

## Note from the Executive Director

After nine wonderful years at EDCTP including one year as the Head of Africa Office and eight at the helms, I am ready to pass on the baton. I shall step down at the end of this year. The process of looking for my replacement is well underway.

Through these years, with the help of many very wonderful and hardworking people I have been very lucky to witness and oversee the growth of EDCTP into one of the major players in supporting research and development of intervention tools against poverty-related and neglected diseases.

This growth is reflected not only by the extended mandate and increased budget of the programme, but also the expanded remit and increased membership that now also includes African countries. Its unique brand of supporting

capacity development and networking (south-south, north-south and north-north) within its primary focus of funding clinical trials has met a lot of success.

Moreover, EDCTP has proven to be a true partnership of African and European scientific communities and policy makers working in close collaboration with global partners on the poverty-related and neglected diseases. The initiative above many similar ones is leading in embracing African leadership and co-ownership not only in research, but also in governance and administration of the programme.

All this would not have been achieved without the support of all of you who I unreservedly thank and ask for your continued support to the programme.



Charles S. Mgone

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## Calls & Grants

### Calls for proposals

#### Research and capacity development in support of the EVD response

**Open date:** 19 March 2015  
**Close date:** 18 June 2015  
**Call budget:** €1.4 million\*

The purpose of this Call for Proposals is to build and strengthen regional, national, institutional and individual capacities to conduct high quality health research (e.g. clinical trials, operational and/or implementation research) during infectious disease outbreaks resulting in health emergencies. Proposals should complement current and future research initiatives for treatment, prevention and containment of EVD or other emerging infectious diseases of particular relevance to Africa.

\* Grant awarding by EDCTP will depend on the final approval of the EDCTP2 work plan and associated budget for 2015 by the European Commission and the EDCTP Association.

#### Open calls for proposals

The following calls for proposals are still open for applications until the closing date of 18 June 2015. Their deadline was extended pending the approval of the EDCTP 2015 Workplan.

- Strategic projects with major cofunding (2-stage procedure)
- Improved treatment and clinical management of poverty-related diseases (2-stage procedure)

### Calls under review

Currently, the proposals for three EDCTP calls are under review:

- 'EDCTP-TDR Clinical Research and Development Fellowships' call (closed 30 January 2015) received a total of 150 applications
- 'Diagnostic tools for poverty-related diseases' (closed 2 March 2015) resulted in 94 applications
- 'Maximising the impact of EDCTP research: translation of research results into policy and practice' (closed 16 March 2015) received 14 applications.

## Calls & Grants (continued)

### Portfolio summary

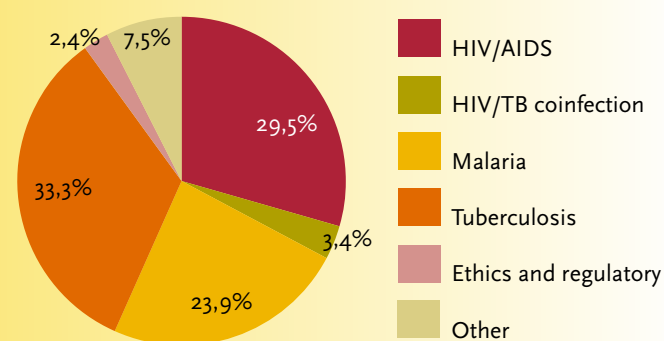
**EDCTP has launched 65 calls for proposals and awarded 254 grants since its inception. A total of 73 grants (29%) were still active at the end of 2014 and 181 (71%) grants were completed. The total grant value of these 254 projects is €211.98 million, including cofunding via EDCTP.**

EDCTP's project portfolio is relatively well-balanced in terms of number of projects and amount of funding per disease area. So far, tuberculosis research has received the largest share of the funding with a total of €70.68 million (33.3%) for 36 projects, followed by 56 HIV projects (€62.5 million; 29.5%) and 42 malaria projects (€50.69 million; 23.9%), while 3.4% of grant funding (€7.23 million) supported 12 projects on HIV/TB co-infection. Funding for ethics and regulatory activities amounted to €5.02 million (2.4%) to support 78 projects and €15.83 million (7.5%) was the total for 30 projects that supported a range of cross-cutting activities, including the EDCTP Regional Networks of Excellence, capacity building and networking grants.

Seventy-three (73) of the 100 clinical trials have finished (two trials were terminated prematurely), with the remainder in the final stages of recruitment or follow-up.

