



European and Developing Countries Clinical Trials Partnership

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Note from the EDCTP General Assembly chairperson



As 2011 draws to a close, I am delighted to take this opportunity to update you as we reflect on the steady stream of promising results emerging from EDCTP-funded projects and begin to look forward to the next EDCTP programme.

In parallel with the core business of the General Assembly, it has been a pleasure to participate in the process of working towards a second phase of EDCTP and to watch early enthusiasm germinate into real commitments. Last autumn the EDCTP partner countries took the first step of meeting in Brussels under the Belgian presidency of the European Union to build a consensus that they would seek a second phase of EDCTP. In the year since that meeting a strategic business plan has been drafted and individual

commitments are now formalised. This will provide a strong foundation to the political process which will take place in Brussels next year. Although these processes are never easy, particularly in times of economic and financial stress, we are quietly confident that the second phase of the EDCTP programme will enable us all to consolidate and expand upon the achievements so far gained from the current one.

Finally, one of the highlights of my experience as General Assembly Chairperson was attending the Sixth EDCTP Forum which took place in Addis Ababa, Ethiopia in October this year and which was attended by scientists and other stakeholders from across the globe. The strong support from the European Commission's Directorate for Research and Innovation, expressed both by the Director-General, Robert Jan-Smits and the Director for Health Research, Ruxandra Draghia-Akli, was particularly galvanising. The packed programme showcased both the range of scientific research conducted in both Europe and Africa to address the three diseases and the quality of capacity building which had been carried out across sub-Saharan Africa. The event testified to the work of researchers and their colleagues and their extraordinary contribution to EDCTP's success.

Prof. Hannah Akuffo
EDCTP General Assembly chairperson

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Outstanding African Scientist Awards

On 12 October 2011 in the closing session of the Sixth EDCTP Forum, the awards for Outstanding African Scientist were announced. Prof. Salim Abdool Karim and Mr Hannock Tweya received the Senior Outstanding Scientist and Junior Outstanding Scientist awards respectively.

Professor Salim Abdool Karim is the Pro-Vice-Chancellor for Research at the University of KwaZulu-Natal in Durban, South Africa. He has made a significant contribution to the fight against HIV/AIDS since the beginning of the epidemic. He has demonstrated both excellence and persistence in research. Despite initial disappointing study outcomes, he pressed on for seventeen years and eight trials before success was achieved. His research showed women can protect themselves from becoming HIV-infected by using an antiretroviral vaginal microbicide. This proof of principle study was the first that showed efficacy, and laid the foundation for an entirely new approach to HIV prevention, one that would enable women to control the decision to protect themselves independently of the male partner. The research was an exemplary study in that it shows promise in addressing a problem in Africa while being spearheaded by Africans.

"Work with people who value excellence" was Prof. Karim's advice to younger scientists in his acceptance speech. He said that EDCTP in giving him the award also honoured the entire team of more than 380 people at CAPRISA, the Centre for the AIDS Programme of Research in South Africa of which he is the director.



Prof. Salim Abdool Karim

Outstanding African Scientist Awards (continued from page 1)

Mr Hannock Tweya of the Lighthouse Trust in Malawi was awarded the Junior Outstanding African Scientist Award. The Lighthouse Trust is a centre of excellence which currently provides care to over 22,000 people living with HIV. Mr Tweya has been involved in home-based care, ART provision and other services of the Trust. He has published papers on various topics including loss to follow-up and HIV in pregnancy.

In his speech Mr Tweya promised the award would be used to advance research aimed at concretely improving people's lives. He expressed as his strong belief that research should be linked to practical health care delivery. He thanked all those who have

supported him so far and expressed his commitment to contribute to the improvement of his country's health system.



About the awards

The EDCTP Awards for Outstanding African Scientists are granted every two years. Criteria include innovative research and creation of intellectual property, impact of research, publications and advocacy for health. The award consists of a cash prize of \in 10,000 for a junior scientist (under 30 years old) and \in 20,000 for a senior scientist and comes with a trophy of recognition. The awards aim to foster the research activities of the winners.

