Head of the Africa Office’s note

News about Calls and Grants
- EDCTP is pleased to announce funding for several proposals
- EDCTP/BMGF 20M Euro grant to develop HIV vaccine trial capacity in Africa

Focus on EDCTP grantees
- An EDCTP Senior Fellow receives a prestigious award for malaria research
- Workshop on HIV trial load assay

Events
- The third EDCTP annual forum, 8-11 October 2006

Meetings and visits
- UA/AAVP regional consultation meeting on HIV vaccines R&D in Africa

EDCTP staff visit to clinical trial sites in Tanzania and Malawi

WHO-EDCTP collaboration on national regulatory framework for Africa
- Global Training Network on regulatory authorisation and evaluation of clinical trials

Announcements
- New networking tool: Project Partners
- The EDCTP Blog

Head of the Africa Office’s note

The year 2006 has come and gone; some may say too quickly. Nevertheless, as the year was drawing to an end, EDCTP relentlessly continued rolling out various activities some of which are reported in the current issue of the newsletter. These include the stepping up of site visits whereby in the last quarter of the year among the places visited included Tanzania and Malawi. As usual during the visits, the Secretariat staff accompanied by the DCCC members met with various African leaders (political and scientific) to advocate for the acceleration of R&D to fight HIV/AIDS, malaria and tuberculosis. Also reported in the current issue are the capacity development activities and advocacy that EDCTP is pursuing including in collaboration with other partners such as the World Health Organisation (WHO), African AIDS Vaccine Programme (AAVP) and International AIDS Vaccine Initiative (IAVI). These include capacity development to support the regulatory framework through the Global Network Training conducted in collaboration with WHO and setting up of priorities and a common advocacy for R&D of HIV vaccines in Africa conducted in partnership with WHO, AAVP, IAVI and other partners.

We are very happy to inform the readers of the achievements of two of our Senior Fellows. In the issue we feature the success of Dr Alexis Nzila, an EDCPT Senior Fellow, from Kenya Medical Research Institute (KEMRI) who was awarded the prestigious Royal Society Prize for advancing discoveries through his work on anti-folate drugs in the treatment of malaria. We are also very proud of Dr Abraham Alabi and his team who have successfully organised a one-week training course on an “in-house” HIV viral load assay for scientists from the West African sub-region. This followed the testing, optimisation and evaluation of the assay after Dr Alabi was awarded an EDCTP Senior Fellowship for that purpose.

On 1 December, to mark the World AIDS Day, EDCTP in collaboration with the Bill & Melinda Gates Foundation launched a 20 million Euro grant for capacity development to conduct clinical trials of preventive HIV vaccines in Africa. This and the news on the Third EDCTP Forum that was held in Stockholm in October this year are all reported in the current newsletter. Indeed 2006 was a hectic and successful year for EDCTP.

We sincerely thank all of you who have helped us make 2006 a very successful year and as we welcome 2007 we wish all our readers, stakeholders and partners a very successful and prosperous new year.

News about Calls and Grants

EDCTP is pleased to announce funding for the following proposals:

## Support for Ethics Courses and Seminars

- **Cardiff University, UK**: “Developing a distance learning research ethics course for East Africa”
- **Institut de Droit de la Santé - University of Neuchâtel, Switzerland**: “Training and Resources in Research Ethics Evaluation for Africa”
- **University of Malawi**: “Proposal for Building and Strengthening National Capacities in Ethical Review and Clinical Trial Monitoring in Malawi”
- **Nigerian Institute of Medical Research, Nigeria**: “Capacity Strengthening of Nigerian Researchers and Ethics Committee Members on Ethics”

## Support for the Establishment and Strengthening of African National Ethics Committees or Institutional Boards

- **Makarere University, Uganda**: “Supporting research through enhancement of the IRB processes at Makerere Medical School”
- **University of Malawi**: “Proposal to strengthen the National Sciences Research Committee (NHSRC) and College of Medicine Ethics Committee (COMREC)”
- **University of Ibadan, Nigeria**: “Strengthening the Capacity of Research Ethics Committees in Africa”

