

Note from the Africa Office



Dear Readers,

I am pleased to introduce to you the August 2012 newsletter which features exciting news on activities from the field and positive steps towards the second phase of the EDCTP programme (EDCTP-II). The second quarter of 2012 has been a very gratifying period marked with public endorsements of EDCTP-II by various likeminded organisations and a meeting of the national representatives from current and prospective Member States of EDCTP. In the same vein, EDCTP hosted the Pharmaceutical Industry Workshop which is part of the process of EDCTP's efforts to galvanise its collaboration with the private sector.

We are delighted to inform our stakeholders that a high-level conference to consult African and international stakeholders on EDCTP-II will be held in Cape Town, South Africa on 5 November 2012. This conference will provide a forum to discuss stakeholder needs and expectations regarding EDCTP-II as well as the opportunities the programme will create.

The EDCTP 2011 annual report is now available on the EDCTP website. This newsletter edition highlights the HIV vaccine capacity building projects, the EDCTP Senior Fellowship scheme and the newly approved projects for funding. Selected visits and meetings are also reported on.

Finally, we are happy to welcome our new staff member, Ms Ana Lúcia Cardoso, who joined the EDCTP Networking team in May 2012.

Dr Michael Makanga

Director of South-South Cooperation and Head of Africa Office

Towards EDCTP-II

Against the background of the current European legislative process and public discussions on the future European Research Framework Horizon 2020, the preparations for the second EDCTP programme (EDCTP-II) are steadily intensifying and engaging a wider audience.

Public endorsements of EDCTP-II

A broad range of advocacy, research and funding organisations as well as Product Development Partnerships have publicly expressed their support for a second EDCTP programme. In three position papers, the organisations involved urged the European Union and its Member States to invest in research and development for poverty-related and neglected diseases. Support for a second, expanded EDCTP programme was expressed as well. These publications can be downloaded from the EDCTP website.

Investing in global health R&D

Four organisations involved in development and global health published *Creating the Tools of Tomorrow: investing in global*

health R&D. The paper argues the urgent need to invest in research and development to fight infectious diseases; maternal, infant and child health issues; and nutritional deficiencies. EDCTP is briefly discussed as "example of a successful partnership for product development." The organisations that published this appeal are the Bill & Melinda Gates Foundation, DWS

(Deutsche Stiftung Weltbevölkerung, a German development foundation), the Global Health Technologies Coalition (in which 40 non-profit organisations participate), and Policy Cures, an independent research and advisory group in the field of neglected diseases.



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Annual Report 2011

The EDCTP Annual Report 2011 is now available on the website in English, French and Portuguese in PDF downloadable documents. These are complemented by an interactive online component which gives access to updated information on all EDCTP funded projects.



Towards EDCTP-II (Continued from page 1)

Poverty-Related and Neglected Diseases in Horizon 2020

More than 30 organisations have advocated that the new European research framework programme, Horizon 2020, prioritises research for poverty related diseases. The position paper *Research and Development for Poverty-Related and Neglected Diseases: a priority in the next EU Research Framework Programme "Horizon 2020"* was brought to the attention of Members of the European Parliament and the governments of the European Member States. The

European Union urged among other things "to ensure sufficient and predictable funding towards EDCTP-II".

The position paper was endorsed by Action for Global Health; Aeras; CBM Severo Ochoa; the COHRED (Council on Health Research for development) Group; Comité Antisida de

Palencia; CPSS; FIND (Foundation for Innovative New Diagnostics); DNDi (Drugs for Neglected Diseases initiative); DSW; European AIDS Treatment Group; Fundación Cultura de Paz; Fundación Cyca (Inesfly); Global Health Advocates; Global Health Europe; IAVI (International Aids Vaccine Initiative); International HIV/AIDS Alliance in Ukraine; International Partnership for Microbicides; Investen; Instituto de Salud Carlos III; ISGlobal Barcelona Institute for Global Health; KNCV tuberculosis Foundation; Malaria Consortium; Malaria No More United Kingdom; MMV (Medicines for Malaria Venture); Path; Planeta Salud; REDVIH; Results; Roll Back Malaria Partnership; Salud por Derecho (Right to Health Foundation); Stop AIDS Alliance; Stop TB; Stop TB Lietuva; TB Alert; TBVI (Tuberculosis Vaccine Initiative); VIH-DA Associació; World Vision.