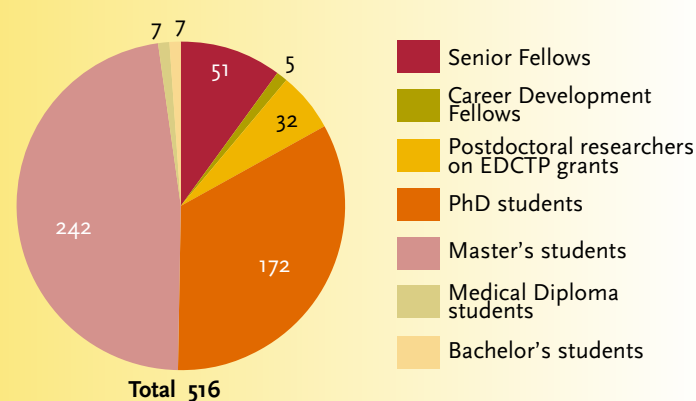
EDCTP has supported the long-term training of 516 African researchers from undergraduate Bachelor's students to postdoctoral researchers (including 51 Senior Fellows, 172 PhD students and 242 Master's students). This includes 10 grants awarded in 2014 for Master's Fellowships in Epidemiology and Medical Statistics, following a call for proposals in 2013 funded by Sweden and UK. Furthermore, the majority of EDCTP grants include short-term training courses and workshops, linked to the overall aims of the project. The EDCTP ethics programme has awarded 75 grants totalling just over €4 million to support the establishment and strengthening of national ethics committees and institutional review boards, as well as training programmes and resources.

**Overview of funding by area 2003-2014**



By end of 2014, 100 clinical trials had received support from EDCTP: 34 trials on malaria, 30 trials on HIV/AIDS, 27 trials on tuberculosis, and 9 trials on HIV/TB co-infections. These trials have tested new and improved drugs for treatment and prevention (59), vaccines (25), diagnostics (11), microbicides (3) and two trials used electronic devices to investigate methods to enhance retention rates in trials and adherence to treatment.

**Number of trainees funded by EDCTP (2003-2014)**



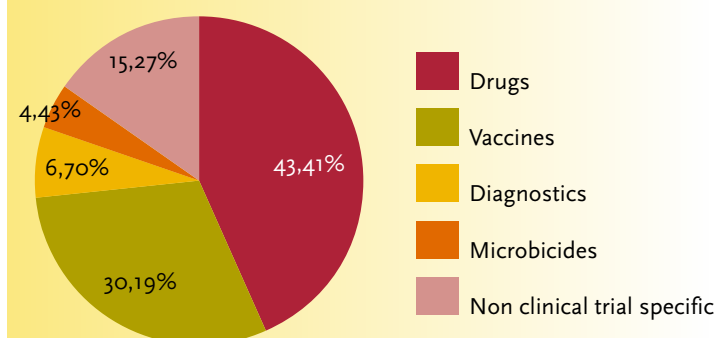
### Research output

EDCTP's funding strategy has focused on research addressing key clinical challenges and policy-relevant questions in sub-Saharan Africa, whilst strengthening research capacity and the enabling environment for research in sub-Saharan Africa.

The majority of clinical trials and studies that closed in 2014 were presented at (inter)national conferences and the results were published in high-profile journals. The studies have also produced results that informed national and international policy.

There have been more than 600 publications from EDCTP-funded projects to date. A recent bibliometric analysis showed that the citation impact of EDCTP-funded papers (2003-2011) was high, particularly in the areas of HIV/AIDS and HIV/TB co-infection. This indicates that EDCTP-funded projects delivered high-quality research that has had a major impact on the field.

**Overview of funding by intervention 2003-2014**



## EDCTP Governance

### EDCTP Staff



EDCTP staff member **Mrs Sayma Siddiqui** was appointed to Grants Financial Assistant as of 1 March 2015 leaving a vacancy for the position of Financial Assistant.



**Mrs Neli Krautsova** was appointed as Grants Financial Assistant as of 6 May 2015.. She has a university degree in accountancy (Belarus) and is a chartered accountant with a UK accountancy qualification (ACCA).



EDCTP Project Officer **Ms Hager Bassyouni** moved from the Calls & Grants team to join the Networking team as North-North Networking Officer starting 1 May 2015.



**Dr Perry Mohammed** joined EDCTP from April 2015 as a Special Advisor working via a secondment for one year from the pharmaceutical company Janssen. He has led a team of medical experts within the company's Global Public Health department aiming to develop a not-for-profit model for increasing HIV drug access in the developing world.

### Strategic Advisory Committee

Fourteen members of the EDCTP Strategic Advisory Committee (SAC) gathered in The Hague for their spring meeting on 29-30 April 2015. The main topics of the discussions were the EDCTP Work Plan for 2016, the next EDCTP Forum (2016) and strategies to consult EDCTP stakeholders to inform decision making on future EDCTP priorities and work plans.