## PhD Scholarships

- **Mthiyane Thuli, South Africa**: “Reconstitution of TB antigen specific IFN-y responses in TB-HIV co-infected participants”
- **Bornwell Sikateyo, Zambia**: “An assessment of the understanding of the informed consent process by participants in microbicide intervention trials in Zambia”

## Career Development Fellowships

- **Dr Else Carole Eboumbou Moukoko, Cameroon**: “Identification of *Plasmodium falciparum* parasite virulence markers for the evaluation of the impact of malaria control intervention according to the local parasite populations”
- **Dr Antony Kebba, Uganda**: “Patterns of HIV-1 specific CD8+ T cell epitope recognition determining plasma viral load trajectory and set point following HIV-1 infection”
- **Dr Molebogeng Xheedha Rangaka, South Africa**: “Immunological investigation of the HIV-tuberculosis associated immune reconstitution inflammatory syndrome”

## Senior Fellowships

- **Dr. Issa Nebie, Burkina Faso**: “Understanding the mechanisms underlying the difference in susceptibility to malaria in an area of hyperendemic malaria in Burkina Faso: The potential role of regulatory T cells”
- **Dr David Nwakanma, The Gambia**: “Evaluation and implementation of high throughput PCR-based method for diagnosis and measurement of *Plasmodium falciparum* parasitaemia in clinical trials”

## Providing Incentives for Joint Capacity Building programmes in Africa with 2 or more EU Institutions

- **Margarita Navia from Fundació Clínica per a la Recerca Biomèdica, Spain**: “Ifakara_Lambarene_Manhiça Partnership”

## Development of an MSc Course in Clinical Trial Methodology

- **Andrew Hall from London School of Hygiene and Tropical Medicine, UK**: “Distance learning Master course in Clinical Trials”

## Support to national networking of African scientists working on HIV/AIDS, Malaria and TB in Africa

- **Abraham Aseffa from Armauer Hansen Research Institute (AHRI), Ethiopia**: “Strengthening the National Tuberculosis Research Network in Ethiopia”
- **Amina Jindani from International Consortium for trials of chemotherapeutic agents in tuberculosis (INTERTB), UK**: “A proposal to establish a network of sites, in sub-Saharan Africa, to conduct clinical trials in tuberculosis and to build their capacity to participate in multi-centre trials”
- **Sheena McCormack from Medical Research Council, UK**: “Identifying the common learning needs of investigators working in poverty-related diseases in African settings, and the materials to address these, notably in the areas of project and data management.”
- **Daniel Kyabayinza from Regional Center For Quality of Health Care (RCQHC), Uganda**: “KIDS-ART-LINC: network of clinical centers treating HIV-infected children with antiretroviral therapy in Africa to inform public health care and treatment programs”
EDCTP/BMGF 20 M Euro grant to develop HIV vaccines trial capacity in Africa

To address the urgent need for developing and preparing sites to conduct HIV vaccine trials in countries seriously affected by the epidemic, the European and Developing Countries Clinical Trials Partnership (EDCTP) and the Bill & Melinda Gates Foundation announce a 20 million euros joint call for proposals to fund capacity building for HIV vaccine trials in sub-Saharan Africa. Each applicant may request up to €4 million over a three-year period.

The call is part of the collaborative effort proposed by the Global HIV Vaccine Enterprise. The initial focus of the funding is for the preparation of sites to be able to conduct phase II clinical trials of HIV candidate vaccines, but where appropriate, it may also be used to conduct trials.

The funded projects are expected to provide a clear research plan, identifying the specific research activities in preparation for future trials as well as a training plan to ensure success in conducting clinical trials and sustainable capacity, within sub-Saharan Africa. The funding will support consortia of competent investigators committed to the project, which should include participants from at least two EDCTP member states; one sub-Saharan African site with a good track record on HIV vaccine or related research as a core site; and one or more additional site(s) in Africa, which would serve as expansion site(s) for future large scale trials. Proposals should therefore involve at least two sub-Saharan African institutions as well as two institutions from different EDCTP-EEIG member states.