Global Product Development Partnerships

A group of global Product Development Partnerships (PDPs) published a similar position paper specifically regarding neglected diseases, the *Key Recommendations for inclusion in Horizon 2020 of research and innovation regarding neglected diseases*. The paper explains and advocates the

PDP approach and gives specific recommendations concerning EDCTP-II. "PDPs strongly support the goal of EDCTP to build partnerships and to support and facilitate clinical trials in Africa. Given the growing significance of EDCTP as an important mechanism for funding and building capacity for global health research, it is timely that its design and scope be revised so that a broader range of PDPs are able to effectively utilize this mechanism". The group consists of Aeras (TB vaccine development); DNDi; FIND; IAVI; IPM (International Partnership for Microbicides); MMV; Path catalyst for global health; and the TB Alliance (Global Alliance for TB Drug Development).

Pharmaceutical Industry Workshop

An EDCTP workshop with representatives of the pharmaceutical industry took place in The Hague on 26 June 2012. The fight against poverty-related and neglected infectious diseases in endemic regions requires close proactive interaction among all players including the pharmaceutical industry. Therefore, the objective of the workshop was to explore the possibilities for extended collaboration with the pharmaceutical industry in the second EDCTP programme.

Representatives from the European Federation of Pharmaceutical Industries and Associations (EFPIA) and several pharmaceutical companies including Bayer, Boehringer-Ingelheim, Crucell, Emergent Biosolutions, GlaxoSmithKline, Johnson & Johnson, Merck Serono and Sanofi participated.

Representatives from the Medicines Patent Pool, the Sabin Vaccine Institute, Quintiles and the Directorate General for Research and Innovation of the European Commission also participated in the discussions.

Dr Line Matthiessen-Guyader, Head of Unit F3 – Infectious Diseases and Public Health, Directorate General for Research and Innovation, European Commission, and Professor Simon Croft, Head of the Faculty of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine co-chaired the meeting and facilitated the discussions.

After presentations by EDCTP on the opportunities for industry to work in partnership with the programme and EFPIA on the role of the pharmaceutical industry in the fight against poverty-related and neglected infectious diseases, the greater part of the meeting was dedicated to a wide-ranging discussion of challenges and opportunities. It revolved around three main topics: clinical

trial networks compliant with good clinical practice; capacity building in personnel, infrastructure, ethics review and regulatory affairs; and EDCTP's role as a broker in creating partnerships and leveraging resources. In his closing remarks Prof. Charles Mgone, EDCTP Executive Director, stressed the fact that the meeting was part of an ongoing process of information exchange and strengthening of collaboration with industry.



Prof. Simon Croft, co-chair of the Pharmaceutical Industry Workshop on 26 June 2012 in The Hague

Meeting prospective new EDCTP member countries

National representatives from current and prospective member countries of EDCTP convened in Copenhagen, Denmark on 15 May 2012. The meeting was hosted by Statens Serum Institut with the support of the Danish Presidency of the European Union. The Danish presidency was represented by the Danish Ministry for Science, Innovation and Higher Education. The aim of the one-day meeting was to provide information on the strategic opportunities and benefits offered by participation in the EDCTP-II programme and to provide a forum for discussion between current and prospective EDCTP member countries. The goal was to begin the process to expand European membership of EDCTP in preparation for EDCTP-II and thereby leverage investments in European national research programmes of relevance to poverty-related diseases.

During this meeting the following areas among others, were addressed:

1. Preparations for Horizon 2020 under the Danish Presidency; expected milestones under the forthcoming presidencies of Cyprus and Ireland
2. The experiences of current EDCTP member countries, from the perspective of Germany, France and Ghana
3. The achievements of EDCTP in the context of the European Research Area
4. The strategic benefits and opportunities for member countries; their roles and responsibilities
5. The current status of preparations for EDCTP-II and next steps.



Conference on EDCTP-II in South Africa, 5 November 2012

A high-level conference to consult African and international stakeholders on the second programme of the European & Developing Countries Clinical Trials Partnership (EDCTP-II, 2014-2024) will be held in Cape Town, South Africa on 5 November 2012. The participants will include African, European and international representatives from policy, industry, non-governmental organisations, product development partners and the research community. This is an important milestone conference towards preparation for the second EDCTP programme.