**Back row, from left to right:** Dr Michael Makanga, Dr Gianpietro van de Goor, Prof. Philippe Sansonetti, Prof. Knut Fylkesnes, Dr Salim Abdulla, Mr Jean Marie Talom, Dr Maryline Bonnet, Prof. Moses Bockarie, Mr Abdoulie Barry, Prof. Marie-Louise Newell, Dr Ole Olesen, Prof. Maria Fraga Oliveira Martins, Prof. Simon Croft and Prof. Clara Menéndez Santos. **Front row, from left to right:** Prof. Gita Ramjee, Dr Eleni Akillu, Prof. Tumani Corrah, Dr Mark Palmer and Prof. Ali Zumla.

## Publications

The proceedings of the High-Level Launch Event for the second EDCTP programme (EDCTP2) in Cape Town, South Africa on 2 December 2014 are published. A short video report of the meeting is also available. The report is available on the EDCTP website ([www.edctp.org](http://www.edctp.org)).

Additionally, EDCTP published a video on the occasion of World TB day 2015. The video presents the PredArt study, coordinated by Professor Graeme Meintjes (University of Cape Town, South Africa), which is conducted in an HIV-TB clinic in Khayelitsha, a community of 500,000



people on the outskirts of Cape Town with very high rates of TB and HIV.

**Watch the video's on the EDCTP YouTube channel ([youtube.com/edctpmedia](http://youtube.com/edctpmedia)).**



It causes them to go back into hospital for further tests and treatment. It can undermine patients confidence in their treatment.



## Focus on Projects

### PanACEA MAMS-TB-01 trial

**The EDCTP-funded PanACEA consortium presented the preliminary results from the MAMS-TB-01 clinical trial at the Conference on Retroviruses and Opportunistic Infections (CROI) in February 2015.**

High-dose (35mg/kg) rifampicin, in combination with standard dose of isoniazid, pyrazinamide and ethambutol, showed a significant shortening of time to culture conversion with a covariate-adjusted hazard ratio of 1.75, 95% confidence interval (1.21-2.55) over the 12 weeks of experimental treatment. Data on treatment up to week 26 and post-treatment follow-up will be analysed and reported together with the results mentioned above in the future main publication.

Chief investigator Martin Boeree (Radboud University Nijmegen, The Netherlands) stated: "This is the largest reduction in time to culture conversion seen in any previous TB trial, to our knowledge. High doses of rifampicin may be an important component in shorter TB regimens in the future."

The MAMS-TB-01 trial enrolled 365 patients from 7 sites in

Tanzania and South Africa in only 11 months. Moreover, it applied an innovative trial design. It was the first of several TB treatment regimen trials which will use the same adaptive clinical trial design that allows several new regimens to be compared to the current standard, and incorporates interim analyses that allow for regimens that show little treatment shortening potential to be excluded from the trial at an early stage.

Dr Patrick Phillips (University College London, United Kingdom) pointed out that "To our knowledge, this is the first trial with an adaptive design evaluating multiple combination treatment regimens in a global health setting. We have shown that novel trial methodology originally developed for oncology trials can successfully be used to evaluate new treatments for tuberculosis."

### REMSTART

**The EDCTP-funded project REMSTART found that a new approach to HIV management reduced deaths by 28 per cent. This approach to care of patients with advanced HIV combines community support and screening for cryptococcal meningitis. The research, published in *The Lancet* on 10 March 2015, suggests that this low-cost intervention could be an effective approach to reducing HIV-related deaths in Africa.**

Researchers from the REMSTART team – led by Dr Saidi Egwaga of the Tanzanian Ministry of Health and Social Welfare and Dr Shabbar Jaffar, Professor of Epidemiology at the London School of Hygiene & Tropical Medicine – conducted a randomised trial of 1,999 HIV patients in Tanzania and Zambia between February 2012 and September 2014.

The trial enrolled patients who had advanced HIV disease and were beginning treatment. Most of the deaths in African HIV programmes occur in this group at around the time or just shortly after HIV treatment is started. All patients were firstly screened for tuberculosis and started quickly on HIV treatment. Patients were then given either standard care from a clinic, or given additional care which consisted of screening for cryptococcal meningitis as well

as weekly home visits for the first four weeks from lay workers to support them with antiretroviral therapy.

The trial found deaths among patients receiving the additional screening for cryptococcal meningitis and home visits were 28% lower than those receiving standard clinic care (134 deaths and 180 deaths respectively over a 12 month follow-up period).

