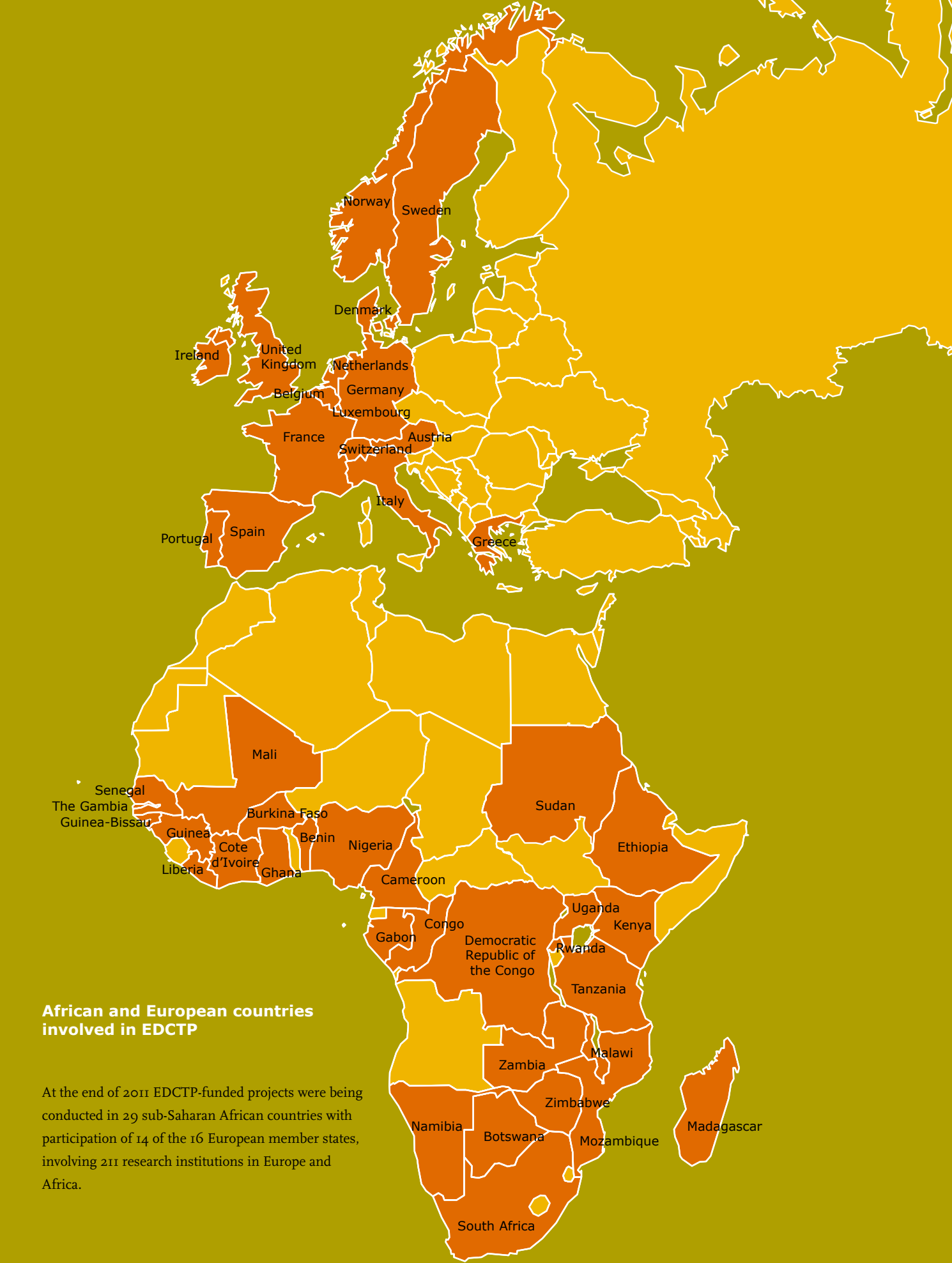
EDCTP

European and Developing Countries Clinical Trials Partnership

Annual Report 2011

Consolidation



African and European countries involved in EDCTP

At the end of 2011 EDCTP-funded projects were being conducted in 29 sub-Saharan African countries with participation of 14 of the 16 European member states, involving 211 research institutions in Europe and Africa.

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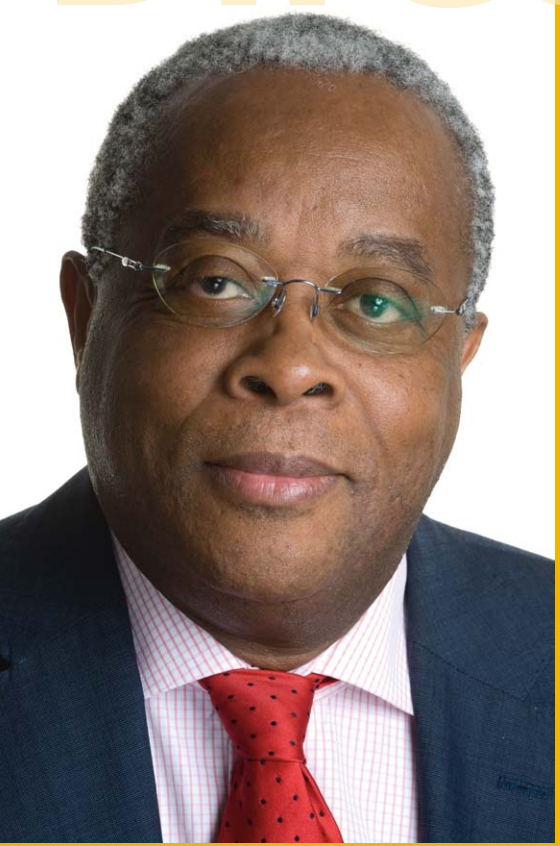


Consolidation as the theme for the 2011 EDCTP Annual Report is very appropriate and pertinent since this was the year that we focused most of our time on the management of on-going projects and active grants. The emphasis was on monitoring the progress of these projects to ensure successful and timely outcomes. From the inception of EDCTP in 2003 till the end of 2011, we have launched a total of 64 calls for proposals; processed 494 applications and awarded 196 grants of which 116 are still active and 80 completed.

During the year, seven calls were launched and 15 grants awarded. As the current programme is approaching the tail end, the emphasis of these calls shifted from large scale clinical trials to the shorter-term projects. Thus in February and August we launched three calls for Senior Fellowship (one of which was restricted to the EDCTP Networks of Excellence for conducting clinical trials) and two for supporting Health Research Ethics Committees. It must be pointed out that these calls are getting more and more competitive. In the two unrestricted Senior Fellowship calls, for instance, there were 73 proposals competing for the available 12 awards and in the Health Research Ethics Committee capacity building calls, 55 proposals vied for the available 20 grants. In addition to these calls there was a 'Member State Initiated Projects' call and a new call under the scheme referred to as the 'Strategic Primer Grants'. This new scheme of calls that was launched in December 2011 is for supporting investigator driven innovative studies to generate data for informing future clinical trials that could potentially be funded under the EDCTP-II programme. The scheme also contributes to maintain momentum and sustain capacity that was generated and developed under the current programme.

The 15 new grants that were signed in 2011 included three that arose from a new joint programming scheme of calls called 'Joint Call by States (JCMS)'. This call was funded by Netherlands, Spain, Sweden and United Kingdom, and called for proposals to evaluate the impact of clinical trials on the delivery of health services, especially pertaining to mothers' and children's welfare.

The maturity of the programme is underpinned by the completion or near completion of several large clinical trials. These include the 4ABC trial that was led by Professor Umberto D'Alessandro that compared the safety and efficacy of four artemisinin-based combination therapies in the treatment of uncomplicated malaria and the phase III pivotal clinical trial of moxafloxacin for the treatment of tuberculosis that was led by Professor Stephen Gillespie. Other studies that concluded in 2011, include the treatment of severe malaria in children using intravenous artesunate that showed a shorter treatment course of three doses given over two days was as effective as that of five doses spread over three days; and acceptance and attitudes of adolescent towards HIV preventive vaccines. These and some other results were presented at the Sixth EDCTP Forum that took place in Addis Ababa, Ethiopia.

The theme of the EDCTP Forum was **Strengthening research partnerships for better health and sustainable development**. The Forum was attended by 535 participants from 54 countries who contributed 265 papers of which 127 were presented orally and 138 on posters; the majority (over 60%) of them arising from EDCTP funded projects.

Once again, none of these would have been possible without the unwavering support that we continue to enjoy from all EDCTP constituencies, partners and stakeholders. We sincerely extend our heartfelt gratitude and appreciation to you all who have made this possible and unashamedly continue to ask for more since the war is far from over.

Charles S. Mgone
Executive Director

2011 in a nutshell

The year 2011 ushered the consolidation phase of the European and Developing Countries Clinical Trials Partnership (EDCTP) programme. This was exemplified by the breadth and variety of the programme for the Sixth EDCTP Forum; the publication of the results of some of the main clinical trials; the volunteers/patients enrolment milestones in on going studies; remarkable research and ethics capacity developed in Africa; as well as the extensive interactions with policy makers in Africa and Europe. Moreover, these results stimulated a new commitment of the participating European countries to a second EDCTP programme for which a strategic business plan was completed.

Towards a second EDCTP programme

Following the positive evaluation of the EDCTP programme, which included a public consultation, EDCTP-EEIG Member States (MS) and the European Commission (EC) unanimously agreed to continue with the Partnership. At the MS Consensus Meeting that was held on 27-28 September 2010 in Brussels, the participating MS, Latvia (observer Member State), African representatives and the EC agreed to continue with a second EDCTP programme.

There was a consensus that the EDCTP-II programme, building on the current one, should be bigger, more ambitious and covering a period of up to twelve years divided into three terms. While still focusing on the current scope of HIV/AIDS, tuberculosis and malaria phase II and III clinical trials, the new programme was to expand gradually to involve all clinical trial phases (I-IV), health service optimisation research, other neglected infectious diseases, increased membership in Europe and collaborating with other developing countries besides sub-Saharan Africa.