The conference will provide a forum to discuss stakeholder needs and expectations regarding EDCTP-II as well as the opportunities the programme will create. Endorsement of the programme as well as commitments and pledges will be sought. Four strategic issues for EDCTP-II will be addressed:

1. The lessons learnt from EDCTP-I
2. The scope of the second programme
3. The role and commitment of the participating European and African countries
4. The participation of the private sector (in particular companies, product development partnerships, foundations and charities) in EDCTP-II.

A conclusive conference report will be published.

The South African Department for Science & Technology, the European Commission and EDCTP are jointly organising the conference on the occasion of the 15th anniversary of the signing of the Science & Technology cooperation agreement between the European Union and South Africa. There will also be visits to clinical trial sites or institutions in the Cape Town area which are beneficiaries of EDCTP funding.



The Cape Town International Convention Centre, venue of the High-level meeting on EDCTP-II

Calls and grants

Funded projects

EDCTP is pleased to announce the funding of the following project:

Call: Senior Fellowship

A randomised trial to assess retention rates using mobile phones versus contact tracing, and characterise trends in HIV-1 prevalence and incidence in a potential HIV vaccine efficacy population of fishing communities around Lake Victoria, Uganda

Project Coordinator: Noah Kiwanuka
(Medical Research Council Programme on AIDS - Uganda Virus Research Institute, Uganda)

Budget: € 199,365

Duration of the project: April 2012–April 2014

EDCTP Governance

New staff member



Ana Lúcia Cardoso - North-North Networking Officer

Ana Lucia Cardoso joined the EDCTP Networking team in May 2012. She will be involved in North-North

research networking activities, working in particular on increasing collaboration with new EU Member States. She worked as academic assistant in the University of Tartu where she supported the development of internet based courses and performed research on human rights and globalisation. Before joining EDCTP she worked in Brussels as Training and Communications Coordinator for the European AIDS Treatment Group, a community based organisation advocating for access to HIV treatment. Ana Lucia has previously worked in the fields of public relations, policy development and fundraising. She was born in Lisbon, Portugal and graduated from the University of Lisbon. She holds a degree in European Studies and Political Science and is pursuing further studies in International Management with a focus on Management of Health Systems.

General Assembly

The EDCTP General Assembly (GA), the overall body that governs EDCTP, convened at the Statens Serum Institute in Copenhagen, Denmark on 14 May 2012. Among other things, the GA discussed ongoing business and approved the Annual Statutory Accounts and the Annual Report for 2011. The 10 proposals on Ethics capacity building and six Senior Fellowships which were recommended for funding by the Scientific Review Boards and the Partnership Board, were also approved. The meeting focussed on preparations for EDCTP-II and the draft Strategic Business Plan for EDCTP-II was released for publication on the EDCTP website.



Focus on projects

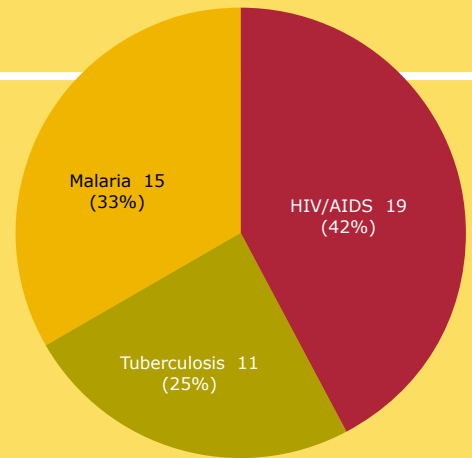
Senior Fellowships

EDCTP runs a highly successful Senior Fellowship scheme aimed at developing African scientific leadership and mentorship. Since the inception of this grant scheme in 2004, EDCTP has granted 45 Senior Fellowships. Eighteen of these Senior Fellows have completed their projects and all of them are still working in the research field in sub-Saharan Africa. These include Abraham Alabi (Nigeria), Wendy Burgers (South Africa), Badara Cisse (Senegal), Didier Ekouevi (Ivory Coast), Keertan Dheda (South Africa), Abdoulaye Djimde (Mali), Daniel Dodoo (Ghana), Willem Hanekom (South Africa), Christian Happi (Nigeria), Mawoia Mukhtar (Sudan), Pauline Mwinzi (Kenya), Nicaise Ndembu (Nigeria), Issa Nebie (Burkina Faso), Mark Nicol (South Africa), Freeya Njai (The Gambia), Davis Nwakanma (Gambia), Alexis Nzila (Kenya/Congo Brazzaville) and Ambrose Talisuna (Uganda).

