



# Call for Proposals: Diagnostic tools for poverty-related diseases

<b>Type of Action</b>	Research and Innovation Action (RIA)
Call Budget	15M Euros
Expected number of grants	4-8
Stage 1: open for letters of intent	2 December 2014
Deadline for letters of intent	2 March 2015, 16:00 (GMT); 17:00 (CET)
Stage 2: open for full applications	30 April 2015
Deadline for full applications	7 July 2015
Status	Open

## Background

Disease diagnosis in sub-Saharan Africa is highly challenging, as the population is predominantly rural and the health care systems often have limited resources. Early and rapid diagnosis of poverty-related diseases (PRDs)<sup>1</sup> offers the best opportunity for patients to receive timely and appropriate treatment, but adequate diagnostic tools are not readily available because of a lack of drive to develop and deploy them in disease-endemic countries. Therefore, there is a clear need for the development and uptake of rapid, accurate, cost-effective, scalable and field-friendly diagnostic tools.

## Scope

The purpose of this Call for Proposals is to provide funding to projects focusing on validation of the clinical performance and/or implementation of new or improved diagnostic tools and technologies for detection of any of the PRDs, including as co-infections. These tools and technologies should improve the performance of diagnosis, prediction, monitoring, intervention or assessment of therapeutic response, with a significant impact on clinical decision and health outcomes. Applications should focus on late stage development (e.g. evaluation and/or demonstration phase trials) or implementation studies in sub-Saharan Africa. Applications should further provide detailed plans for World Health Organisation (WHO) endorsement and/or implementation of the diagnostic tools and technologies upon successful completion of the project. Proposals focused entirely on early-stage, laboratory-based studies using biobanked samples are outside the scope of this call. Priority will be given to point-of-care diagnostics for use in resource-limited settings.

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 for activities of a different duration.

## Expected impact

Projects funded under this Call for Proposals should lead to improvements in patient care through early detection and treatment of disease and/or enhanced monitoring and tracking of disease progression and therapeutic response. Projects should thus contribute towards the implementation of innovative, rapid and simple diagnostics that can be deployed at low cost in health systems in resource-poor settings.

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<sup>1</sup> For this call, 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); echinococcosis; foodborne trematodiasis; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola.



## 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<sup>2</sup> of the EDCTP Association and one of the legal entities must be established in a sub-Saharan African country<sup>3</sup>. 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 2 March 2015, 17:00 CET. The evaluation results for the first stage will be available by 30 April 2015.

Second stage: successful applicants in the first stage will be invited to submit a full proposal via EDCTPgrants by 7 July 2015, 17:00 CET. The evaluation results for the second stage will be available by 30 September 2015.

## 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**

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<sup>2</sup> So far, the following 13 European Participating States have joined the EDCTP Association as members: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, and the United Kingdom.

<sup>3</sup> 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



- 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
- **Improvements in patient care through early detection and treatment of disease and/or enhanced monitoring and tracking of disease progression**
- **Contribution towards the implementation of innovative, rapid and simple diagnostics that can be deployed at low cost in health systems in resource-poor settings.**

## 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 15M Euros.



The requested EDCTP contribution per project should not exceed € 3.0 million, including indirect costs of 25%.

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<sup>4</sup>. 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** carefully before submitting an application

## **Further information**

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

- Dr Monique Rijks-Surette at [surette@edctp.org](mailto:surette@edctp.org)

For questions and issues about EDCTPgrants and the online application submission please contact EDCTP via [grantshelpdesk@edctp.org](mailto:grantshelpdesk@edctp.org) or +31 (0) 70 344 08 80.

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<sup>4</sup> Grant awarding by EDCTP will depend on the successful conclusion of a delegation agreement between the European Commission and the EDCTP Association for implementation of the EDCTP2 programme.