Mr Hannock Tweya

Sixth EDCTP Forum

The Sixth EDCTP Forum in Addis Ababa, Ethiopia, brought together 535 delegates from 58 countries worldwide. They included researchers (the majority from EDCTP-funded projects), policy makers, and representatives of funding organisations, Product Development Partnerships (PDPs), pharmaceutical industry and other partners. A wide range of research topics were covered in oral presentations, poster sessions and satellite meetings. Participants shared experiences and ideas that will contribute to future research in the fight against HIV/AIDS, tuberculosis and malaria. The Forum came at a very exciting and opportune time, the bridging period between the end of the first EDCTP programme and the preparatory stage of the imminent second phase of the partnership. EDCTP wishes to thank all who attended and contributed to the success of this Forum.

Forum sponsors

EDCTP gratefully acknowledges the Forum sponsors for their generous support. These include the following EDCTP Member States: Belgium, Germany, Luxembourg, Netherlands, South Africa, Spain, Sweden, Switzerland and United Kingdom. In addition, EDCTP is grateful for the sponsorship from Aeras, Research Africa, Emergent BioSolutions, Novartis, and ShinPoong Pharma.

Research presented

The umbrella theme of the Sixth EDCTP Forum was Strengthening Research Partnerships for Better Health and Sustainable Development. The policy-oriented speeches at the start of the Forum celebrated the success of EDCTP, its role as a model for research partnership and stressed the need for all parties involved to renew their commitment to the fight against the poverty related diseases, to successfully realise the second phase of the EDCTP programme.

The Forum programme was structured around parallel sessions dealing with HIV/AIDS, tuberculosis and malaria. Keynote addresses for each disease summarised recent advances in research, supported by presentations from ongoing or recently concluded EDCTP-funded studies. Most presentations reflected three overarching themes regarding research in sub-Saharan Africa: clinical research and its results, development of research capacity, and research partnerships between Europe and Africa and within Africa.

Presentations on the cross-cutting topics addressed the functioning of ethics committees and the importance of research ethics for scientists themselves; clinical data management; and initiatives to strengthen partnerships and build capacity. In the context of the cross-cutting sessions the four EDCTP supported Networks of Excellence presented progress made so far, and lessons learnt. Challenges and opportunities were discussed.

EDCTP partners

Eleven global health organisations delivered presentations about their work and the areas where they collaborate or wish to collaborate with EDCTP. The presentations were by Aeras, the African AIDS Vaccine Programme, the African Network for Drugs and Diagnostics Innovation, the Bill & Melinda Gates Foundation, Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts, Global Health Trials, International AIDS Vaccine Initiative, Medicines for Malaria Venture, African Society for Laboratory Medicine, Microbicides Development Programme and UNITAID.

A summary of the Sixth EDCTP Forum proceedings will be published in January 2012. Please visit the Sixth Forum blog at www.edctpforum.org/sixthforumblog for more information and summaries of sessions. Presentations are available for download at www.edctpforum.org.



Official opening ceremony of the Sixth EDCTP Forum, 9 October 2011 in Addis Ababa, Ethiopia.

EDCTP Governance

DCCC

The Developing Countries Coordinating
Committee (DCCC) held its 27th meeting just
before the Forum in Addis Ababa from 8-9
October 2011. The members deliberated on
the involvement of the DCCC in the
preparations for the proposed second phase of
EDCTP and the composition of its future
Scientific Advisory Committee. The DCCC also
discussed updates on its various working
groups as well as the development of
performance indicators for the Networks of
Excellence, and the best ways of engaging
policy makers.

Dr Jean Bosco Ouedraogo (Burkina Faso), a representative of the West African Health Organisation (WAHO) replaced Professor David Ofori-Adjei who took up other assignments in Ghana. Dr Hulda Swai (South Africa) and Professor Matee (Tanzania) will have completed their term of service in the DCCC at

the end of 2011. Professor Nkandu Luo, DCCC member from Zambia was also elected Minister of Local Government, Housing, Early Education and Environmental Protection of the Republic of Zambia. EDCTP congratulates Professor Luo and Professor Ofori-Adjei upon their new appointments, and thanks all outgoing members for their contribution to the Partnership.

Partnership Board

EDCTP's independent panel of experts, the Partnership Board (PB), met in Addis Ababa after the Forum on 13 October 2011. The PB designs the strategic framework of EDCTP and advises the General Assembly on technical and scientific matters relating to the EDCTP programme. Among other things, the PB discussed the ongoing and new activities for EDCTP in the interim period, strategies to strengthen monitoring and evaluation of these activities, and preparations for the second

phase of the EDCTP programme. Additionally, all agreed that the Sixth EDCTP Forum had been a great success and recommended that the planning for the next Forum should begin.