Under the Belgian Presidency of the European Union, the participating MS presented their intention to continue with EDCTP to the EU Competitiveness Council on 26 November 2010.

Following that meeting, a Strategic Business Plan for EDCTP-II, 2014-2024, has been drafted through an extended dialogue between partner countries. This was facilitated by a drafting committee comprising members from Germany, Ghana, Latvia, Spain and the United Kingdom. As part of this process, during the second half of 2011 EDCTP General Assembly (GA) members presented their country's indicative financial commitments. They also expressed their commitment to exploring future mechanisms to increase cooperation between national programmes with the goal of greater integration of European national programmes in the scope of EDCTP. The Strategic Business Plan will provide a strong foundation for the legislative process which will take place in Brussels in 2012 and 2013.

Sixth EDCTP Forum

The Sixth EDCTP Forum was held in Addis Ababa, Ethiopia on 9-12 October 2011. The theme of the forum was 'Strengthening Research Partnerships for Better Health and Sustainable Development'. The event was attended by 535 participants from 32 African countries and 22 other nations worldwide.

The Forum clearly showed the maturation of the EDCTP programme as evidenced by 265 presentations, including 138 posters among which more than 60% were from EDCTP-funded projects. The majority of the presenters were African scientists working in Africa. Since 2003, EDCTP has funded nearly 200 projects including 57 clinical trials that took place or are going on in 29 sub-Saharan countries in partnership with 14 EDCTP European countries. These projects brought together researchers from 211 institutions in Africa and Europe, many of whom participated at the Forum in Addis Ababa. This clearly shows the importance of EDCTP and the EDCTP forums as platforms for collaborative research and networking. Additionally, 12 global health organisations that are EDCTP partners, presented their work and the areas where they collaborate or wish to collaborate with EDCTP.

While much has changed since the launch of the organisation in 2003, the strong commitment to improving health through partnership remains at the heart of EDCTP's activities, as is the belief that better health can help achieve sustainable development. Underpinning this, in his speech during the opening ceremony, Robert-Jan Smits, Director-General for Research & Innovation at the European Commission (EC) said what has been achieved provides a fine example of what can be done when there is a "true and equal partnership between stakeholders". He expressed the hope that the next European Union research funding programme, Horizon 2020, will provide support for EDCTP, allowing it to build on what has been achieved and also to expand its mandate.

The scientific presentations structured by disease, i.e. HIV/AIDS, tuberculosis (TB) and malaria, were connected by three overarching themes with regard to sub-Saharan Africa: clinical research and achievements and findings; developing scientific research capacity; and North-South and South-South partnerships for quality improvement research. These presentations and other Forum activities have been published in the *Sixth EDCTP Forum Proceedings* and in the *Journal of Tropical Medicine and International Health*.

Dr Ruxandra Draghia-Akli, Director for Health Research at the EC's Directorate-General for Research and Innovation, delivered the final address at the Forum. She called for the creation of "an unbroken implementation chain, from discovery to better health". She described EDCTP as a role model for partnering on global health challenges, which was breaking new ground in terms of collaboration, strategy, governance and implementation. Looking at the future, she stressed that the EDCTP Partnership had to move forward in terms of wider participation by European public and private partners.

EDCTP Outstanding African Scientist Awards

At the final plenary session of the Sixth EDCTP Forum the two EDCTP Awards to outstanding senior and junior African scientists working on HIV/AIDS, tuberculosis and malaria were presented. The winner of the Senior Scientist Award was Professor Salim Abdool Karim, Director of the Centre for the AIDS Programme of Research in South Africa (CAPRISA). He said in his acceptance speech that, in giving him the award, EDCTP was honouring not only himself but also the entire team of some 380 people at CAPRISA.

Prof. Salim Abdool Karim

Mr Hannock Tweya

EDCTP's Junior Scientist Award went to Hannock Tweya of the Lighthouse Trust, Malawi. Mr Tweya has been involved in many aspects of the work of the Trust which provides care to over 22,000 people living with HIV, including home-based care, anti-retroviral therapy (ART) provision and other services. He has published on loss to follow-up in research cohorts and HIV in pregnancy, among other topics. Thanking EDCTP for the award, Mr Tweya said he would use it to advance research that would improve people's lives.

EDCTP calls and grants

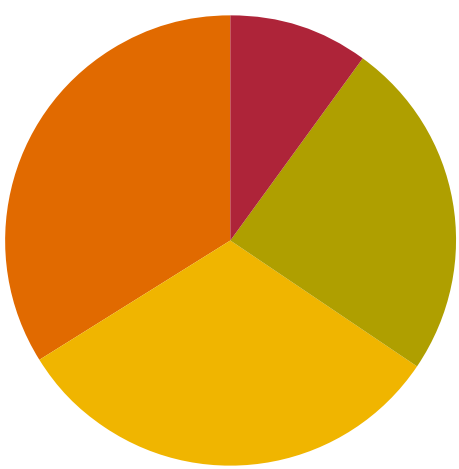
In 2011, six calls for proposals were launched including three for Senior Fellowships, two open and one attached to EDCTP Networks of Excellence (NoEs); two for strengthening ethics review capacity; one for Member States Initiated projects (MSI) and one Strategic Primer Grants. This last scheme provides pump-priming to allow researchers to explore novel and innovative research approaches that may lead to the development and testing of new or improved clinical interventions against HIV/AIDS, malaria and tuberculosis.

By the end of 2011, EDCTP has funded (contract signed) 196 projects to a total amount of approximately € 356 million including cofunding. Of these projects, 44 are on HIV/AIDS research, 31 on tuberculosis research and 34 on malaria research, and the remaining 87 projects were non-disease specific.

Overview of EDCTP calls for proposals launched in 2011

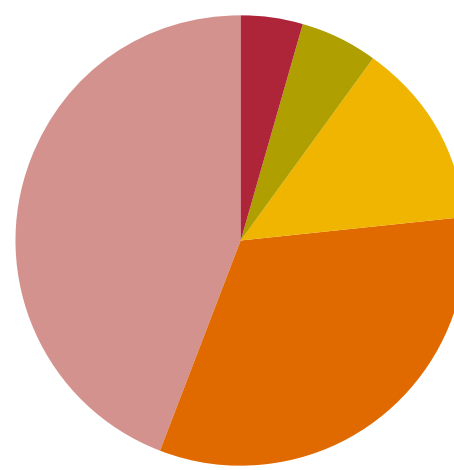
Call/Disease area	Budget (€)	Launch date	Deadline	No. of projects approved
Senior Fellowships (First call)	€ 1.20M	15-02-2011	15-06-2011	7
Senior Fellowships (Second call)	€ 1.20M	15-08-2011	15-12-2011	Pending
Senior Fellowships linked to NoE	€ 0.40M	15-02-2011	15-06-2011	0
Ethics/Institutional Review Boards (First call)	€ 0.50M	15-02-2011	15-06-2011	10
Ethics/Institution Review Boards (Second call)	€ 0.50M	15-08-2011	15-12-2011	Pending
Member States Initiated (MSI) projects	€ 2.55M	15-08-2011	15-12-2011	Pending
Strategic Primer Grants	€ 5.50M	12-12-2011	12-02-2012	Pending
Total budget	€ 11.85M			17+

Overview of funding by disease (2003-2011) (€ '000)



Non-disease specific	€ 19,714
Malaria	€ 48,517
Tuberculosis	€ 62,368
HIV/AIDS	€ 66,446

Overview of funding by intervention (2003-2011) (€ '000)



Microbicides	€ 8,882
Diagnostics	€ 10,857
Non-disease specific	€26,647
Vaccines	€63,711
Drugs	€ 86,948

HIV/AIDS

The UNAIDS World AIDS Day Report 2011 showed a decrease in the number of deaths from AIDS-related illness and new HIV infections. Despite this important progress sub-Saharan Africa still remains the region most affected by HIV. In 2010, 68 per cent of all HIV-infected people were living in sub-Saharan Africa. This burden is aggravated by HIV and TB co-disease, the leading cause of death; 82 per cent of HIV-positive TB cases live in the region. As at 31 December 2011, the total funding for the 44 EDCTP projects on HIV/AIDS amounted to € 118.1 million. The current portfolio of projects includes HIV/AIDS treatment trials; studies evaluating HIV resistance to anti-retroviral treatment; prevention of HIV transmission from mother-to-child (MTCT); phases I and II vaccine trials; microbicides trials; and projects to strengthening of long-term clinical and laboratory research capacity for future HIV vaccine trials.

HIV/AIDS therapy

Evaluation of second-line therapy

EDCTP is funding the Eastern and Southern Africa Research Network for Evaluation of Second Line Therapy ifirstn HIV infection (EARNEST) phase III clinical trial. This is the largest ongoing trial in this area and compares several boosted protease inhibitor-containing second line regimens for patients failing first-line therapy. It is conducted in 14 clinical trial centres in five African countries: Kenya, Malawi, Uganda, Zambia and Zimbabwe. The recruitment into EARNEST was completed on 29 April 2011 after an impressive number of 1277 patients had been enrolled in a period of just over one year. The critical question being addressed is which anti-retroviral drugs (ARVs) to prescribe to patients failing first-line therapy in resource-limited settings. The outcome of this clinical trial will provide knowledge relevant to national control programmes and to policy makers. It is expected to contribute to national treatment guidelines and the worldwide public health approach to rolling out ART.

HIV-TB co-infection: early TB intervention

The RAFA project (rifampicin or early ARV for West Africa) addresses HIV-TB co-infection. It evaluates whether aggressive early management of tuberculosis in HIV-infected patients can reduce the high levels of mortality due to the HIV-TB co-infection by the early administration of high doses of the anti-tuberculous drug rifampicin. This is to be compared to other standard TB drugs and a follow up initiation of HIV antiretroviral standard treatment after two months. The study started in 2011 and opened three recruitment sites in Benin, Guinea and Senegal in May, June and July respectively. By the end of 2011, 79 patients had been recruited. The project introduced innovative solar power sourcing to improve the capacity and functionality of the West African research facilities.

