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Clinical Trials Partnership

## EDCTP-TDR Clinical Research and Development Fellowships

Type of action	TMA
Call budget	€1.5 M
Maximum funding	€100,000
Funding level	Up to 100% of eligible costs
Opening date	30 November 2017, 17:00 CET
Deadline	28 February 2018, 17:00 CET
Call Identifier	TMA2017IF

Please note that the Special Programme for Research and Training in Tropical Diseases (TDR) will not participate in the 2017 Call for proposals.

The Special Programme for Research and Training in Tropical Diseases (TDR) had to withdraw its participation in this EDCTP and TDR Joint Call including the related TDR funding. Thus, the Call will only be carried out as an EDCTP fellowship scheme, and only on the basis of EDCTP funding. Consequently, it will be dedicated to individual junior to mid-career researchers and clinical staff employed by organisations with a legal personality and established in sub-Saharan Africa.

### Description

#### Background

Researchers from low and middle-income countries (LMIC)<sup>1</sup>, in particular in sub-Saharan Africa (SSA)<sup>2</sup> who are involved in clinical research activities have limited opportunities to acquire experience and develop skills for conducting clinical trials outside an academic or public-sector setting. As a result, there are few researchers and clinical staff from SSA assuming leading roles in clinical research for poverty-related diseases (PRDs). The development of human capacities through fellowships will lead to enhanced and sustainable research capacity in SSA on diagnostics, drugs and vaccines for PRDs by supporting career progression and retention of researchers in SSA.

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<sup>1</sup> Countries as defined by the World Bank: low-income economies are defined as those with a GNI per capita, calculated using the [World Bank Atlas method](#), of \$1,025 or less in 2015; lower middle-income economies are those with a GNI per capita between \$1,026 and \$4,035; upper middle-income economies are those with a GNI per capita between \$4,036 and \$12,475; high-income economies are those with a GNI per capita of \$12,476 or more.

<sup>2</sup> Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo (Democratic People's Republic), Congo (Republic), Côte d'Ivoire, Djibouti, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, *São Tomé and Príncipe*, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, Zimbabwe.



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As part of EDCTP's capacity building efforts, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the EDCTP signed a Memorandum of Understanding in January 2013 to implement a fellowship scheme that offers placements in European-based companies to individual researchers and clinical staff from sub-Saharan Africa working in the implementation of clinical trials.

This Call will have a leverage effect on the number of individuals trained, resulting in an increased impact on research and development capacity in SSA. The partnership will ensure synergies between the different parties involved, and will facilitate communication with researchers and clinical staff, pharmaceutical companies, clinical research organisations (CROs), clinical or academic affiliated research organisations, and product development partnerships (PDPs).

### **Scope**

The purpose of this Call for Proposals is to provide funding towards actions that aim to support researchers and key members of clinical trial research teams from SSA to acquire specific skills in clinical trials research through placements in pharmaceutical companies, CROs, clinical or academic affiliated research organisations, and PDPs.

The scheme targets junior to mid-career researchers or clinical staff (clinicians, pharmacists, medical statisticians, data managers, other health researchers) who are currently working on activities in the scope of the EDCTP2 programme **(1)**. EDCTP supports researchers who are employed by a legal entity in a sub-Saharan African country. Placements supported by EDCTP are for a minimum period of 15 months (3 months will be used to prepare for the placement), following which there will be a re-integration period of 6 months.

Application for a Clinical Research and Development Fellowship must be submitted by an organisation with a legal personality and established in sub-Saharan Africa ('the applicant legal entity') on behalf of the prospective fellow employed by that organisation. Fellows must commit to return to their home organisation for a minimum of two years after completion of the fellowship. Fellows should identify the skills and training sought and should demonstrate how the experience would be applied upon return to the home organisation.

This Call will include an evaluation and selection process in compliance with the provisions set in the Rules for Participation of Horizon 2020 and the EDCTP2 basic act. EDCTP will fund fellows employed by a sub-Saharan African legal entity (the fellow's home organisation and applicant legal entity) to be placed in European-based host organisations (pharmaceutical companies, CROs, clinical or academic affiliated research organisations and PDPs) to train and develop specific clinical research skills of relevance to PRDs. The EDCTP grant includes funds for re-integration.



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Host organisations may offer placements in the following areas: design and conduct of clinical trial studies, including operational planning, management and evaluation; clinical development of vaccines including associated epidemiological studies; assessment of drug development programmes; diagnostics; biostatistics/epidemiology; data management and pharmacovigilance. A list of participating pharmaceutical companies, CROs, clinical or academic affiliated research organisations and PDPs (i.e. host organisations) and available placements will be published on the EDCTP website. EDCTP will collaborate with EFPIA.

### **Expected impact**

Actions funded under this Call for Proposals will support the development of human resources and should promote high quality research and development in SSA. Fellowships are expected to add significantly to the development of the best and most promising researchers from SSA, in order to enhance and maximise their contribution in research institutions in SSA, including training of peers. The actions should also contribute to strengthening collaboration between research institutions, researchers and clinical staff in SSA, pharmaceutical companies, CROs, clinical or academic affiliated research organisations and PDPs.