General Assembly

The General Assembly met in The Hague on 18 November 2011. Professor Hanna Akuffo was re-elected as chairperson. The representatives of the Member States, the European Commission (EC) and the various constituencies discussed the activities of EDCTP in the last six months. The General Assembly approved the recommended Senior Fellowships and Ethics grants as well as the proposal for launching 'EDCTP Strategic Primer Grants' call. The meeting concluded with an update by the EC representative on the political process regarding EDCTP-II and a deliberation on how the Member States could best contribute to this process by further detailing the strategic business plan.

Abdoulie Barry's first months as new DFA

Mr Abdoulie Barry joined EDCTP as the new Director of Finance and Administration (DFA) at the beginning of September 2011. He brings extensive experience in financial management, auditing, installation of financial management systems and management of donor funded projects.

Abdoulie Barry: "This is an exciting time to join EDCTP and no better time as the organisation is busy putting in place strategies to successfully complete the first phase of the programme before the end of 2014; while at the same time laying the foundations for an even more ambitious EDCTP-II programme. Great people and great partners from different cultures committed to excellence make EDCTP an exciting place to work."

Prior to joining EDCTP he worked for the Medical Research Council (UK) in The Gambia for eleven years. He is a member of both the Chartered Association of Certified Accountants (ACCA) and Chartered Association of Management Accountants (ACMA). The thesis for his MBA degree (University of Manchester) was on Activity-Based Management (ABM)

in a sub-Saharan research site, discussing how financial systems can be used to support the implementation of an ABM system. Earlier he worked for major accountancy and consultancy firms taking on assignments for international organisations such as World Bank, African Development Bank and UNDP.



Mr Abdoulie Barry

Calls and grants

New call for proposals: EDCTP Strategic Primer grants

This grant will provide funding for research groups in sub-Saharan Africa and Europe to conduct innovative, ambitious studies that will:

- Generate results to inform future clinical trials
- $\bullet\,$ Sustain and strengthen the capacity built up under EDCTP I
- Increase networking of African and European Member States' research programmes.

Funding is available to support clinical research studies of up to two years duration to address high priority research issues and barriers to progress. The purpose of the award is to provide pump-priming

to allow researchers to explore novel and innovative lines of research that may lead to the development and testing of new or improved clinical interventions against HIV/AIDS, tuberculosis or malaria. Applications must involve researchers based at public institutions in two or more EDCTP-EEIG Member States and researchers at institutions in one or more sub-Saharan African countries.

Deadlines and applications

The deadline for preliminary applications is **14 February 2012**. More information about this call and the application form is available at www.edctp.org.

Focus on Networks of Excellence

Extension of contracts

As capacity development and partnerships in research networks are long-term endeavours, the current contracts of the EDCTP funded Networks of Excellence will be extended. A joint meeting was arranged during the Forum on 11 October 2011 to facilitate sharing of experiences among the Networks and to discuss future priorities and conditions. All the networks presented outlines of their future plans some of which were specific to particular network and others cross-cutting. Among the several activities deliberated upon a few are listed here: improvement of communication among the network partners through creation of communication platforms, aiming for laboratory accreditations within some of the networks, development of e-based learning and training facilities for clinical trials, improvement of trial monitoring capacity, expansion of the networks to other countries within the region, and continued investment in research infrastructure for both short- and long-term professional training in all networks.

Sustainability

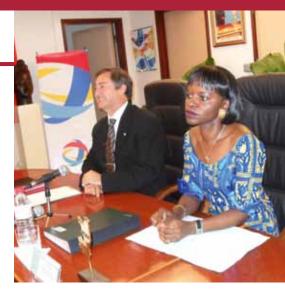
Common to all the networks is an essential challenge. How do the networks make lasting what has been built so far? Sustainability of the regional research capacity will have to be secured by new grants and support from different sources including hosting countries.

All four networks have invested in developing grant writing capacity and are in the process of developing sustainability strategies and exploring different fund raising approaches.