HIV-TB co-infection: safe treatment combinations

The clinical management of tuberculosis and HIV co-infection cases is made difficult by several factors including important interactions between the rifamycins (rifampin and rifabutin) and the antiretroviral drugs in the class of protease inhibitors. The Senior Fellowship project of Dr Seni Kouanda is investigating the pharmacokinetics parameters of rifabutin in combination with lopinavir and ritonavir. The definition of optimal doses will inform future larger phase III trials comparing safety, tolerability and efficacy of combined treatment regimens. The study takes place in Burkina Faso and enrols HIV-infected patients with tuberculosis.

HIV/AIDS prevention: microbicides

EDCTP funded three studies aimed at development of clinical, laboratory and field facilities, as well as training of staff to increase the capacity to conduct trials of vaginal microbicides against sexual transmission of HIV. All three projects have been successfully completed. While consecutive microbicide trials have produced disappointing results, the achievements of these projects such as the established cohorts and research capacity, will contribute to future HIV research in sub-Saharan Africa.

Preparing for microbicide trials in Mozambique

The project to establish HIV microbicide clinical trial capacity in Mozambique and expand an existing site in South Africa led by Dr Sheena McCormack from the Medical Research Council UK (MRC UK), was completed in 2011. The objectives of this study were to conduct a microbicide feasibility and pilot study in Mozambique under the umbrella of the Microbicides Development Programme (MDP) and build capacity at the Reproductive Health and HIV Research Unit (RHRU) in Johannesburg, South Africa. Clinical infrastructure was improved in order to complete this site's targets for the phase III MDP301 microbicide

trial exploring the PRO 2000 vaginal gel. Regretfully, this MDP301 effectiveness trial, which was conducted among almost 9,400 women in four African countries, found no evidence that the PRO 2000 microbicide reduced the risk of HIV infection.
The study in Mozambique sought to determine the feasibility of conducting a microbicide trial of a daily vaginal gel and to generate information on the way adherence for microbicides should be assessed. The trial started in June 2010 and completed follow up of volunteers in November 2010. This feasibility study, which aimed to evaluate the population and study site in the Healthcare centres of Mavalane and Manhiça in preparation for a possible phase III vaginal microbicide trial, provided the first HIV incidence data in Mozambique.

The project was implemented in collaboration with the Community Development Foundation and the Instituto Nacional de Saúde (Mozambique), the University of Witwatersrand (South Africa), the University of Barcelona (Spain), UK Department for International Development, the Medical Research Council and the Imperial College London (United Kingdom), the International Partnership for Microbicides and Endo Pharmaceuticals Solutions.

Preparing for microbicides trials in Rwanda and Kenya

Dr Janneke van de Wijgert from the Centre for Poverty-related Communicable Diseases (CPCD) of the Academic Medical Center (AMC), University of Amsterdam in the Netherlands, led a project to prepare research sites in Kigali, Rwanda and in Mombasa, Kenya. phase III effectiveness trials of microbicides have to be conducted in female populations with a high incidence of heterosexually-acquired HIV. HIV incidence data is crucial in the planning, design and interpretation of microbicide trials and the target populations of such trials are generally HIV-negative high-risk populations.

During the site preparation, HIV incidence was estimated by cross sectional and longitudinal cohort studies. The cohort studies evaluated the sites' recruitment and retention strategies, and assessed other relevant outcomes for microbicides studies, including reproductive tract infections and pregnancy rates. The HIV incidence studies in Kigali and Mombasa were completed successfully in 2010 and the rest of the activities completed in 2011.

The project improved the clinical laboratory and data management infrastructure and provided training to a wide research community. The capacity building through this project also established the reproductive health clinic at the Kigali Teaching Hospital, increasing treatment options for cervical cancer and infertility. Moreover, the study results have been instrumental for the Rwandan Ministry of Health to develop a new HIV prevention policy focusing on female sex workers. The results for human papilloma virus (HPV) will be useful in the evaluation of the newly implemented cervical cancer screening and HPV vaccination program.

The reproductive health clinic established at the Kigali Teaching Hospital has increased treatment options for cervical cancer and infertility. Additionally, the successful Belgium-Kenya-Netherlands-Rwanda collaboration established in this project led to another EDCTP project led by Dr Kishor Mandaliya entitled "Characterisation of novel microbicide safety biomarkers in East and South Africa".

Preparing for microbicides trials in Tanzania and Uganda

Prof. Richard Hayes of the London School of Hygiene and Tropical Medicine (United Kingdom) led a project to expand the capacity for phase I, II and III clinical trials of candidate vaginal microbicides in Tanzania and Uganda.

The project demonstrated that the study populations of women at high risk of contracting HIV in both Tanzania and Uganda are suitable for the implementation of future trials of microbicides or other HIV prevention tools, with high HIV incidence and high retention rates. The high pregnancy rate and low use of effective contraceptive methods in our

study pointed to the need for more intensive measures in any future trial to promote contraceptive use and reduce the rate of pregnancy. As a result of the studies, the MRC (United Kingdom) funded a project titled "Intravaginal practices in Tanzania and Uganda: Relationships with the vaginal micro-environment, HIV and other STIs" which was carried out in close collaboration with the EDCTP project. The aim of this research was to better understand potential risk factors for HIV infection among women.

In Mwanza, Tanzania research infrastructure required to test new interventions, including microbicide trials, was successfully developed. Research team members were trained to conduct research according to international scientific and ethical standards. A system to recruit and follow up women working in these settings and retain them in active follow-up for a period of up to one year was developed. A strong community liaison system was established to ensure effective communication between researchers, the participants, and other local stakeholders. Collaboration between researchers and local health officials was key to the success of research activities at the sites.

In Uganda the first female high-risk cohort has been set up which provided important information for policy makers and scientists. The new clinical trial site is ready to conduct clinical trials while the high-risk cohort offers a platform for future new research in the fields of social science, basic science and intervention studies.

HIV/AIDS vaccine development

The joint call for proposals launched by EDCTP and the Bill & Melinda Gates Foundation on World AIDS Day 2006 resulted in six projects. These studies aim to develop capacity to conduct future HIV clinical trials in Africa based on international regulatory standards.

Neglected HIV high-risk groups: fishing communities in Malawi and Uganda

EDCTP funded a study on fisher folk communities which are identified as high-risk groups for HIV infection in Uganda and Malawi. This project will generate information on how best to prevent the spread of HIV/AIDS throughout these communities that are characterised by high personal mobility. This project is almost completed and the first results were presented at the EDCTP Forum in October 2011. The study team assessed the social and behavioural patterns in the fishing communities and the prevailing awareness of HIV. This work is useful for long-term HIV prevention research, especially the large scale clinical trials necessary for AIDS vaccine development.

SASHA project

In 2011, the South African Studies on HIV in Adolescents (SASHA) project was the first of the six capacity building projects to be completed. This multi-centre project, led by Prof. Linda-Gail Bekker of the Desmond Tutu HIV Centre, South Africa, successfully conducted a study of the possibilities for conducting HIV vaccine prevention trials in South Africa with adolescents. This is a particularly high-risk group for HIV infection in this setting. By using the Human Papilloma Virus (HPV) vaccine as a proxy, the project showed that it is feasible to enrol and retain 12-17 year olds in clinical trials. This project also generated information that facilitated the development of ethical-legal guides for conducting clinical trials with adolescents, which was rolled out nationally. Moreover, all six sites involved in this study now have the necessary infrastructure and trained personnel for conducting adolescent vaccine trials.

The Consortium of Adolescent Trials in South Africa (CATSA) was established through this project and is now a leader in the adolescent research field in Southern Africa. Community preparation for future clinical trials with adolescents was established in all six sites involved in the study. The study was cofunded by the Bill & Melinda Gates Foundation, the National Agency for AIDS Research (France), Irish Aid (Ireland), the Netherlands Organisation for Scientific Research (Netherlands), the Swedish International Development Cooperation Agency (Sweden), the Swiss National Science Foundation (Switzerland) and the Medical Research Council (United Kingdom).

Clinical studies

Several clinical studies on HIV vaccines, the PedVacc and the TaMoVac studies, are ongoing. The PedVacc studies aim to evaluate safety and immunogenicity of a candidate HIV-1 vaccine, MVA.HIVA, administered to healthy infants born to HIV-1 and HIV-2-uninfected mothers. In 2011, the recruitment of volunteers was successfully completed in The Gambia and Kenya, and immunological analyses have started. The studies examine the safety of MVA.HIVA, a new type of HIV vaccine in infants. The vaccine vector modified vaccinia Ankara (MVA) is a weakened virus previously used as a smallpox vaccine. Individual HIV genes from the genome have been added to this, but the vaccine does not contain the whole HIV virus genome, and cannot cause HIV infection or AIDS. MVA.HIVA is one component that could form part of a more complex future vaccine.

In Tanzania and Mozambique, the TaMoVac I and II studies assess the safety and immunogenicity of plasmid DNA + MVA-CMDR and explore new delivery methods and optimal strategies of priming and boosting the immune system against HIV. TaMoVac I is screening and enrolling healthy volunteers. The study protocol is being amended to include an additional booster vaccine, the recombinant protein rpg140, to the DNA-MVA regime, in the Tanzanian part of the TaMoVac I study.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Tuberculosis

In the fight against TB four major concerns drive research. These are the need for a fast and reliable method of diagnosing TB; shortening of the standard treatment; safe and effective treatment of TB and HIV co-infection; and prevention through a better vaccine.

TB diagnosis is currently a lengthy process which delays treatment, thereby increasing the risk of disease transmission and making monitoring of drug resistance more difficult. Moreover, the standard method of diagnosing the disease has low sensitivity among HIV co-infected patients. The six month standard treatment of the disease creates a strong adherence challenge to patients and the consequent increased risk of development of drug-resistant strains of the bacteria. TB and HIV co-infection poses a dual enigma of increased TB caseload and complexity of the combined treatment of the two diseases.

Options for the prevention of TB are limited as the only available TB vaccine, BCG, does not protect adolescents and adults from developing TB, and HIV-infected infants and children may also not be adequately protected. EDCTP-funded research targets these areas of diagnostics, treatment and prevention of TB. As at 31 December 2011, the total funding of these 31 projects amounted to € 110.4 million.