This grant scheme has been instrumental in developing the careers of mid-level to senior

African scientists to become more competitive internationally and to obtain larger grants from EDCTP and alternative funding sources. Moreover, a number of Senior Fellows have received international prestigious awards. EDCTP was informed of international prizes being awarded to Keertan Dheda (South Africa), Christian Happi (Nigeria), Eugene Kinyanda (Uganda), Alexis Nzila (Kenya) and Kamija Phiri (Malawi).

Through this grant senior fellows normally establish research teams and contribute directly to the development of African research capacity through supervision of MSc, PhD and post-docs in their projects. Some students who trained under senior fellows have been successful in getting similar grants. In certain circumstances the fellowship scheme has contributed to ground breaking research that led to change of policy and practice. In September 2010, WHO recommended that Xpert MTB/RIF replace smear microscopy as the first line

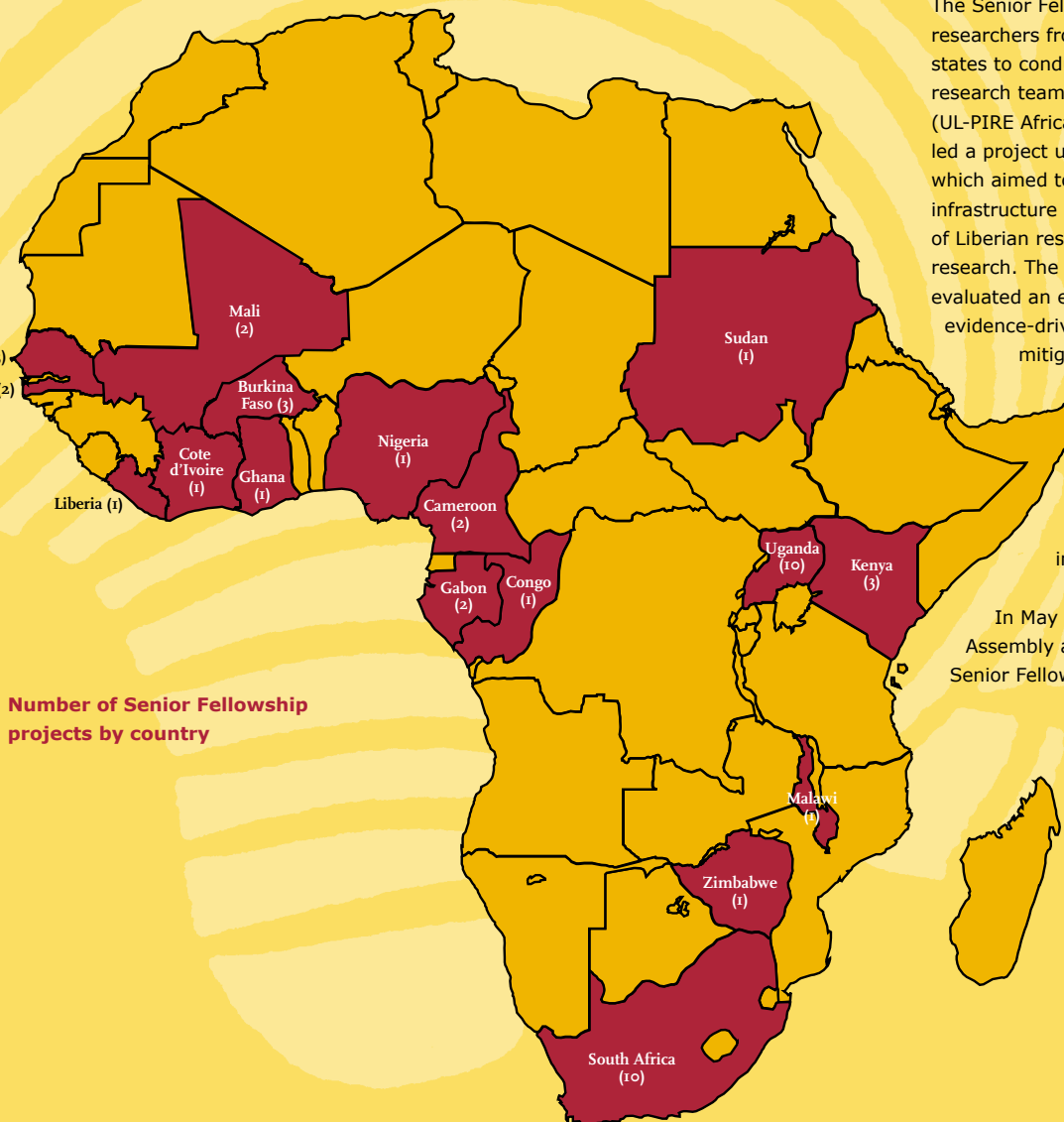


Number of Senior Fellowship projects by disease.