Reaching out to the private sector

The Central African Network on Tuberculosis, HIV/AIDS and Malaria (CANTAM) has been successful in attracting new funding from outside EDCTP, this time from the private sector. Total Oil Company has committed an investment of € 150,000 per year for five years to support research activities within the network. The lead institution of CANTAM is the Fondation Congolaise pour la Recherche Médicale (FCRM), a legally independent, non-govermental institution hosted by the Faculty of Health Sciences in Brazzaville.

Professor Francine Ntoumi, the Project
Coordinator for CANTAM, reports:
"Sustainability of the network's activities is
critical and this requires active involvement
of both local and international partners. In
this light, CANTAM approached a local
company, TOTAL E&P Congo, presenting the
case that it would be in the interest of the
company to support research on tropical
diseases and diseases affecting the
Congolese population at large. Against the
backdrop of firsthand experience of the main
causes of hospitalisation of the company's



Jacques Azibert (CEO of Total E&P Congo) and Francine Ntoumi (CANTAM)

personnel and their families, TOTAL E&P Congo responded favourably to this request. The company therefore suggested addressing the burden of malaria and diarrheal diseases in order to tackle the local priorities. The contract was signed in April 2011; it was the first health research project run by a local organisation supported by TOTAL E&P Congo. It is a strong sign of what is possible as well as a challenge for both partners. Therefore, a steering committee composed of three representatives of TOTAL and three from FCRM has been established. Its role is to evaluate the progress of all activities conducted under this grant."

Calls and grants (continued from page 3)

Funded projects

EDCTP is pleased to announce the funding of five new projects:

Call: Evaluating the impact of clinical trials in Africa

An evaluation of the impact of malaria clinical trials on the delivery of health care, particularly for women and children, in sub-Saharan Africa

Project Coordinator: Kwaku Poku Asante (Kintampo Health Research

Centre, Ghana) Budget: € 248,820

Duration of the project: October 2011-July 2013

Call: Support of Member States Initiated (MSI) Projects within the scope of EDCTP activity areas

Fozivudine in Africa trials initiative (FATI) – a stepwise drug development programme for an improved AZT treatment:

Project Coordinator: Michael Hoelscher (Klinikum der Universität München, Institute for Medical Bioinformatics, Germany)

Budget: € 2,227,288 (€ 480,888 EDCTP)

Duration of the project: October 2011-June 2013

Collaboration and integration of Tuberculosis Vaccine Trials in Europe and Africa (TBTEA)

Project Coordinator: Stefan Kaufman (Max Planck Society, Germany)

Budget: € 10,643,327 (€ 764,558 EDCTP)

Duration of the project: September 2011-June 2013

Towards strengthening of the West African Network of Excellence for TB, AIDS and malaria: WANETAM plus

Project Coordinator: Assan Jaye (Medical Research Council

Laboratories, The Gambia)

Budget: € 4,260,967 (€737,642 EDCTP)

Duration of the project: October 2011-June 2013

The impact of retreatment with an artemisinin-based combination on malaria incidence and its potential selection of resistant strains

Project Coordinator: Jean-Pierre Van Geertruyden (University of

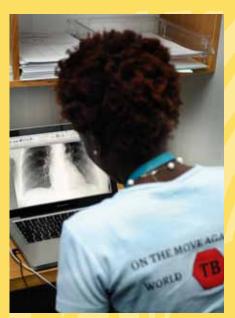
Antwerp, Belgium)

Budget: € 777,910 (€ 192,904 EDCTP)

Duration of the project: September 2011-June 2013

Focus on projects

TB vaccine MVA85A trial: first volunteers enrolled in Senegal



Staff member reviewing a lung x-ray from the MVA85A trial

Aeras and the Oxford-Emergent Tuberculosis Consortium (OECT) announced the start of the Phase IIb proof-of-concept efficacy trial of the new tuberculosis vaccine MVA85A. Since 4 August 2011, volunteers are being enrolled in the Senegal site of the candidate TB vaccine MVA85A clinical trial. The trial is primarily funded by EDCTP.

The study is designed to evaluate whether a new tuberculosis vaccine will boost immunity to the TB causing bacteria and reduce sickness from tuberculosis. The vaccine candidate will be tested in approximately 1400 volunteers aged 18-50 who are infected with HIV. People infected with HIV are at far greater risk of developing TB disease than HIV-negative people. Tragically, this has already resulted in a devastating TB and HIV co-epidemic.