Participation of the private sector is strongly encouraged, however, all project coordinators must be individuals working in public institutions who are residents of either EDCTP-EEIG member states or sub-Saharan African countries.

For further details and to view the call text, including the information on how to submit applications, please visit the EDCTP website at: www.edctp.org.

The deadline for submission of applications is 31 March 2007.

The EDCTP is supported by the European Union.

List of the EDCTP-EEIG member states
Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

List of the sub-Saharan African states

Focus on EDCTP grantees

An EDCTP Senior Fellow receives a prestigious award for malaria research

Dr Alexis Nzila, an EDCTP Senior Fellow, from the Kenya Medical Research Institute (KEMRI) was awarded a prestigious Royal Society prize for advancing discoveries into antifolate drugs for the treatment of malaria.

Dr Nzila obtained an EDCTP fellowship in 2004 to work on the understanding of the mechanism of the antimalarial piperazine resistance. The current award, The Royal Society prize, is in recognition of his work on the mechanism of antifolate resistance and the discovery of antifolates drugs for malaria treatment. Dr Nzila has developed an innovative approach by drawing parallels between malaria and cancer cells. Cancer cells and the malaria parasites multiply readily and rely on the availability of folates to grow. By comparing the role of folates in cancer cells to their function in malaria, Dr Nzila was able to better understand their role in malaria.

Fansidar (Suphadoxine-Pyrimethamine), an antifolate drug, is used to inhibit the production of folate molecules to prevent malaria from multiplying. The malaria parasite, however, can develop resistance quickly. Dr Nzila’s team found that resistance to Fansidar was a result of the parasite’s ability to change amino acids in the enzymes that this drug targets. By monitoring changes in the enzyme genes, the researchers found they could predict whether a parasite would be sensitive or resistant to Fansidar. Using information from cancer, Dr Nzila’s
The third EDCTP annual forum, 9-11 October 2006

The Third EDCTP Annual Forum was held from 9 to 11 October 2006 at the headquarters of the Swedish Society of Medicine in Stockholm, Sweden. Around 140 participants gathered at this beautiful venue to discuss various topics around the theme of ‘Partnership and African Leadership: Challenges and Opportunities’. The forum covered items such as building capacity in scientific leadership in Africa, networking, making clinical trials cost effective and partnership and African leadership in conducting clinical trials. Experiences from the field and reports from EDCTP grantees were also presented. Lessons from the forum include the knowledge that there is a great commitment for the EDCTP programme in Africa; however, more projects need to be implemented. It was also observed that the African involvement could be used to foster integration of research programmes in the north and that the need for sustainable capacity building is still great. The national programmes of the European countries that participate in EDCTP are being mobilised to achieve the objectives of Article 169. It was also noted that it is apparent that more needs to be done and that many development partners are aware and supportive of EDCTP as a tool for delivering new products to Africa, but this requires a genuine partnership with Africa.

Presentations at the forum clearly reflected the progress EDCTP is making in achieving its objectives. Commitment from partners from both continents was demonstrated. The overall challenge is for EDCTP to scale their activities and proceed on their chosen path. A full report on the forum will soon be available at the EDCTP website. Preparations are currently underway to organise the Fourth EDCTP Forum. This will take place in Burkina Faso from 22-24 October 2007. More information on this event will be presented in the next EDCTP Newsletter.
In the third quarter of 2006 EDCTP continued its collaborative activities with the African AIDS Vaccine Programme (AAVP). It co-sponsored an Africa Union (AU)/AAVP regional consultation on HIV vaccine research and development for Africa that took place in Addis Ababa (Ethiopia) from 25 to 26 September 2006. This followed a similar EDCTP co-sponsored sub-regional consultation on HIV vaccine research and development in Africa for the member countries of Common Market for Eastern and Southern African (COMESA) in June 2006 that was hosted by the government of Kenya. Apart from support from EDCTP, the AU Commission convened the Addis Ababa consultation in collaboration with the World Health Organisation (WHO), United Nations Joint Programme on HIV/AIDS (UNAIDS), International AIDS Vaccine Initiative (IAVI) and the United States Military HIV Research Programme (USMHRP).