diagnostic test for TB in areas with high prevalence of MDR-TB or HIV. The preliminary results of a study by senior Fellow Mark Nicol (South Africa) contributed substantially to the scientific evidence in a report submitted to the WHO Strategic and Technical Advisory Group (STAG).

The Senior Fellowships have also helped researchers from fragile and war-ravaged states to conduct research work and start up research teams. Dr Stephen B. Kennedy (UL-PIRE Africa Center, University of Liberia) led a project under a Senior Fellowship grant which aimed to support research infrastructure development and train a cadre of Liberian researchers in HIV/AIDS research. The project also implemented and evaluated an effective science-based, evidence-driven, research programme to mitigate HIV/STDs among rural youth at high-risk in post-conflict Liberia. This project has laid the foundation for the conduct of HIV biomedical research in this country.

In May 2012, the EDCTP General Assembly approved an additional six Senior Fellowships.



Number of Senior Fellowship projects by country

Focus on projects (Continued from page 4)

The 2006 call on HIV vaccine capacity building

The joint call for proposals launched by EDCTP and the Bill & Melinda Gates Foundation on World AIDS Day 2006 resulted in six projects. The studies aimed to develop capacity to conduct future HIV vaccine clinical trials in Africa based on international regulatory standards. Three projects, led by Professor Linda-Gail Bekker (Desmond Tutu HIV Centre, South Africa), Dr Saidi Kapiga (London School of Hygiene and Tropical Medicine, United Kingdom), and Professor Pontiano Kaleebu (Uganda Virus Research Institute/Medical Research Council, Uganda) have been completed.

Prof. Bekker's SASHA project studied the feasibility of conducting HIV vaccine prevention trials in South Africa with adolescents, a group which is particularly at high-risk for HIV infection. By using the HPV vaccine as a proxy, the project showed that it is feasible to enrol and retain 12-17 years olds in a clinical trial. The project also developed an ethical-legal guide for conducting clinical trials with adolescents. Moreover, all six sites in this study now have the necessary infrastructure for future vaccine trials with adolescents.

Dr Kapiga conducted a capacity development project in preparation for HIV vaccine trials in Burkina Faso and Tanzania. The main

objectives were to develop and maintain a study cohort among a high-risk population for HIV vaccine trials; characterise HIV-1 viral isolates and assess factors associated with viral genotypes among identified target populations; and determine immunological and genetic factors that could confer resistance to HIV infection and/or slow down the progression of the disease. The study showed that the newly-established cohort in Moshi, Tanzania, is suitable for future HIV vaccine trials. According to preliminary results, there are multiple HIV subtypes present in Moshi and Mwanza with a substantial proportion of recombinant viruses. This suggests that Tanzania offers opportunities to test new vaccines against a range of virus subtypes. The project also strengthened capacity in the Mwanza Intervention Trials Unit (MITU) and developed a Good Clinical Practice (GCP)-compliant data management system in the Burkina Faso and Tanzania sites.

Prof. Kaleebu led a study on fishing communities, which are identified as high-risk groups for HIV infection in Malawi and Uganda. Fishermen are a mobile community, who often spend extended periods on the water and away from their homes. They have limited to no access to health services, and have been largely excluded from AIDS programmes and research. As a result, communities were

suspected to suffer from high rates of HIV infection. The study had two major goals. The first was to map the prevalence of HIV and the ways in which it spreads throughout these mobile communities. This information provides guidelines on how to best prevent the spread of HIV and AIDS. Second, the study evaluated the strain of HIV circulating amongst these populations in view of future vaccine trials. The study also looked at the early-stage immune responses observed in individuals who become HIV-infected during the study. The study found high prevalence and incidence rates in the Uganda site which indicates suitability for future HIV prevention research. In the Malawi population, HIV rates were surprisingly similar to those of the general population despite a strong indication of high-risk behaviour (high herpes rate) in this community.

