



EDCTP as a model of Europe-African partnership for human capacity development in clinical research: the EDCTP-TDR Clinical Research and Development Fellowships Scheme

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BACKGROUND

The goal of the **European & Developing Countries Clinical Trials Partnership (EDCTP)** is to support collaborative research that accelerates the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria as well as other poverty-related and neglected infectious diseases in sub-Saharan Africa (SSA), with a focus on phase II and III clinical trials.

EDCTP facilitates the alignment and coordination of European countries' research activities to work in partnership with SSA countries, private sector and other partners. This approach aims at maximising synergy and cost-effectiveness while ensuring co-ownership and strengthened cooperation with SSA countries, in particular, for capacity development and promotion of sustainable programmes.

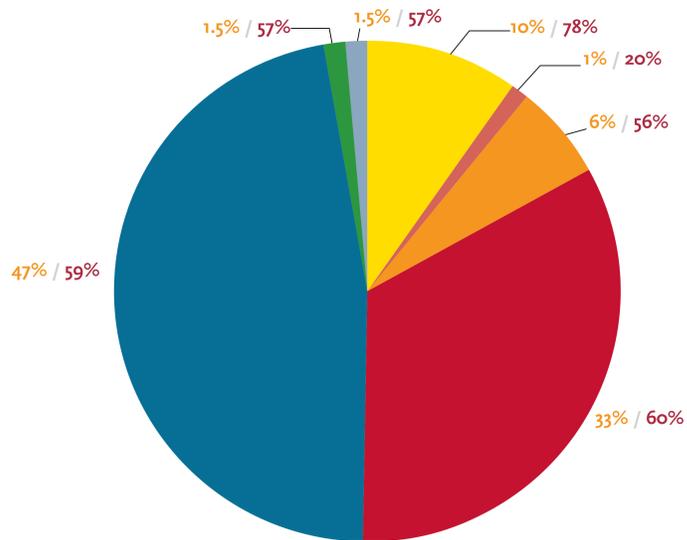
DEVELOPING A CADRE OF AFRICAN RESEARCHERS TO SUPPORT AND CONDUCT CLINICAL TRIALS

As part of its strategy to build sustainable research capacity in SSA, EDCTP provides grants that attract and retain scientific leadership in Africa. These grants include:

- Fellowships and studentships
- Support for improving and updating infrastructure and facilities
- Strengthening the ethical and legal framework for conducting clinical trials.

By the end of 2014, EDCTP had supported a total of 516 African trainees at various career stages.

Trainees in progress or completed (2003-2014)



Career stage	No. of trainees (%)	No. of Males (%)
Senior Fellows	51 (10%)	40 (78%)
Career Development Fellows	5 (1%)	1 (20%)
Postdoctoral researchers on EDCTP grants	32 (6%)	18 (56%)
PhD students	172 (33%)	104 (60%)
Master's students	242 (47%)	143 (59%)
Bachelor's students	7 (1.5%)	3 (43%)
Medical doctors' diploma	7 (1.5%)	4 (57%)
Total	516 (100%)	313 (61%)

FELLOWSHIPS

The Senior Fellowship grant scheme launched in 2004, supports the development of African scientific leadership and mentorship. This scheme has been instrumental in developing the careers of mid-level to senior African scientists in helping them to become more competitive internationally, to build research teams and to develop the scientific excellence and leadership required for larger grants from EDCTP and other funding sources.

Approximately 10% of the Senior Fellows have used this grant scheme to return from academic institutions abroad to research positions in their respective home countries in SSA. Sixteen (31%) of the Fellows conducted clinical trials as part of their fellowships. The other Senior Fellows focussed on clinical and epidemiological research.

STUDENTSIPS AND POSTDOCTORAL RESEARCHERS

Bachelor's, Master's, PhD, MD students and postdoctoral researchers are supported through EDCTP grants for clinical research and through dedicated capacity building funding schemes and initiatives. One example of EDCTP's support to studentships is the collaboration between EDCTP and the London School of Hygiene & Tropical Medicine (LSHTM) for the Master's in Clinical Trials (by distance learning). Between 2007 and 2014, 25 students have received support from EDCTP to undertake this Master's degree.

In 2013, EDCTP launched a Call for Proposals for a Master's Fellowship in Epidemiology and Medical Statistics aimed at building research capacity in SSA by supporting the training and career development of junior researchers. The scheme provided awards of ≤ two years for the fellow to undertake a Master's course in epidemiology or medical statistics at an internationally recognised centre of excellence and to conduct a field study of 6-12 months duration at an institution in SSA to build practical skills.

EDCTP-TDR CLINICAL RESEARCH AND DEVELOPMENT FELLOWSHIPS SCHEME

EDCTP together with the Special Programme for Research and Training in Tropical Diseases (TDR), the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) decided in 2014 to jointly implement a fellowship scheme that will support researchers from low-to-middle income countries (LMICs) to develop specific skills in clinical trial research through placements of up to two years in multinational pharmaceutical companies or product development partnerships (PDPs).