TB diagnostics

Current strategies are insufficient to control tuberculosis in sub-Saharan Africa, particularly to limit transmission in individuals already infected with HIV. The World Health Organisation estimates that of the 9.15 million tuberculosis cases annually, only half of the cases are reported. Several novel and improved technologies have recently been developed to improve diagnosis. However, they have not been adequately tested in field trials. In contrast to other infectious diseases, there are currently no commercially available, accurate and validated point-of-care (POC) tests for TB. Therefore, in 2009 EDCTP issued a call for research proposals to address this problem. The response to this call resulted in three TB diagnostics projects. The African-European Tuberculosis Consortium (AE-TBC) study started recruitment in November 2010 and is ongoing. The other two projects, studies evaluating new and emerging diagnostics for childhood TB in high burden countries (TB CHILD) and studies to evaluate multiple novel and emerging technologies for TB diagnosis, in smear-negative and HIV-infected persons (TB-NEAT), started enrollment of patients in April 2011.

AE-TBC

The African-European Tuberculosis Consortium (AE-TBC) is composed of seven African and five European institutions. Its objective is to develop new, sensitive, inexpensive and field-friendly TB diagnostic tests. The study is ongoing and aims to recruit 800 HIV-negative and 400 HIV-positive adults with suspected TB in order to evaluate the ability of a multi-marker test to identify active disease. This study is the first EDCTP project to have a clinical trial site in Namibia.

TB CHILD

The TB CHILD study conducts evidence-based clinical evaluation studies on new and improved TB diagnostics in order to find sensitive, fast and affordable tools. The clinical evaluation trial focuses on childhood tuberculosis with a recruitment target of 600 children between 16 weeks and 14 years of age. A second study of early evaluation in adults is also being conducted. The collected evidence-based evaluation data will go beyond conventional diagnostic accuracy. The analysis will also look at accuracy of diagnostic algorithms (beyond single tests); impact of new tests on routine clinical decision-making and potential contributions to the health care system. There are three clinical trial sites: two in Tanzania and one in Uganda. Enrolment of patients for both studies started in April 2011.

TB-NEAT

The EDCTP-funded TB-NEAT consortium, led by Prof. Keertan Dheda, seeks to facilitate the development of POC tests for TB and to validate new technologies in day-to-day clinical primary-care practice in Africa. The project is to evaluate these new technologies for TB diagnosis in smear-negative, HIV-infected persons in countries highly afflicted by HIV and TB. The grant includes four main studies and three sub-studies. At the same time the grant will establish high-quality field testing sites and biobanks, and train African scientists.

Xpert MTB/RIF

As part of the TB-NEAT consortium, the team of EDCTP Senior Fellow Prof. Mark Nicol (University of Cape Town, South Africa) concluded a study of the impact of the Xpert MTB/RIF test at clinic and patient level. Already in 2010, the preliminary results were a substantial component of a report submitted to the WHO Strategic and Technical Advisory Group (STAG) for TB that endorsed the use of the test for diagnosing tuberculosis. The test is a cartridge-based, automated diagnostic test called the GeneXpert MTB/RIF. It utilises a real-time polymerase chain reaction (PCR) amplification system that processes an integrated specimen and is designed for use at or close to the point of care. In April 2011 *The Lancet* published an article with Prof. Nicol as one of the authors, which demonstrated that the test can be used effectively in resource-poor settings to simplify early and accurate diagnosis of patients for TB and rifampicin resistance. The potential impact is a reduction in the morbidity associated with diagnostic delay, dropout and mistreatment. The overall study of the effectiveness of the test comprised sites in South Africa, Uganda,

Azerbaijan, India, the Philippines and Peru. It was funded by the Foundation for Innovative New Diagnostics, the Bill & Melinda Gates Foundation, EDCTP, the Wellcome Trust and the UK Department for International Development.

TB treatment

Pan-African Consortium for Evaluation of Antituberculosis Antibiotics (PanACEA)

The current standard TB treatment takes six months to complete and many patients do not complete their prescribed treatment. This leads to treatment failure and potentially to emergence of drug resistant strains of the bacterium. Therefore, new anti-TB drugs with shorter treatment regimens are urgently needed.

EDCTP has granted funding to a consortium of three European universities and 12 African clinical trial centres, providing an overarching structure for three treatment development programmes. This Pan African Consortium for Evaluation of Antituberculosis Antibiotics (PanACEA) aims to shorten and simplify TB therapy. It integrates the clinical studies and the development of the required registration-quality clinical trial capacity at 12 sites in sub-Saharan Africa. The long term goal is to establish a sustainable framework for clinical trials of TB drugs.

The three projects under the umbrella of PanACEA are:

1) REMox: the rapid evaluation of Moxifloxacin in tuberculosis, under the medical responsibility of University College of London (United Kingdom);
2) SQ-109: the evaluation of a novel TB drug (SQ109), under the medical responsibility of the Department of Infectious Diseases and Tropical Medicine, University of München (Germany);
3) HIGHRIF: the rapid evaluation of high dose rifampicin and other rifamycins in tuberculosis, under the medical responsibility of the Medical Centre of the Radboud University Nijmegen (The Netherlands).

REMox

The REMox study is part of the global REMox clinical trial which aims to establish the efficacy of a possible new drug against tuberculosis in order to reduce treatment time from six to four months. The study is

coordinated by Prof. Stephen H. Gillespie of St. Andrews University in Scotland, and sponsored by the TB Alliance. EDCTP funded part of the REMox study that is conducted in Africa which constitutes approximately 70% of the total number of study patients. By the end of 2011 enrolment of patients was almost completed. Further data on cure rate will be collected during a follow-up period for patients of 18 months.

This is a three-arm, double-blind phase III study in which moxifloxacin substitutes for two different drugs in the current first-line standard TB therapy, ethambutol and isoniazid, and is administered for a total of four months. REMox will determine whether either of these two new, four-month regimens are not inferior to standard six-month therapy in terms of failure and relapse. As part of the study, the capacity development component for African clinical trial centres to perform studies to the highest international regulatory standards was significantly scaled up for Kenya (Nairobi), Tanzania (Moshi and Mbeya), Zambia (Lusaka) and at several sites in South Africa. Training has been an integral part of the project; courses in Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP) are provided to all sites on a regular basis.

This project is jointly funded by EDCTP, the Bill & Melinda Gates Foundation, Irish Aid, the Netherlands Organisation for Scientific Research, the Medical Research Council United Kingdom, the United Kingdom Department for International Development (DIFID), and the United States Agency for International Development (USAID). The pharmaceutical companies Bayer Healthcare AG and Sanofi provided the trial drugs and other support. EDCTP has contributed a total of € 7.43 million to REMox since 2005 and will continue supporting the study with a further € 1.59 million through 2012 and into 2013. The total project value of the global REMox TB trial is € 28.10 million.

RIFAQUIN

Under the same grant scheme to promote simplification and shortening of TB treatment, EDCTP funded the RIFAQUIN study, led by Dr Amina Jindani (St George's University of London, United Kingdom). The trial aims to compare a standard control regimen with two alternative treatment regimens in which isoniazid is substituted with moxifloxacin and the standard dose of rifapentine is doubled in the continuation phase (1200 mg instead of 600 mg). The two studied regimens differ in the duration of treatment in the continuation phase (2 and 4 months). The study completed enrolment of patients in 2011.

TB vaccines

The current tuberculosis vaccine BCG shows incomplete and variable efficacy in preventing the disease in infants and children, especially in the immunocompromised populations. Moreover, it does not protect adults from developing tuberculosis. A number of novel candidate TB vaccines have been developed and now have to be tested in phase II and phase III trials over the course of the next decade. To produce robust results, efficacy trials will have to be conducted at multiple sites involving patients from different populations. Each participating site would need to possess or develop regulatory-quality capabilities. Therefore, capacity building is an important part of the EDCTP-funded TB vaccine studies.

In 2011, one of the preparatory projects for TB vaccine clinical trials in Kenya led by Dr Anja van 't Hoogt was successfully completed. This project involved prospective epidemiological studies of TB in neonates and adolescents in preparation for future clinical trials in Kenya. A similar project led by Dr Philippa Musoke is still ongoing in Uganda. EDCTP is also funding clinical trials of the two currently most advanced candidate tuberculosis vaccines: the AERAS 402/ Crucell Ad35 study and the TB-021 project to study the efficacy of MVA85A/AERAS-485.

AERAS 402/Crucell Ad35

The EDCTP-funded multicentre phase II trial of a new TB vaccine in African infants aims to evaluate the immunogenicity and efficacy of the Crucell recombinant Ad35 vaccine in HIV-uninfected infants. The AERAS 402/Crucell Ad35 study was initially led by Prof. Gregory Hussey and is now coordinated by Dr Hassan Mohamed (South African TB Vaccine Initiative, University of Cape Town, South Africa). This project has a major capacity development component aimed at ensuring that four distinct trial sites in sub-Saharan Africa develop the requisite infrastructural capacity to conduct phase IIB and phase III trials of new TB vaccines within the next five years: the South African Tuberculosis Vaccine Initiative (South Africa), the KEMRI/CDC field research station in Kenya, the Manhiça Health Research Centre in Mozambique, and the Kampala field site of Makerere University in Uganda.

MVA85A/AERAS-485

This trial is evaluating whether a new tuberculosis vaccine MVA85A will boost immunity and reduce illness from TB. It is testing this vaccine candidate in approximately 1400 adults age 18-50 infected with HIV. People infected with HIV are at far greater risk of developing TB disease than HIV-negative people. In August 2011 Aeras and the Oxford-Emergent Tuberculosis Consortium (OECT), as study sponsors, announced the start of this phase IIb proof-of-concept efficacy trial as enrolment of volunteers commenced in the Senegal site. This study is led by Dr Martin Ota of the Medical Research Council in The Gambia.

