits within the global product development pipeline for the disease. Proposals that are in line with [EDCTP's strategic research agenda](#) are particularly 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 shall contribute towards the achievement of the United Nations' Sustainable Development Goal 3 (SDG3: 'Ensure healthy lives and promote well-being for all at all ages'). Projects should lead to the advancement of drugs candidates through the development pipeline towards registration or WHO endorsement, leading to more effective clinical management of PRDs in sub-Saharan Africa.

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⁽¹⁾ of the EDCTP Association and one of the legal entities must be established in a sub-Saharan African country⁽²⁾. 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 2017** via [EDCTPgrants](#). Applicants will be notified of the first-stage outcome by **22 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, 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 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. 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 (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 a 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 € 30 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 signature of the 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

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: Jean Marie Vianney Habarugira at 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
- For guidance on online application procedure, please refer to the [Guidelines for applicants](#) (PDF)
- For more information about EDCTP2 procedures, please refer to the [EDCTP2 Grants Manual](#) (PDF) and [EDCTP2 FAQs](#).