Professor Shabbar Jaffar said: "The combination of screening and community lay worker support reduced the death rate among patients with advanced HIV by almost a third. About 10 million people in Africa are on antiretroviral therapy, but there is a disparity in the number of people who die in the first year of treatment compared to wealthier regions like Europe. The screening for cryptococcal meningitis was also a significant component in the success of our trial. We now know that screening combined with giving pre-emptive treatment for this type of fungal meningitis is an effective strategy in reducing the high number of HIV deaths associated with it in Africa."

Publication: Sayoki Mfinanga, Shabbar Jaffar et al. on behalf of the REMSTART trial team, Cryptococcal meningitis screening and community-based early adherence support in people with advanced HIV infection starting antiretroviral therapy in Tanzania and Zambia: an open-label, randomised controlled trial. *The Lancet* – DOI: 10.1016/S0140-6736(15)60164-7.



## Meetings

### ECSCA-HC and WAHO regional health research programmes

EDCTP participated in two African sub-regional strategic policy meetings with the objective of strengthening regional cooperation: the 60th East, Central and Southern Africa Health Community (ECSCA-HC) health ministers conference held in Munyonyo, Uganda, 16-18 February; and the West African Health Organisation (WAHO) meeting on the development of a strategic plan for regional health research for West Africa (2016-2020) held in Côte d'Ivoire from 23-27 February. Both meetings had a situational analysis of the research on health in the sub-regions and discussions on their future strategic plans. Dr Michael Makanga, Director for South-South Cooperation represented EDCTP at both meetings.

### AACHRD 30-31 March 2015

The African Advisory Committee on Health Research and Development (AACHRD) met for its 29th session in Harare, Zimbabwe on 30-31 March 2015. The AACHRD advises the Director of WHO Africa Region on the research agenda and the generation, translation and dissemination of valuable knowledge. On 31 March, Dr Michael Makanga, EDCTP Director of South-South Cooperation, presented EDCTP2 from an African perspective. The process to improve consultation and feedback between EDCTP and African countries was extensively discussed at this meeting in a session moderated by Prof. Charles Mgone.

### EDCTP visit to Republic of Congo

From 22 to 28 February 2015, an EDCTP team comprising Mr Abdoulie Barry (Director of Finance and Administration), Dr Ole Olsen (Director of North-North Cooperation), Dr Thomas Nyirenda (South-South Networking and Capacity Development manager) and Ms Michelle Nderu (Project Officer), visited EDCTP-funded projects in the Republic of Congo.

This visit was conducted in order to establish personal contact and dialogue with the teams implementing the work in the field by visiting selected research institutions, meeting with principle investigators/project coordinators and key project team members; to assess technical progress made in implementation of the projects' primary objectives and deliverables including identification of key areas for capacity building and networking; to assess the systems of internal finance control and reporting; to inform managers, researchers and their teams about the goals of EDCTP and ensure

### Fourth African Regulatory Conference 2015

The IFPMA African Regulatory Network and the Drug Information Association (DIA) with support from the Gates Foundation and the World Bank organised the 4th African Regulatory Conference in Dakar, Senegal on 27-28 April. The conference discussed the evolving regulatory landscape in Africa and ways to further harmonisation. Dr Thomas Nyirenda, South-South Networking and Capacity Development Manager, attended and represented EDCTP as speaker in the session on clinical trials.



Dr Ole Olesen, Hon. Mr Bruno Itoua and Dr Thomas Nyirenda at a meeting in Brazzaville, Congo

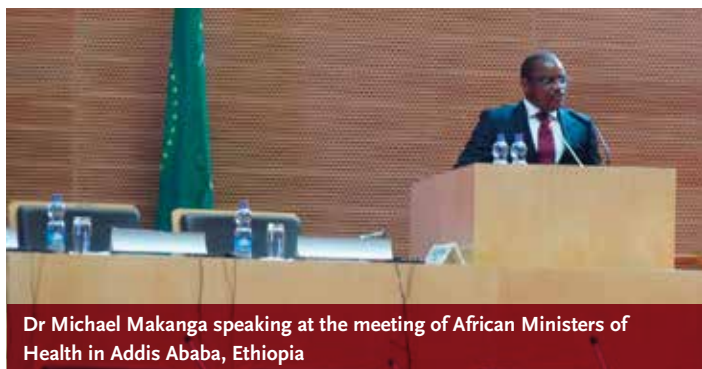
their achievement in Congo; to increase the visibility of EDCTP through strategic engagement with policy makers, regulators, key ethics review committee/board members and European Union delegation; to assess the readiness/capabilities of project sites/laboratories to implement new EDCTP projects; and to collect information and identify potential areas of future collaborations in research and capacity strengthening activities within the scope of EDCTP.