The trial is conducted at two sites: in Dakar, Senegal, by the Laboratory for Bacteriology-Virology of University Hospital Centre Aristide Le Dantec, and in Khayelitsha, South Africa, by the Institute of Infectious Disease and Molecular Medicine of the University of Cape Town. 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.

Malaria

Since 2007 a scale-up of joint malaria control and prevention intervention measures have saved many lives, but the burden of disease remains significant. According to the World Health Organisation World Malaria Report 2011, 655,000 people died from malaria in 2010, mostly in sub-Saharan Africa (91%), most of them children under five years of age. The growing risk of resistance against effective antimalarial drugs is one of the threats to the international goal to eliminate malaria deaths by 2015. EDCTP contributes to the fight against malaria by funding research into the clinical development of new drugs and drug combinations and candidate vaccines. As at 31 December 2011, the total funding for the 34 EDCTP malaria projects amounted to € 76.2 million. EDCTP projects include studies of both artemisinin based combination therapies (ACTs) and non-ACTs, aiming at establishing therapies that are safe and highly effective in real world situations. Ongoing studies involve special patient groups such as infants, malnourished children, HIV/AIDS co-infected individuals and pregnant mothers. Further, EDCTP supports clinical research of candidate malaria vaccines, specifically viral vectored combination vaccines (AdCh63 ME-TRAP prime and MVA ME-TRAP boost) and a MSP3-GLURP fusion protein malaria vaccine (GMZ2). Moreover, all these projects reflect the EDCTP strategy of integrating regulatory quality research with investment in clinical capacity development and expanding research networks in sub-Saharan Africa.

Malaria treatment

Malaria in pregnancy trial

One of the EDCTP-funded Malaria in Pregnancy studies made tremendous progress in 2011 and reached a major milestone of completing recruitment in January 2012. By then, the Malaria in Pregnancy Preventive Alternative Drugs (MiPPAD) study had enrolled a total of 4,734 pregnant women, after screening 17,947 women in Benin, Gabon, Mozambique and Tanzania. These studies led by Prof. Clara Menéndez (Barcelona Centre for International Health Research, Spain) evaluate the safety, tolerability and efficacy of an alternative drug for preventive treatment of malaria in pregnant women.

Malaria is an important cause of low birth weight which is a major determinant of infant mortality and a major cause of severe anaemia contributing to maternal mortality. The study is part of a global effort by the Malaria in Pregnancy (MiP) Consortium to find effective ways of preventing malaria in pregnant women and their infants. The MiPPAD study is evaluating the safety, tolerability and efficacy of mefloquine (MQ) as an alternative to the standard drug sulfadoxine-pyrimethamine used for Intermittent Preventive Treatment in pregnancy in combination with Long Lasting Insecticide Treated Nets. For this randomised, controlled trial HIV-un-infected pregnant women were recruited and are being followed up until their infants are one year old. It is conducted at nine sites in four countries: Benin, Gabon, Mozambique and Tanzania.

Several institutions support the MiPPAD project: the Barcelona Centre for International Health Research (Spain); the Université d'Abomey-Calavi (Benin); the Albert Schweitzer Hospital (Gabon); the Kenya Medical Research Institute/ Centers for Disease Control and Prevention (Kenya); the Manhiça Health Research Centre (Mozambique); the Ifakara Health Institute (Tanzania); the Vienna School of Clinical Research (Austria); the Institut de Recherche pour le Développement (France); and the Institute of Tropical Medicine and University of Tübingen (Germany).

The studies are cofunded by the Austrian Federal Ministry of Science (Austria); the Institut de Recherche pour le Développement (France); the University of Tübingen and the German Aerospace Center (Germany), the Carlos III Health Institute (Spain), and the Malaria in Pregnancy Consortium, which is funded through a grant from the Bill & Melinda Gates Foundation to the Liverpool School of Tropical Medicine (United Kingdom).

Treating children with severe malaria

The results for the SMAC studies on artesunate treatment for severe malaria in African children were published online at the *Journal of Infectious Diseases* on 16 December 2011. The Severe Malaria in African Children network (SMAC) phase II studies, coordinated by Prof. Peter G. Kremsner, have shown that treating seriously ill children with three doses over two days of the drug artesunate is as effective as with five doses over three days, the standard regimen. This alternative regimen would lower the risk of incomplete treatment, improve efficiency and reduce the cost of administering the treatment.

Through hospitals located in Gabon and Malawi the SMAC network enrolled 171 children aged between six months and ten years old. All children with severe malaria that fulfilled the study recruitment criteria were enrolled and randomised into two groups with different treatment regimens of intravenously administered artesunate. One group was given the current WHO recommended regimen of five doses over 72 hours and the other group given a slightly higher dose but only in three doses over 48 hours. All the children received the same overall quantity of artesunate. In all patients, parasite clearance occurred rapidly. The results showed that the 3-dose regimen was similar to the 5-dose regimen at clearing parasites. The next step in further improving treatment regimen is to explore the benefits of delivering artesunate intramuscularly instead of intravenously.

The SMAC network consists of five centres: the Albert Schweitzer Hospital in Lambaréné (Gabon); the Royal Victoria Hospital/Medical Research Council (MRC) Laboratories in Banjul (The Gambia); the School of Medical Sciences at the University of Science and Technology in Kumasi (Ghana); the Centre for Geographic Medicine (Coast) Kenya Medical Research Institute in Kilifi (Kenya); and the Queen Elizabeth Central Hospital in Blantyre (Malawi).The study was led by Prof. Kremsner at the Albert Schweitzer Research Centre in Lambaréné and Libreville (Gabon). The study coordination and management was done by Dr Carsten Köhler at the University of Tübingen.

The trial was cofunded by the Vienna School of Clinical Research (Austria); the Federal Ministry of Education and Research and the Bernhard Nocht Institute for Tropical Medicine (Germany); the Medicines for Malaria Venture (Switzerland); the Department for International cooperation and the St. George's University of London (United Kingdom); the GlaxoSmithKline Foundation (United States). The artesunate for injection was donated by the Walter Reed Army Institute of Research (United States).

4ABC study: Three new antimalarials safe and efficacious in children

The results of a large EDCTP-funded study comparing safety and efficacy of four new artemisinin-based therapy drugs have been published in *PLoS Medicine* on 8 November 2011. The Four Artemisinin-Based Combinations (4ABC) study group screened more than 10,000 children between 6 and 59 months old. A total of 4,116 children were included in the study and treated. Three novel artemisinin-based combination drugs were found to be safe and efficacious in treating children with uncomplicated malaria. The study was conceived to provide African Ministries of Health with reliable information on relative safety and efficacy of available ACTs. Its results supported the WHO recommendation of dihydroartemisinin-piperaquine (DHAPQ) as a treatment option for uncomplicated *Plasmodium falciparum* malaria.

The 4ABC study was coordinated by Prof. Umberto D'Alessandro (Institute of Tropical Medicine, Antwerp, Belgium, currently seconded at Medical Research Council unit in The Gambia). Its main objective was to compare the safety and efficacy of four artemisinin-based combinations (ACT): amodiaquine-artesunate (ASAQ), dihydroartemisinin-piperaquine (DHAPQ), artemether-lumefantrine (AL) and chlorproguanil/dapsone-artesunate (CD+A) for single and repeat treatment of uncomplicated malaria in African children. The study covered diverse epidemiological settings and balanced regional distribution in Africa. Children were actively followed up for 28 days and thereafter passively for an extra six months. PCR-adjusted efficacy of DHAPQ, AL and ASAQ, both at day 28 and 63, was high and similar among the three treatments, while CD+A was less efficacious. For the PCR-unadjusted efficacy, DHAPQ performed better, followed by ASAQ and then AL. CD+A had the lowest efficacy and this treatment arm was discontinued in 2008.

The study was conducted at 12 trial centres in seven sub-Saharan African countries: Burkina Faso, Gabon, Mozambique, Nigeria, Rwanda, Uganda, and Zambia. The Institute of Tropical Medicine (Belgium) was the study sponsor. The study was funded by EDCTP, and cofunded by the Belgian Directorate-General for Development Cooperation. Medicines for Malaria Venture (MMV) provided additional funding. The company Sigma-tau contributed DHAPQ and Sanofi-Aventis ASAQ.

WANECAM: Pyramax® sub-study started in Mali

The West African Network for Clinical Trials of Antimalarial Drugs (WANECAM) conducts studies which compare safety and efficacy of two new candidate antimalarial drugs with that of the existing ACTs that are the standard treatment for uncomplicated malaria in the region. The project is coordinated by Associate Professor Abdoulaye Djimdé of the University of Bamako (Mali). In October 2011 WANECAM started screening patients at a clinical trial site in Sotuba near Bamako, Mali, for its

pyronaridine-artesunate sub-study. Pyramax® is provided by Shin Poong Pharmaceutical Company Ltd (South Korea).

This is a multicentre phase IIIb/IV randomised, open label, three-arm clinical trial assessing the safety and efficacy of repeated administration of pyronaridine-artesunate (PA), dihydroartemisinin-piperaquine (DHA-PQP) or artemether-lumefantrine (AL) or artesunate-amodiaquine (ASAQ). Patient enrolment started in October 2011 and the total number of patients being randomised in each study arm will be 1344. The study involves sites in Burkina Faso, the Republic of Guinea and Mali and is expected to conclude in 2014. Moreover, this EDCTP project integrates capacity development in the conduct of the trial and aims to develop the regional capacity to conduct state of the art clinical trials. It provides for improvement of research infrastructure, development of research collaboration and training of medical and research staff, including three PhD and three Master's students.

Besides the clinical trial sites, a large number of research institutions contribute to this study: the Centre National de Recherche et de Formation sur le Paludisme (CNRFP) in Ouagadougou and the Institut de Recherche en Sciences de la Santé (IRSS) in Bobo-Dioulasso (Burkina Faso); the Medical Research Council (MRC) The Gambia in Fajara (The Gambia); the University of Bamako & Malaria Research and Training Centre (MRTC) in Bamako (Mali); the Centre National de Formation et de Recherche en Santé Rurale (CNFRSR) de Mafèrinyah in Conakry (Republic of Guinea); the Université Claude Bernard Lyon 1, Lyon (France); the University of Heidelberg (Germany), the Karolinska University Hospital, Stockholm (Sweden); and the London School of Hygiene & Tropical Medicine, London (United Kingdom).

