Clinical trials to reduce health inequities in pregnant women, newborns and children

EDCTP
European & Developing Countries Clinical Trials Partnership

Type of action	RIA
Call budget	€38.23 M
Funding level	Up to 100% of eligible costs
Expected number of grants	5-10
Stage 1 Opening date	4 July 2017, 17:00 CET
Stage 1 Deadline	13 October 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	RIA2017MC

Description

Background

Poverty-related diseases (PRDs) remain the leading causes of morbidity and mortality in sub-Saharan Africa, especially during pregnancy and childhood. Despite progress in other age groups, effective treatment and prevention of PRDs in mothers, newborns and children is often lacking and/or lagging. The frequent exclusion of pregnant women and children from clinical trials and the paucity of available products that target these groups are factors that contribute to these populations having the lowest health indicators. Additional challenges relate to the limited financial incentives associated with the adaption of off-patent medicines to the specific needs of pregnant women and paediatric populations. Therefore, concerted efforts are needed to increase access to potentially life-saving, cost-effective interventions to prevent and treat PRDs in pregnant women, newborns and children and to enhance use of existing interventions in these populations.

Scope

The objective of this call is to accelerate the adaption and/or optimisation of treatment and prevention products (excluding vaccines) for PRDs in sub-Saharan Africa for use in pregnant women, newborns and/or children. This call is restricted to the following diseases: HIV, malaria, tuberculosis, diarrhoeal diseases and lower respiratory infections. Proposals that are in line with the priorities of EDCTP's strategic research agenda are encouraged.

Proposals should focus on adaption of existing medicines, including off-patent products, to the specific needs of pregnant women, newborns and/or children. Proposals should typically include one (or more) clinical trials conducted in sub-Saharan Africa to assess the pharmacokinetics, efficacy and safety, and/or the development of age-appropriate formulations. However, other trial methodologies and study designs may be considered where the methodology is justified in the proposal as being the most appropriate to provide robust evidence. Projects must assure that the clinical trials are appropriately conducted, respecting current legislation and considering the ethical aspects and particular needs of the study subjects and their families.

The proposal must include full details of the product development milestones including specific go/no-go criteria for the proposed clinical trial(s) as well as specific plans for the subsequent regulatory approval process; for trials involving children, this is ideally a paediatric investigation

plan, which should aim at obtaining a relevant market authorisation, such as the Paediatric Use Marketing Authorisation (PUMA).

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 are expected to contribute to expanding the availability of medicines for PRDs for pregnant women, newborns and children in sub-Saharan Africa. Projects should provide evidence for better use of medicinal products in pregnant women and/or paediatric populations, and the acquired knowledge should be used towards obtaining a relevant market authorisation such as the Paediatric Use Marketing Authorisation (PUMA) for products for newborns and children or an equivalent for products for pregnant women.

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 **13 October 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 results are expected to be made available by **4 August 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 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.

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 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 €38.23 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: Dr Christy Comeaux at comeaux@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
- For more information about EDCTP2 procedures, please refer to the EDCTP2 Grants Manual and EDCTP2 FAQs