The Republic of Congo has seen an increase in the number of EDCTP-funded projects between 2004 and 2013 and attracted more than

1.8 million euros research funding. This country visit focused on the Central African Network for TB, AIDS and Malaria (CANTAM). The Minister for Scientific Research and Technological Innovation for Congo, Honourable Mr Bruno Itoua, officially welcomed the EDCTP team to Congo and facilitated meetings with relevant players that included the Ministry of Public Health, the CANTAM Secretariat, Brazzaville TB Clinic, Makelekele Children's hospital, the National Ethics Committee, National Reference Laboratory, Marien Ngouabi University, the EU Delegation in Brazzaville and the World Health Organisation African Regional Office (WHO-AFRO).

### AU ministerial meeting on health

African Ministers of Health met in Addis Ababa on 16 and 17 April for a meeting on the challenges to inclusive and universal access to health care in relationship with health, population and drug control. The ministerial session was prepared by the first meeting of the Specialized Technical Committee on Health, Population and Drug Control (STC-HPDC-1) of the African Union (13-15 April). Dr Michael Makanga contributed to the discussions of the committee and held a presentation on 'Conducting clinical trials as a means of seeking an African solution' at the ministerial meeting.



Dr Michael Makanga speaking at the meeting of African Ministers of Health in Addis Ababa, Ethiopia

## Meetings (continued)

### Annual TBVI projects meeting

Professor Charles Mgone, EDCTP Executive Director, and Dr Ole Olesen, EDCTP Director of North-North cooperation, attended the Annual Projects Meeting of the Dutch TBVI (Tuberculosis Vaccine Initiative) on 11-12 February 2015. On 11 February, Prof. Mgone contributed to the kick-off meeting for TBVAC2020, a consortium of 40 research institutions coordinated by TBVI which aims to advance novel and promising TB vaccine candidates from discovery to preclinical and early clinical development. Dr Olesen, member of the external advisory committee for TBVAC2020, delivered first feedback at the closing session of the meeting on 12 February.

### Gulbenkian Foundation and EDCTP sign agreement



Professor Charles Mgone and Mrs Isabel Mota, Calouste Gulbenkian Foundation, greeting before signing the agreement of collaboration

On 9 March 2015, EDCTP Executive Director Prof. Charles Mgone and the Administrator of the Gulbenkian Foundation Mrs. Isabel Mota signed an agreement of collaboration for strengthening health research ethics review capacity in sub-Saharan Africa. The Portuguese Calouste Gulbenkian Foundation will

### MVVC2 meeting

The annual meeting of the Malaria Vectored Vaccines Consortium (MMVC) working on malaria vaccine project MVVC2 took place in Oxford, United Kingdom on 4-5 March 2015. MVVC2 is a two-year project coordinated by the European Vaccine Initiative (EVI) building on the work conducted by MMVC, which established a strong network between four African and several European partners. MVVC2 comprises field trials of a new combination malaria vaccine in West African adults and children funded by EDCTP and third parties. EDCTP was represented by Project Officer Mr Jean Marie Vianney Habarugira who presented the different types of funding schemes in EDCTP2 and took part in the discussion on the continuity and sustainability of the MMVC consortium.

### Fourth Global TB Vaccine Forum



Dr Ole Olesen speaks at the Fourth Global TB Vaccine Forum in Shanghai, China

The fourth Global TB Vaccine Forum convened in Shanghai, China from 21-24 April 2015. This meeting was organised by TBVI and Aeras together with the Fudan University and the Shanghai Pulmonary Hospital, under the auspices of the Stop TB Partnership Working Group on new vaccines. EDCTP was represented by Dr Ole Olesen, Director of North-North Cooperation, who presented the EDCTP2 funding opportunities and urged innovative approaches to vaccine development. Ms Daniela Pereira (Communication) provided information on the EDCTP2 programme and funding possibilities from the EDCTP stand.



The EDCTP information table

### HIV Vaccine Development in Africa

Dr Thomas Nyirenda, EDCTP South-South Networking and Capacity Development Manager, represented EDCTP at the Pan-African meeting on 'Considerations for a Pan-African HIV Vaccine Development Agenda' in Kigali, Rwanda from 16-20 March 2015. He participated as moderator for the session on regulatory aspects. The main

meeting was organised by the Global HIV Vaccine Enterprise, followed by the 'Regulatory Capacity Workshop on Vaccine Clinical Trial Review from Ebola to HIV'. The regulatory workshop was jointly organised by the Global HIV Vaccine Enterprise, the Canadian government and the Alliance for advancing HIV Vaccines.

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