The study is funded by EDCTP with cofunding from Medicines for Malaria Venture; the University Claude Bernard Lyon 1 (France); the German Ministry for Education and Research (Germany), SIDA (Sweden); the Medical Research Council (United Kingdom); CNRFP and IRSS (Burkina Faso), MRTC (Mali); and CNFRSR (Republic of Guinea). Additionally, four pharmaceutical companies are contributing to the project: Novartis, Sanofi, Shin Poong Pharmaceutical Company Ltd. and Sigma-tau s.p.a.

Malaria candidate vaccines

The two EDCTP Malaria Vaccine studies are included in the overview of malaria vaccine projects published by the World Health Organisation: the GMZ2 field study and the Malaria Vectored Vaccine Consortium (MVVC) study. The World Health Organisation – Initiative for Vaccine Research published an update of its malaria 'rainbow' tables in November 2011.

GMZ2 candidate malaria vaccine

The GMZ2 study, led by Dr Dawit Ejigu, developing a promising candidate malaria vaccine GMZ2, completed a phase Ib clinical trial in Gabonese children. Thereafter the consortium embarked on a multicentre phase IIb trial in Burkina Faso, Gabon, Ghana and Uganda. GMZ2 was developed by the Statens Serum Institut in Denmark. It is a fusion protein of *Plasmodium falciparum* merozoite surface protein 3 (MSP3) and a glutamate rich protein (GLURP) that mediates an immune response against the blood stage of the parasite.

The results of the phase I study were published by S. Bélard and others in the *PLoS ONE* journal in August 2011. GMZ2 proved to be safe, immunogenic and well tolerated in one to five year old Gabonese children. According to the authors, two phase I clinical trials, one in naïve European adults and one in malaria-exposed Gabonese adults showed that GMZ2 was well tolerated and immunogenic. Thirty children, one to five years of age, were randomised to receive three doses of either 30 µg or 100 µg of GMZ2, or rabies vaccine. GMZ2, adjuvanted in aluminum hydroxide, was administered on days 0, 28 and 56. All participants received a full course of their respective vaccination and were followed up for one year. Both

30 µg and 100 µg GMZ2 vaccine doses were well tolerated and induced antibodies and memory B-cells against GMZ2 as well as its antigenic constituents MSP3 and GLURP.

This result supported the multicentre phase IIb clinical trial that was implemented in Burkina Faso, Gabon, Ghana and Uganda. Vaccination was already underway at the trial site of the consortium in Gabon, the Medical Research Unit at Albert Schweitzer Hospital in Lambaréné (MRU-ASH), since November 2010. The other trial sites started and completed recruitment in 2011. A total of 1,870 children have received the three planned vaccinations. So far, all safety reports have been satisfactory and follow-up of the volunteers continues.

The GMZ2 consortium is funded by EDCTP and is composed of Centre National de Recherche et de Formation sur le Paludisme (Burkina Faso), the Statens Serum Institut (Denmark), the Medical Research Unit at Albert Schweitzer Hospital (Gabon), the Medical Research Council Laboratories (The Gambia), University of Tübingen (Germany), Navrongo Health Research Centre (Ghana), the African Malaria Network Trust (Tanzania), Makerere University (Uganda) and the London School of Hygiene and Tropical Medicine (United Kingdom).

MVVC: candidate vaccine antigen ME-TRAP

The Malaria Vectored Vaccine Consortium (MVVC), coordinated by Dr Egeruan Babatunde Imoukhuede (European Vaccine Initiative), conducts a clinical trial of AdCh63/MVA ME-TRAP. The phase I trial in Kenyan adults and children was undertaken at the KEMRI-Wellcome Trust Research Programme unit at Kilifi, Kenya. The phase I study with Gambian volenteers was undertaken at the Sukuta site near Banjul in The Gambia. If the phase I study results from Kenya and The Gambia fulfil the go/no-go criteria, the phase IIb study will be undertaken at two or three sites following a small lead-in safety study at each site. The sites are the University of Dakar in Keur Sossé, Senegal, the CNRFP Banfora in Burkina Faso, and the KEMRI-Wellcome Trust Research Programme site in Kilifi, Kenya.

The candidate vaccine antigen ME-TRAP acts at the liver stage, while AdCh63 and Modified Virus Ankara (MVA) are the vectors for this vaccine which is administered with the prime-boost strategy. Pre-clinical studies as well as completed and ongoing phase I clinical trials have found recombinant adenoviruses to be an effective means of inducing strong CD8 T cell responses that are known to be protective against liver-stage malaria. These immune responses may be enhanced by a boosting immunisation with the increasingly widely used MVA vector. These trials aim to evaluate the efficacy of a potent prime-boost combination of an adenovirus vector followed by an MVA vector in preventing clinical malaria.

The phase Ib trials in adults started in June 2010 in Kenya and The Gambia and thus far showed good safety and immunogenicity profiles. In preparation for the phase IIb trials, baseline epidemiological studies are being conducted in Burkina Faso and Senegal. In 2011, the trial site at the Sukuta Health Centre in The Gambia was refurbished and the new Keur Sossé Research Centre in Senegal was finished and fully equipped with EDCTP funding. Six scientists have already enrolled in long-term training programmes: one postdoctoral Fellow, three PhD candidates, and two MSc students. One of the PhD sub-studies will evaluate the impact of clinical trials on the quality of health care delivery.

The eight MVVC partners include academic institutions, collaborative research programmes, and a biotech spin-out: the Vienna School of Clinical Research (Austria); the Centre National de Recherche et de Formation sur le Paludisme (Burkina Faso); the Medical Research Council (MRC) Laboratories (The Gambia); the European Vaccine Initiative (Germany); biotechnology company Okairos (Italy); KEMRI-Wellcome Trust Research Programme (Kenya); the Université Cheik Anta Diop (Senegal); and the University of Oxford Centre for Clinical Vaccinology and Tropical Medicine (United Kingdom).

Supporting African research leadership

EDCTP aims to achieve sustainable capacity for conducting clinical trials by attracting, developing and retaining scientific leadership in Africa; improving and updating infrastructure and facilities, and strengthening the ethical and regulatory framework for conducting trials. This section presents the progress made in developing capacity through EDCTP's training awards, fellowship schemes and ethics grants.

Developing leading African researchers

As part of its capacity development, EDCTP aims to contribute to the development of a cadre of leading African researchers. In the initial phase of EDCTP, separate funding schemes for capacity development, apart from clinical trials, provided support for fellowships (Career Development and Senior), studentships (MSc and PhD), ethics and regulatory activities. In 2007 EDCTP revised its funding strategy and integrated the capacity development and networking activities with multi-centre clinical trials, forming Integrated Projects. EDCTP continues to offer Senior Fellowships to support researchers to build and lead research groups at sub-Saharan African institutions. In addition, training and capacity development are key components of the EDCTP Networks of Excellence, which host postgraduate students through their networks and run training courses and workshops.

Approximately 260 post-graduate students have been or are working towards their MSc and PhD degrees with the support of EDCTP at the end of 2011.

PhD training

EDCTP launched a call to support stand-alone PhD training for African scientists in 2005. Of the seven candidates who received awards, six have completed their studies and one is continuing. Two students completed their studies in 2011: Dr Yimer Getnet (Ethiopia) who undertook his PhD as part of collaboration between the Karolinska Institute (Sweden) and Addis Ababa University, and Dr Bornwell Sikateyo (Zambia), who completed the PhD at the London School of Hygiene and Tropical Medicine with the Anthropologies of African Biosciences Group. Dr Sikateyo is currently a Director for the Research Resource Centre of the Southern Africa Consortium for Research Excellence (SACORE) at the University of Zambia.

Career Development Fellowships

Under the 2005 call for proposals EDCTP supported five Career Development Fellowships (CDF). All the grantees had completed their projects by 2011. Several of these EDCTP Fellows have been highly productive. An example is Dr Esperança Sevene, who conducted work in Mozambique on intensive safety monitoring of anti-malarial and antiretroviral drugs in pregnancy.

EDCTP support for postgraduate and postdoctoral degrees and studies

EDCTP grant scheme	MSc	PhD	Postdoctoral
Senior Fellowships	9*		38
Career Development Fellowships			5
PhD studentships		7	
MSc studentships and institutional support for MSc degree courses	41		
Networks of Excellence	44	9	3
Integrated Projects and Clinical Trials	71	79	19
Total number of trainees	165	95	65

Note: * these are MSc students supervised by EDCTP Senior Fellows.

Dr Sevene published eight peer-reviewed publications linked to this project and her work has contributed significantly towards informing policy decisions in this area.

Senior Fellowships

There have been ten Senior Fellowship calls since 2004 and these have resulted in the award of 38 Senior Fellowships (total grant value € 7,825,486) as of 31 December 2011, with an additional seven fellowships in the grant negotiation stage. By the end of December 2011, 14 fellows had completed their EDCTP projects. All 14 Senior Fellows who had completed their projects by 2011 remain active in research and are based in sub-Saharan Africa. Approximately 50% of these former Senior Fellows have obtained new funding from EDCTP as project coordinators and collaborators on large-scale grants.

The Senior Fellowship programme has been a highly cost-effective EDCTP investment for developing the careers of mid to senior level African scientists to become more competitive internationally and progress to obtaining larger grants. Some fellowships served as re-entry grants for African scientists returning from abroad and new research teams were built across all four sub-Saharan Africa regions. EDCTP had supported fellowships in 16 sub-Saharan countries by the end of 2011.

Gender balance

Gender balance is one of the concerns in evaluating applications for the funding of projects and EDCTP is proud to fund the scientific and medical work of so many women in its projects. In total, 54 out of 196 EDCTP-funded projects (28%) are led by female scientists as Project Coordinators.