The objectives of this consultation were:

- To present the efforts of the AAVP in advancing the goals and strategic directions of the AU/New Partnership for African Development (NEPAD) Health Strategy
- To discuss both the Yaoundé Statement made at the Third AAVP Forum in Cameroon and its recommendations as well as to explore the potential contribution of the AU and the other regional economic communities
- To promote the development of regional networks for facilitating common regional approaches to HIV vaccine development, enhanced cross-country and cross-institutional collaboration, accelerated development of national HIV vaccine plans and their integration into overall national HIV/AIDS plans and strategies, among others.

The consultation recommended that AU and other African economic communities should:

- Endorse and support the Yaoundé Statement that urged continental and regional bodies, such as the AU, and their member nations to continue to consider the fight against HIV/AIDS as a priority, and to integrate vaccine research and development into their policies and programmes
- Appoint a focal point for HIV vaccine research
- Promote development of African national HIV vaccine research plans
- Promote harmonisation of national regulatory, ethical and legal frameworks
- Support the establishment of bulk procurement mechanisms for drugs and vaccines.

The EDCTP will continue to support AAVP and its partners in 2007.

**EDCTP staff visit to clinical trial sites in Tanzania and Malawi**

**Tanzania visit**

Professor Charles Mgone, Head of Africa Office (HAO); Mr. Simon Belcher, Financial Manager (FM); and Dr Michael Makanga, Capacity Building Manager (CBM), made a site visit to Tanzania from the 16-20 October 2006. The team visited Kilimanjaro Christian Medical Centre (KCMC) in Moshi and the National Institute for Medical Research (NIMR) in Dar es Salaam. KCMC research site is preparing to undertake an EDCTP supported multicentre study on the rapid evaluation of moxifloxacin in the treatment of sputum smear positive tuberculosis, REMoxTB study. This study will be conducted in collaboration with Professor Stephen H. Gillespie of the Royal Free and University College Medical School Centre for Medical Microbiology in London as principle investigator (PI) and Professor Noel Sam as Tanzanian investigator. KCMC also a beneficiary of a capacity building grant for conducting TB vaccine trials in high-risk populations in East Africa under the leadership of Dr Howard Engers of the Armaker Hansen Research Institute (AHRI), Addis Ababa, Ethiopia as PI and Professor John Shao as the Tanzanian investigator. NIMR is the hosting institution for Dr Andrew Kitua member of the Developing Countries Coordinating Committee (DCCC) who also accompanied the EDCTP Secretariat team during the Dar es Salaam part of the visit.

Tanzanian sites are also involved with other studies including optimisation of tuberculosis and HIV co-treatment in Africa: Pharmacokinetic and pharmacogenetic aspects on drug-drug interactions between rifampicin and efavirenz; and site preparation and capacity strengthening for trials of vaginal microbicides in Tanzania and Uganda. The former has Professor Leif Bertilsson of the Karolinska Institutet as PI, and Professors Jane Sayi and Ferdinand Mugusi of Muhimbili University College of Health Sciences, Dar es Salaam as the Tanzanian investigators. The later has Professor Richard John Hayes of the London School of Hygiene as the PI and Mr John Changalucha of the National Institute for Medical Research (NIMR), Mwanza as the Tanzanian investigator. The African Malaria Network Trust (AMANET) secretariat hosted in Dar es Salaam is also running a free web-based health research ethics training project with funding from EDCTP.

The EDCTP team together with the DCCC member from Tanzania, Dr. Andrew Kitua had separate meetings with several officials including Ms Henrietta Kolb, the Attaché Governance of the delegation of the European Union in Dar es Salaam; officials of the Tanzanian ministry of health including Dr Gilbert Mliga, the Director of Human Resources for Health; Dr. Zachery Berege, the Director of Health Services; Dr Bumi Mwamasage, the Assistant Director of Allied Health Training; Dr Raphael Kalinga, the Acting Director Preventive Services and Assistant Director Epidemiology and Disease Control; Dr Amos Mwakilasas, the Assistant Director for Continuing Education;
Mr Chris Berry of the Department for International Development (DFID) Office; Professor Yohana Mashalla, Chairperson of the NIMR Ethics Committee; and the World Health Organisation (WHO) representative resident in Tanzania Dr Maganu.