The trial is a collaboration of the Medical Research Council (MRC) in The Gambia, MRC UK, Aeras and the University of Oxford. It is conducted at two research centres, the University of Cape Town (UCT) Institute of Infectious Disease and Molecular Medicine in Khayelitsha, South Africa and the Laboratoire de Bacteriologie-Virologie du Centre Hospitalier Universitaire Aristide Le Dantec in Dakar, Senegal. The Scientific Institute of Public Health (WIV-ISP) in Belgium, which first identified the Ag85A as a possible vaccine candidate, is providing laboratory services for the study.

WANECAM's antimalarials study enrols patients for Pyramax® sub-study

As no effective malaria vaccine has reached the market yet and because of the unavoidable increase in resistance of malaria parasites to most conventional antimalarial drugs, it is essential to support the development of new antimalarials. At present, artemisinin-based combination therapies (ACTs) are recommended as first-line treatment by WHO for uncomplicated Plasmodium falciparum malaria in all endemic countries. Already many countries have deployed ACTs and repeated use of ACTs within short periods of time is common in these areas, however, there is limited data on safety and efficacy as regards the repeated use of these combination products.

In response to this, Dr Abdoulaye Djimdé and his study group in the Malaria Research and Training Center (MRTC), Université de Bamako, Bamako (Mali) are conducting a Phase IIIb/IV comparative, randomised, multi-centre, open label, parallel, 3-arm clinical study. Its aim is to assess the safety and efficacy of repeated administration of ACTs in children and adult patients with acute uncomplicated *Plasmodium sp.* malaria over a period of two years.

Each centre is comparing 3 drugs:
dihydroartemisinin-piperaquine (Eurartesim™,
DHA-PQP) and pyronaridine-artesunate
(Pyramax®, PA) to the comparator drug,
which will be either artesunate- amodiaquine
(ASAQ). Eurartesim™ and Pyramax® are two
new GMP-grade ACTs developed by Sigma-Tau
Pharmaceuticals, Italy and Shin Poong
Pharmaceuticals, respectively in collaboration
with the Medicines for Malaria Venture (MMV).
Patients will be randomly assigned to one of
the above-mentioned treatment arms and
each arm will enroll 1344 subjects.

The study is done in collaboration with four African institutions – Centre National de Recherche et de Formation sur le Paludisme (Burkina Faso), Institut de Recherche en Science de la Santé (Burkina Faso), Centre National de formation et de Recherche en Santé Rurale (Guinea), MRC Gambia (Gambia) – and four European partners – Université Claude Bernard (France), Karolinska University Hospital (Sweden), London School of Hygiene & Tropical Medicine (United Kingdom) and the University of Heidelberg (Germany. The partners formed the West African Network for Clinical Trials of Antimalarial Drugs (WANECAM, www.wanecam. org) with the aim of establishing a cross-border research team.

The project is funded by EDCTP and MMV.

Patient enrolment for the pyronaridineartesunate (PA) arm started last month in Sotuba, near Bamako (Mali), and it will be shortly followed by the other 5 study sites, namely: Bougoula-Hameau and Kolle in Mali; Niankoloko-Banfora and Sakaby in Burkina Faso; and Maferinyah in Guinea. In preparation for this, the WANECAM network has also significantly improved the research capacity and infrastructure in these sites.

Overall, it is expected that these studies will generate important safety and efficacy data on the repetitive usage of the two new ACTs under investigation (i.e. pyronaridine-artesunate and dihydroartemisinin-piperaquine) that will allow for a better estimate of their added value compared to the ACTs currently on the market. DHAPQ treatment was recently included in the WHO list of recommended ACTs, and it is expected that pyronaridine-artesunate may also be added to the recommended ACTs in the near future.



Meetings and visits

African-EU research and technology conference in Johannesburg

The INCO Conference 2011 on "International Research and Innovation Partnerships to meet Global Challenges" took place in Johannesburg, South Africa on 27-28 September 2011. The programme focused on African-EU co-operation. EDCTP Executive Director Prof. Charles Mgone spoke on health research in the session dedicated to Africa-EU science and technology partnerships. The INCO program is designed to support the participation of third countries in Framework programme 7.