Health research ethics and registration of clinical trials

The EDCTP ethics grant scheme

The EDCTP ethics grant scheme commenced in 2005 and by the end of 2011 a total of 54 grants had been awarded towards strengthening ethics capacity in sub-Saharan Africa with a total signed value of € 3,209,930. Thus far, 29 ethics projects have been successfully completed. The aim of the grants is to strengthen the ethics frame work capacity of sub-Saharan institutions and countries. This is with the ultimate aim of developing the appropriate human resource and infrastructure required to enable functional, competent, independent and sustainable ethics review boards in Africa.

In 2011, two ethics calls were launched, both of which aimed to support the establishment and the strengthening of African National Ethics Committees (NECs) and Institutional Review Boards (IRBs). The first call was launched on 15 February 2011 and the second in August 2011. Ten projects were approved for funding by the EDCTP General Assembly in November 2011 and were under negotiation by the end of 2011. For the August 2011 call a total of 28 applications were received, of which 25 were eligible for further review.

EDCTP sustains the ethics grant scheme, as effective and efficient ethics review of health research, including clinical trials, is essential to developing medicines, interventions and medical technologies in and for Africa. The funded projects fall into three categories: training projects, institutional development and networking.

Ethics training

The training of members of ethics committees or institutional review boards is supported, for instance through the development of online training programmes. Grants have been awarded to both African and European organisations such as the ERECCA (Enhancing Research Ethics Capacity and Compliance in Africa; http://t2000-05.sun.ac.za/erecca/index.html) online courses on Good Clinical practice and Ethics Research Ethics Review led by Prof. Keymanthri Moodley (University of Stellenbosch, South Africa); and TRREE for Africa (Training and Resources in Research Ethics Evaluation for Africa; http://elearning.trree.org) led by Professor Dominique Sprumont (Switzerland).

TRREE is a consortium of ethics experts from the South and the North. Since 2006, the consortium provides a web-based training programme on 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. TRREE currently provides free and open access to e-learning modules in English, French, German and Portuguese. National supplements provide an overview of local regulations relevant to research in Africa (Cameroon, Mali, Mozambique, Nigeria, Senegal and Tanzania).

Moreover, courses on Good Clinical Practice (GCP) and human subjects protection training are often part of larger projects, while more formal training courses resulting in a diploma or certificate have also been supported. For instance, ten members from the National Health Research Ethics Committee in Nigeria received support to obtain a diploma in research ethics. On the institutional level, the New HIV Vaccine and Microbicide Advocacy Society (NHVMAS) piloted a novel programme to train laypersons who are on Institutional Review Boards (IRBs). ICH Good Clinical Practice ethical review guidelines require Ethics Committees to have at least one lay member in their composition. These are expected not only to address the rights of research participants, but also the specific needs of their communities. Since the majority of laypersons have no training to engage with the research process, they often find it difficult to fulfil their role of research gatekeepers for their community. This project addressing this ethics gap was led by Dr Morenike Oluwatoyin Ukpong was successfully completed in January 2011. (Website: www.nhvmas-ng.org)

Establishing and strengthening institutions

Grants for support, establishment and strengthening of ethics capacity at both the institutional and national level form the second category. The purpose of these grants is to contribute to the establishment of independent and functional Institutional Review Boards and National Ethics Committees (NECs). For example, EDCTP funded a project that started in 2005, for the "Establishment and support of a National Ethics Committee in Gabon" led by Dr Pierre-Blaise Matsiegui. Today, the Gabonese NEC is leading initiatives on establishing a broader network involving Ethics Committees in Central Africa.

Through this grant scheme, ethics research committees have been established in countries with limited resources in this area, such as Benin, Democratic Republic of Congo, Liberia and Rwanda. Grants contributed to improving human capacity in ethics, infrastructure and office equipment. In many cases a website was set up to facilitate sharing of information, and documents essential to the operation of the ethics review committee such as Standard Operating Procedures and guidelines were prepared with reference to templates provided by the World Health Organisation.

In 2011, the Kenya Medical Research Institute (KEMRI) completed a project led by Dr Christine Wasunna which aimed to build capacity for independent ethics review and monitoring of KEMRI-approved studies and to improve research oversight. The project was implemented by KEMRI in

partnership with the Expert Committee on Clinical Trials of the Pharmacy and Poisons Boards (PPB ECCT). The project aims to establish internationally accepted ethics review standards at KEMRI and to provide a framework for auditing research approved by the KEMRI Ethics Research Committee (ERC) and PPB ECCT.

The ERC members and selected participants have undertaken several training courses in GCP/GCLP, clinical research monitoring and targeted training on ethics in social and behavioural science research. KEMRI is currently developing a registry for clinical trials in order to regulate approval and monitoring of all clinical trials taking place in Kenya, with joint financial support from EDCTP, KEMRI and PPB.

Reinforcing ethics capacity through networking

The objective of this third group of projects is to network, coordinate and thereby support national ethics initiatives. Examples in this category of ethics grants are the Southern African Research Ethics Network (SAREN) which aims at establishing a network of Chairpersons of sub-Saharan Research Ethics Committees, and the MARC (Mapping African Research Ethics and Drug Regulatory Capacity) project. (Website: www.researchethicsweb.org)

The MARC project provides an online, continuously updated map of Africa's health research ethics committees (RECs) and provides a web-based platform aimed at increasing contact and communication between these committees. A secondary objective is to map medicines regulatory authorities (MRAs) and facilitate contact between these authorities and research ethics review committees.

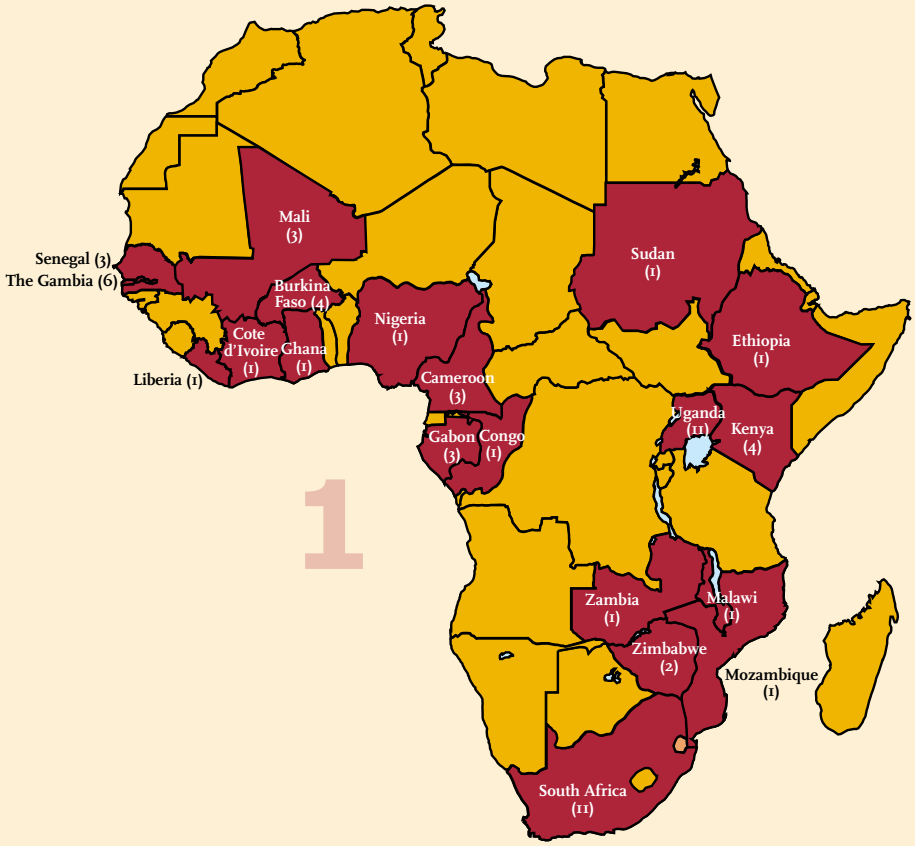
MARC is implemented through collaboration between the Council on Health Research for Development (COHRED) in Geneva, Switzerland and the South African Research Ethics Training Initiative (SARETI) at the University of KwaZulu-Natal, South Africa. The project is coordinated by Prof. Carel IJsselmuiden, Director of COHRED. In September 2011, MARC hosted the first African Conference for Administrators of Research Ethics Committees (AAREC). The meeting was hosted in Kasane, Botswana, and brought together 40 REC administrators from 21 African countries. By the end of 2011, MARC has mapped a total of 153 RECs in 33 African countries.

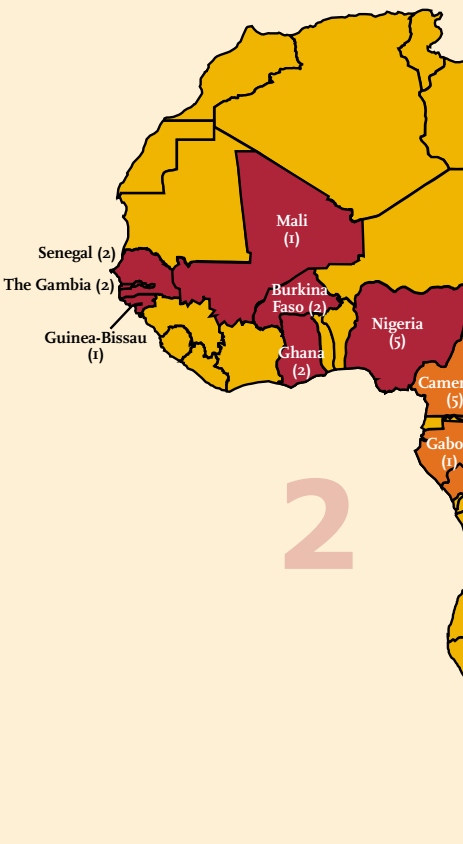
PACTR: Online interactive map of clinical trials in Africa

In August 2011, the Pan African Clinical Trials Registry (PACTR) officially launched a mapping component to its database of clinical trials. The fully searchable map provides a visual display of trial locations, as they are registered. This registry is now open to all randomised controlled clinical trials of all diseases conducted in Africa. PACTR is a member of the World Health Organization (WHO) Network of Primary Registers and funded by EDCTP. Its primary partners are The South African Cochrane Centre based at the South African Medical Research Council and The Cochrane Infectious Diseases Group based at the Liverpool School of Tropical Medicine. (Website: www.pactr.org)