Malawi visit

The FM and CBM made a site visit to Malawi on the 3 to the 6 December, 2006. The team visited the Blantyre malaria project and the college of medicine in Blantyre. The former is one of the five African sites preparing to undertake EDCTP funded multicentre studies involving phase II and III clinical trials investigating the use of intravenous artesunate formulation that complies with international good manufacturing practice (GMP) guidelines, for treatment of severe malaria in African children. The later site has two EDCTP funded projects namely: Building and strengthening national capacities in ethical review and clinical trial monitoring in Malawi; and strengthening of the National Health Sciences Committee (NHSRC) and College of Medicine Ethics Committee (COMREC) with Dr Paul Ndebere and Professor Joseph Mfutso Bengo as principle grantees respectively.

The EDCTP team had separate meetings with Dr Matshidiso Moeti, the WHO representative to Malawi, Professor Malcom Molyneux, Director Wellcome Trust Centre in Blantyre and senior collaborator/advisor of the anthropological and bio-ethics study of clinical research in Blantyre; Ms Joann Schmidt, interim director of research support centre university of Malawi, College of Medicine; Dr Wynn Chalira and Dr Aaron Glyn Sosola, registrar and deputy registrar & head of technical services respectively of the Pharmacy and Poisons Board in Malawi; Dr Charles Mwansambo, chairperson of NHSRC; and Dr Damson Kathyola, deputy director of research Ministry of Health, among others.

WHO-EDCTP collaboration on national regulatory framework for Africa

Global Training Network on regulatory authorisation and evaluation of clinical trials

In July 2006, EDCTP and WHO signed an agreement to develop the first phase of a regulatory framework to ensure appropriate oversight of clinical trials in Africa. These activities are already underway and are aimed at addressing the lack of expertise in authorising and evaluating clinical trials; conduct of the ethical review process; and ensuring that the legal basis on health research is developed and is consistent with international standards of good clinical practice (GCP), good clinical laboratory practise (GCLP) and good manufacturing...
New networking tool: Project Partners

EDCTP has just launched a new networking tool called Project Partners on the EDCTP website. Project Partners works through a profile search program where participants are required to create a profile for themselves. Profile details include areas of personal expertise, work history and the kind of collaboration needed. This profile is searchable by any logged in Project Partners user. When people are interested in working with each other they can send each other emails through the site to enquire about possible collaboration. This process eliminates spam and unwanted mail, as contact details are never shown without permission. The purpose of this tool is to provide both European scientists and African counterparts with an easy link to connect them with each other. The Project Partners site can be used to find the partners that EDCTP requests for different grant applications. Networking tools such as Project Partners are needed especially to help younger scientists form new scientific partnerships, and to bring European and African scientists closer together, so that long lasting collaborations can be made. Experienced scientists can help the next generation by logging into the site and offering partnerships to their younger counterparts. Project Partners can be found at www.edctp.org, please register now.

The EDCTP Blog

EDCTP is pleased to announce the launch of the EDCTP Blog, an important tool in sharing knowledge and information for improving the understanding of poverty reduction in developing countries through health improvement of the populations. The Blog is open to anyone interested in the work of EDCTP and would like to contribute and participate in discussions related to the 3 PRD’s (Poverty Related Diseases). The blog will bring together information, news, ideas and discussions of all types of themes connected to our work and most importantly, visitors will be able to raise questions, gain knowledge and give opinions on the subjects discussed.

The authors – the regular bloggers – are members of the EDCTP staff and constituencies, such as ENNP and DCCC members. From time to time we will have guest authors related (or not) to EDCTP to bring an outside view and discuss specific topics of their area. Blog visitors can contribute to increase the discussions by posting comments after registration.

Please visit our blog at www.edctp.org/blog to find out more and register online to participate in the discussions.

Announcements