AU-EU Senior Officials meet on research partnerships

Senior Officials from the African Union and the European Union met for discussions on research partnership in Addis Ababa on 10 October 2011. EDCTP, considered a model for research collaboration, was invited to attend the meeting. Its High Representative Dr Pascoal Mocumbi presented the Partnership.

ANDI stakeholder meeting in Addis Ababa

The fourth stakeholder meeting of the African Network for Drugs and Diagnostics Innovation (ANDI) took place on 24-27 October. During this conference ANDI recognised 32 African Centres of Excellence. The centres in the five sub-regions of Africa conduct research and innovation activities regarding drugs, diagnostics, vaccines, medical devices and traditional medicines. ANDI envisages the centres forming a network that will link and increase R&D and manufacturing by African institutions. Prof. Charles Mgone chaired the session on the centres of excellence.

EC Director General for Research and Innovation visits EDCTP Cape Town office

Robert-Jan Smits, EC Director General for Research and Innovation, visited an EDCTP clinical trial site and EDCTP's Africa Office in Cape Town on 10 November 2011. The EU-EC delegation visited the Emavundleni Prevention Centre in Crossroads one of the sites for an



EDCTP-funded HIV study, the CATSA-project. At the Africa Office, the delegation met with Prof. Ali Dhansay, acting president of the Medical Research Council of South Africa, Dr Michael Makanga, Head of EDCTP Africa Office and EDCTP staff at the Africa Office. The MRC activities and an EDCTP research project were presented. Prof. Keertan Dheda presented the ongoing TB NEAT project which seeks to facilitate the development of point-of-care tests for tuberculosis (TB), and to validate new technologies in clinical primary-care practice in Africa.

Focus on Ethics

Training program on research ethics and regulation

TRREE is a consortium of ethics experts from the South and the North working together to promote the highest standards in research ethics. Since 2006, the consortium provides a web-based training programme on the ethics and regulation of health research involving humans. The TRREE training programme focuses on internationally recognised ethical principles and regulations while integrating local issues and perspectives relevant to North-South research partnerships. It is recognised as a continuing education program by the Swiss Medical Association and the Swiss Pharmacists Association.

The TRREE programme aims at increasing knowledge as well as the practical skills of

members of Research Ethics Committees. It also provides basic training for investigators and other healthcare professionals, students, national drug and research authorities, media professionals or anyone concerned with the protection of research participants.

TRREE currently provides free and open access to e-learning modules in English, French, German and Portuguese. Among the modules are an introduction, one on ethics review and one on informed consent. National supplements provide an overview of local regulations relevant to research in Africa (Senegal, Mali, Nigeria, Cameroon, Tanzania and Mozambique) and Europe (Switzerland and Germany). In addition, the TRREE

provides e-Resources: a participatory website with international, regional and national regulatory and policy resources. These resources are available in English and Portuguese.

For more information about TRREE training programme, please visit www.trree.org.

The EDCTP Newsletter is available in three languages namely English, French and Portuguese in electronic format on our website (www.edctp.org). Persons who wish to receive the electronic format should subscribe online (www.edctp.org, click on Newsroom).

EDCTP photo contest extended

In August 2011 EDCTP launched its first photo contest. The aim was for participants to capture different perspectives on EDCTP-funded projects. Photographs would be assessed in three categories: science, health care and capacity building. Less photographs than expected were received by the initial deadline on 26 September 2011. Considering the short period for submission of photographs, the selection committee of the photo contest felt unable to appoint a winner. There was too limited diversity in subject matter and quality of the submissions to achieve the objective of the contest and to declare a winner.

EDCTP appreciates very much the work that applicants have put into taking the photographs and participating in this contest. Therefore, EDCTP decided to extend this Photo Contest until 16 April 2012. Participants that have already submitted their photographs will remain in the contest and are also invited to enter more photographs.

Further information about the extension of the photo contest, compliance with local ethics requirements and how to enter will be available at www.edctp.org in January 2012.

European & Developing Countries Clinical Trials Partnership

EDCTP - Europe Office

P.O.Box 93015, 2509 AA The Hague The Netherlands

Tel: +31 70 344 0880 Fax: +31 70 344 0899

EDCTP - Africa Office

P.O.Box 19070, Tygerberg 7505, Cape Town South Africa

Tel: +27 21 938 0819 Fax: +27 21 938 0569

E-mail: info@edctp.org **Web:** www.edctp.org