The European Commission and the Gates Foundation provide financial support and EFPIA and the IFPMA facilitate contacts with potential host organisations.

The first EDCTP-TDR Clinical Research and Development Fellowships Call for Proposals was published in October 2014. The purpose of this Joint Call for Proposals is to support researchers and key members of clinical trial research teams from LMICs to acquire specialist skills in clinical research and development through placements in a corporate environment. The fellowship scheme targets junior to mid-career researchers or clinical staff who are employed by an institution in a LMIC where they are working on activities in the scope of EDCTP or TDR. The EDCTP-TDR partnership includes a joint evaluation and selection process of applications submitted to this Call. However, grant awarding and budget management are managed separately by each funding organisation.

Selection process

Applications are screened for admissibility and eligibility by EDCTP and TDR. Eligible applications are reviewed by a Selection Committee composed by experts in setting up, implementing or advising on capacity building initiatives, in particular on training and mentorship. Each proposal is assessed independently by at least three members of the Committee.

Host organisations



Partnership advantages

- Development of a common vision and understanding of goals and objectives, enhancing the capacity of each organisation and avoiding duplication of efforts
- EDCTP builds on >10 years' experience that TDR has in implementing a similar capacity building initiative
- Common communication with the host organisations (i.e. pharmaceutical companies, PDPs) and the home institutions and the fellows in LMICs
- Pharmaceutical research benefits from interactions with scientists from different backgrounds and regions of the World, including perspectives and experiences that will optimise knowledge exchange that is beneficial to the development of new or improved treatments for poverty-related diseases
- A larger number of scientists and clinical staff can be trained, which will ultimately have an impact on R&D capacity of LMICs.

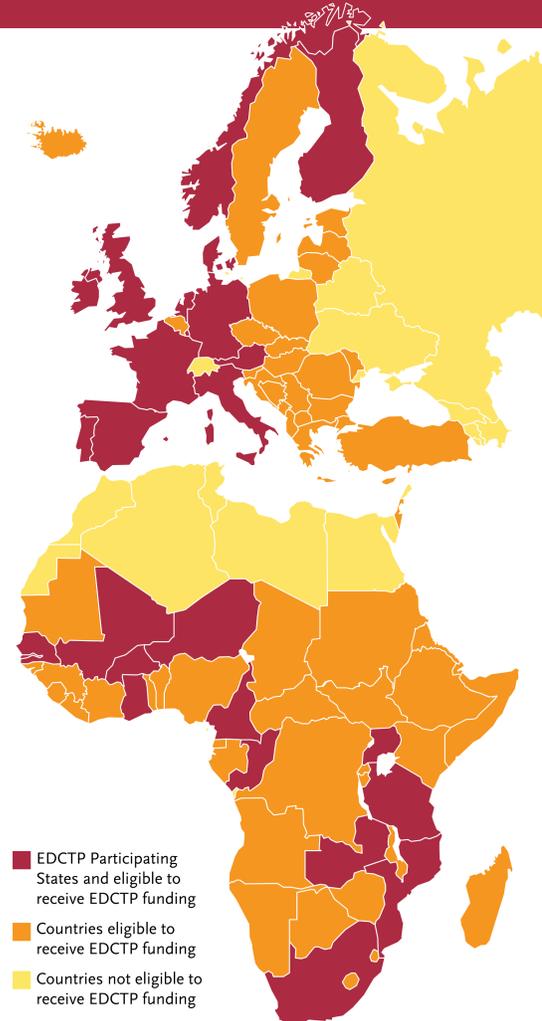
Expected learning outcomes

- Specific skills related to the design, conduct and/or analysis of clinical trials and clinical research, beyond what can be gained from classical academic studies or usual employment

- Learning state-of-the-art methods in clinical research in therapeutic areas covered by EDCTP and TDR as well as on cross-cutting issues (e.g. data management, pharmacovigilance, regulatory processes).

Measuring impact

- This initiative will develop human resources to promote high quality research and development in LMICs. Fellows are expected to improve their professional skills significantly through the fellowships, and upon their return will also contribute to enhanced capacity of research institutions in LMICs, including training of peers. Furthermore, the scheme will strengthen collaboration between research institutions, researchers and clinical staff in LMICs, pharmaceutical companies and PDPs. The impact of the programme will be measured through a series of evaluations, which will use specific indicators to assess if the short and long-term objectives of the initiative are being accomplished. A focus will be given to ensuring the goal of translating individual capacity into institutional capacity.



At the end of 2014, EDCTP projects were being funded in 30 sub-Saharan African countries and 12 European Participating States, involving 238 research institutions across Europe and Africa.