Clinical studies on HIV vaccines that are in progress include the PedVacc study led by Professor Tomáš Hanke (University of Oxford, United Kingdom), the TaMoVac studies led by Professor Muhammad Bakari from the Muhimbili University of Health and Allied Sciences (MUHAS, Tanzania), and the AfrEVacc (the African-European HIV Vaccine development network) led by Prof. Jonathan Weber (Imperial College London, United Kingdom).

See also the recent EDCTP video on some HIV projects on YouTube channel EDCTP media (www.youtube.com/edctpmedia).

Boat used in project led by Prof. Pontiano Kaleebu to reach fishing communities



Meetings

EDCTP visits sites in Tanzania



Participants of a meeting between EACCR and EDCTP at KCRI during a site visit to Tanzania on 16 April 2012

EDCTP visited several major sites in Tanzania from 16 to 20 April 2012. The team comprised Mr Abdoulie Barry, Director of Finance and Administration, Dr Thomas Nyirenda, South-South Networking and Capacity Development Manager, and Professor Omu Anzala, member of the Developing Countries Coordination Committee (DCCC).

At the Kilimanjaro Clinical Research Institute (KCRI) in Moshi, the team met with the coordinators and network work package leaders of the East African Consortium for Clinical Research (EACCR) to discuss the ongoing activities of the Network of Excellence in the coming two years as well as new activities planned under EDCTP-Plus for 2012 and 2013.

The remaining days were dedicated to technical and financial assessments of projects at KCRI, Moshi; Muhimbili University of Health and Allied Sciences (MUHAS) Research Institute, Dar es Salaam; Ifakara Research Institute (IHI), Bagamoyo; and Mbeya Medical Research Programme (MMRP), Mbeya. Several PhD students presented their work. The assessments focussed on the progress of EDCTP projects conducted at the various sites and aspects of financial management and control.

Forum 2012

Forum 2012 is the 14th global meeting of the Global Forum for Health Research which was jointly organised by the Council on Health Research for Development (COHRED) and the South African Departments of Science & Technology and Health. Under the theme of "Beyond Aid... Research and Innovation as key drivers for Health, Equity and Development", COHRED and the Global Forum for Health Research focused on potentials, solutions, and developing capacities in low- and middle-income countries and emerging economies, and how global collaboration can leverage this for a new era of global development support. The meeting was held in Cape Town, South Africa, from 24 to 26 April 2012. It brought together key actors who contribute to research and innovation work for health, equity and development, including governments, industry, social enterprises, non-governmental organisations, researchers, media, financiers-donors-sponsors, international organisations.

Professor Hannah Akuffo, Chair of the EDCTP General Assembly, and Dr Michael Makanga, EDCTP Director South-South Cooperation and Head of Africa Office, were actively involved

TB CHILD consortium meeting

The EDCTP-funded project TB CHILD evaluates new and emerging diagnostics for childhood tuberculosis in high-burden countries. The project has two main studies running in three clinical trial sites. One study focuses on testing various new diagnostic techniques in adults. The second study focuses on children aged 6 weeks and 14 years old with suspected TB and is testing a total of eleven diagnostic techniques. The trial sites are at the Ifakara Health Institute (IHI) in Bagamoyo, the National Institute of Medical Research-Mbeya Medical Research Programme (NIMR-MMRP) in Mbeya, both in Tanzania, and at the Nsambya Hospital in Kampala, Uganda. The project is due to end in May 2013.

The consortium held its second general meeting in Rome on 10 July 2012. Technical and scientific issues were discussed. Recruitment for the adult study is going well. The study in children is experiencing some difficulties in recruitment and retention but the team expected to be able to recruit the target number of children. Four post-graduate studies are ongoing. The meeting was attended by many members of the consortium and presided over by the Project Manager Dr Klaus Reither. EDCTP was represented by the Project Officer for TB Child.

as panel members in two sessions where the EDCTP programme model and individual project case studies were highlighted. EDCTP activities were also exhibited at the Market Place of the Forum 2012.



Dr Pascoal Mocumbi, EDCTP High Representative, and Dr Michael Makanga, Head of the EDCTP Africa Office, at the Forum 2012

The EDCTP Newsletter is available in three languages namely English, French and Portuguese in electronic format on our website (www.edctp.org). To receive the electronic format, please subscribe online (www.edctp.org, click on Newsletter sign up).

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