### **Eligibility criteria**

**In addition to the [standard admissibility and eligibility conditions](#), the following additional eligibility conditions will apply to this call:**

1. The applicant must be a legal entity with a legal personality established in a sub-Saharan African country and must have an employment contract with the fellow. **(2)**
2. The fellow must: **(2)**
  - be a post-graduate (MSc or PhD) or medical graduate with clinical and/or research experience in infectious diseases;
  - have obtained their post graduate or medical graduate degree within 15 years of submission of the application;
  - be a researcher or clinical staff member employed for the last 12 months in an organisation with a legal personality, established in sub-Saharan Africa, and who has been conducting clinical research activities in the scope of the EDCTP2 programme;
  - provide a letter of support from the home organisation for the fellowship which is justifying the training needs of the fellow and explaining how the home organisation will benefit from the fellowship and how the re-integration of the fellow will be ensured; **(3)**
  - not have been funded under this fellowship scheme before. **(4)**
3. Placements sought shall be for a period of 15 months, following which there will be a re-integration period of up to 6 months.
4. The requested EDCTP contribution per action shall not exceed € 100,000.



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## Notes:

1. 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); echinococcosis; foodborne trematodiasis; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; 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 or yellow fever.
2. Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of this Training & Mobility Action. It aims to support researchers and key members of clinical trial research teams from sub-Saharan Africa to acquire specific skills in clinical research and development. It is in line with the activities called for by the EU legislator (EDCTP2 basic act, Annex II, activity 1c and 1d) and contributes to the specific objectives of the EDCTP2 programme which calls, e.g., for cooperation with sub-Saharan Africa on building their capacity for conducting clinical trials in compliance with fundamental ethical principles, relevant legislations and international standards, and for extended cooperation with private partners (EDCTP2 basic act, Annex I, objectives 2b and 2d).
3. The points to be addressed in the support letter are elaborated in the application form: Confirm that the Fellow is a current employee of the home organisation (details of contract duration should be included); State that the home organisation supports this fellowship application; Confirm that the Fellow is fully eligible in accordance with the criteria as set out in the Call Text; Confirm that the Fellow will be supported with a leave of absence for the duration of the fellowship; Confirm that the Fellow has the ability to successfully undertake the training he/she is applying for; Explain how the fellowship will enhance the career development of the Fellow; Explain how the proposed training will strengthen the home organisation's capacity to conduct clinical research upon return of the Fellow; Confirm that the Fellow will have a similar position at the home organisation once the fellowship has been completed.
4. Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of the EDCTP2 programme which requires that the capacity for conducting clinical trials in sub-Saharan Africa are built and strengthened (EDCTP2 basic act, Annex II). Allowing fellows in sub-Saharan Africa to only receive once a specific EDCTP2 fellowship will increase the number of different fellows supported and promoted under the EDCTP2 programme, and in



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turn strengthen more broadly the corresponding clinical research capacity in sub-Saharan Africa.

## Procedure and application process

### Submission and evaluation procedure

This is a single-stage application procedure. Proposals must be submitted by **28 February 2018** via [EDCTPgrants](#). Evaluation results are expected to be made available by **31 July 2018**.

Proposals should comprise of a proposed training plan reflecting the training needs of the applicant, a re-integration plan and the requested EDCTP contribution for the action. The full proposal will be reviewed by an independent evaluation committee comprising experts identified by the EDCTP 2-IS.

### Evaluation, scoring and thresholds

Following the check of admissibility, and eligibility conditions, the 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.

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.
- Suitability of the candidate, considering their track record, degree of independence and/or potential, and how the fellowship will further the individual's career.
- Quality of the project and its fit with the fellow's expertise and career development plan, including acquired competencies and skills to be developed further.

#### 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.
- Contribution of the fellowship to the fellow's clinical research skills and career development.



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- Contribution to strengthening clinical research capacity at the home or host organisation.
- Effectiveness of the proposed measures to exploit and disseminate results generated during the fellowship (including management of IPR), to communicate the fellowship activities, and, where relevant, to manage clinical data.
- Sustainability and retention of capacity post-award.

### 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).
- Suitability of the fellow's home organisation to support the fellowship project.
- Intention of the fellow's home organisation to develop and commit to a career post-fellowship or re-integration plan.

Scoring will be in line with section 6.7.2 of the [2017 Work Plan](#).

Proposals above the threshold will be forwarded to prospective host organisations listed in the Call for Proposals. Host organisations interested in hosting a fellow will select up to five candidates for interview. Interviews are held between the potential host organisation, the candidate and the home organisation, following which a matching process of candidates and host organisations is conducted by EDCTP.

### **Financial provisions**

The call budget is 1.5 million EUR.

The requested EDCTP contribution per project should not exceed 100,000 EUR. The funding level is up to 100% of eligible costs.



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### **Grant agreement**

The legal entity employing the successful fellow ('home organisation') is required to sign a grant agreement with EDCTP (EDCTP2 [mono-beneficiary](#) grant agreement with options for fellowships) within three months of receipt of the evaluation outcome letter.

### Supplementary agreements

Prior to the conclusion of the EDCTP2 grant agreement, the fellow will be required to sign a letter of engagement with their home organisation.

### **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**

- List of participating host organisations
- Template of application form – Full Application (Word)

### **More information**

- For questions related to this call for proposals, please contact: Michelle Nderu at [nderu@edctp.org](mailto:nderu@edctp.org)
- For questions and issues about [EDCTPgrants](#) and the online application submission please contact EDCTP via [edctpgrants@edctp.org](mailto: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](#)