NAKAVULE P/S
2006/07

EDCTP Capacity





1 Number of Senior Fellowships and training projects funded per country

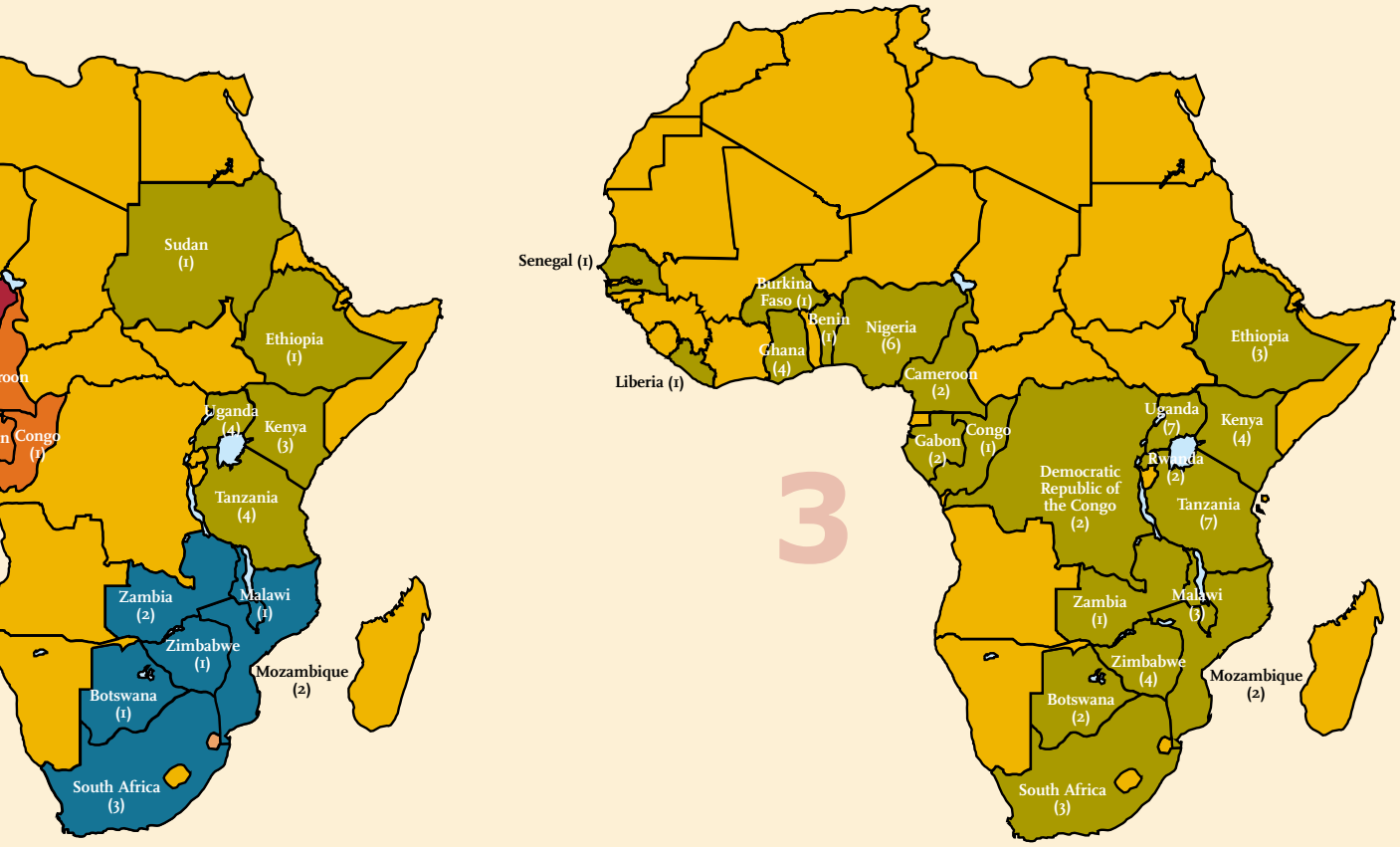
EDCTP supported capacity development activities in Africa include Senior Fellowships and training grants awarded directly to individuals (e.g. MSc studentships, PhD scholarships and Career Development).

The purpose of the Senior Fellowship grant scheme is to develop and retain qualified researchers capable of building and leading research groups at sub-Saharan institutions.

The figures do not include MSc, PhD and postdoctoral candidates supported as part of Integrated Projects.

2 Number of institutions collaborating in the EDCTP Networks of Excellence

The Networks of Excellence facilitate regional collaboration by uniting diverse institutions that bring their individual strengths (e.g. GCP, GCLP, data management and laboratory techniques) to the network. By collaborating they learn, develop capacity together, and thereby raise the quality of clinical research and practice in sub-Saharan Africa.



Western Africa: WANETAM

Project Coordinator: Prof. Soleymane Mboup
12 institutions in 7 sub-Saharan Africa countries

Central Africa: CANTAM

Project Coordinator: Prof. Francine Ntoumi
6 institutions in 3 sub-Saharan Africa countries and
1 institution in 1 European country

Eastern Africa: EACCR

Project Coordinator: Prof. Pontiano Kaleebu
8 institutions in 5 sub-Saharan Africa countries and
8 institutions in 5 European countries

Southern Africa: TESA

Project Coordinator: Dr Alexander Pym
9 institutions in 6 sub-Saharan Africa countries and
6 institutions in 5 European countries

3 Number of ethics projects funded per country

The aim of the ethics grant scheme is to strengthen the ethics framework of sub-Saharan institutions and countries. The ultimate aim is to develop the appropriate human resource and infrastructure required to enable functional, competent, independent and sustainable ethics review boards in Africa.

EDCTP has awarded a total of 64 grants for projects to strengthen ethics capacity in 21 countries in sub-Saharan Africa. Five ethics grants are coordinated from European countries (Austria, Switzerland and United Kingdom).

Building networks

Networking in Europe

In 2011, the EDCTP General Assembly (GA) supported the networking of member states' activities and furthered the mission of EDCTP through advocacy activities and increased communication with the relevant national and institutional research bodies. EDCTP attended several national meetings at the invitation of GA members. These included workshops, symposia or conferences relating to current national programmes or future initiatives in France, Germany, the Netherlands, Norway, and Sweden amongst others. These meetings provided advocacy and networking opportunities and framed the contribution to EDCTP in the context of national commitments to alleviating the burden of poverty-related diseases. In addition to providing a platform for advocacy in partner countries, the GA members also represented EDCTP directly at international meetings. Furthermore, the GA members facilitated introductions to prospective national partners active in related fields such as international cooperation and development and highlighted opportunities for collaboration with existing projects.

Among other conferences, EDCTP contributed to the Sixth Conference of the International AIDS Society on HIV pathogenesis, treatment and prevention. This is the world's largest open scientific conference on HIV/AIDS and was held in Rome, Italy from 17-20 July 2011. EDCTP Executive Director, Prof. Charles Mgone contributed to the special session hosted by the European Commission on the support of the European Union for HIV/AIDS research. His presentation discussed EDCTP as a model of Europe-Africa research partnership.

Private Sector

Private sector relations initiative

In 2011 EDCTP continued to forge close collaborations with like-minded organisations including other international funders, the pharmaceutical industry and Product Development Partnerships (PDPs). Through the years several large and small to medium size pharmaceutical companies have been involved in EDCTP-projects, mainly through providing investigational products and registered comparative products for specific clinical trials. In 2011, the EDCTP private sector relations working group led by the Executive Director, explored the possibilities of a broader and more direct involvement of the private sector in the EDCTP programme.

The working group contacted pharmaceutical companies to identify the major players engaged in EDCTP relevant research and other activities. In a second step, interviews with high-level representatives of large pharmaceutical companies and related industries such as Clinical Research Organisations, were conducted to identify barriers, challenges and opportunities for closer collaboration. The aim was to prepare for a workshop in 2012 to define a framework for stronger and broader public-private partnerships and an extended collaboration with the large pharmaceutical companies in the second EDCTP programme.

Private sector funding for CANTAM

The Central African Network on Tuberculosis, HIV/AIDS and Malaria (CANTAM), one of the EDCTP funded Networks of Excellence, was successful in attracting complementary funding from the private sector. Total Oil Company has committed a substantial yearly investment for a period of five years to support research activities within the network. The contract was signed in April 2011. This is the first health research project run by a local organisation to be supported by TOTAL E&P Congo.

Product Development Partnerships

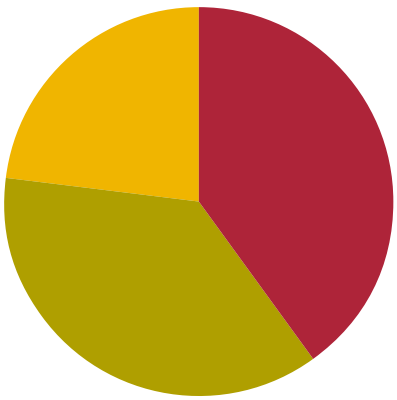
Product Development Partnerships (PDPs) are important EDCTP partners and are involved in many EDCTP funded projects, where they provide third-party funding, act as clinical trial sponsors and occasionally as clinical research coordinators. EDCTP has actively participated in PDP global activities such as the Annual Product Development Partnerships (PDPs) meeting organised by the Bill & Melinda Gates Foundation (BMGF) on 24-26 May 2011. This

meeting reviewed the current role, strategy and impact of PDPs in global health; discussed innovations in product development and funding mechanisms; and shared experiences of phase III studies.

As at 31 December 2011, PDPs were partners in 19 EDCTP funded projects and had committed approximately € 38.9 million towards these projects.

In 2011 EDCTP attended several stakeholder meetings and conferences organised by these partners. Additionally, to further enhance third-party collaborations, EDCTP included a special session for EDCTP partners in the programme of the Sixth EDCTP Forum.

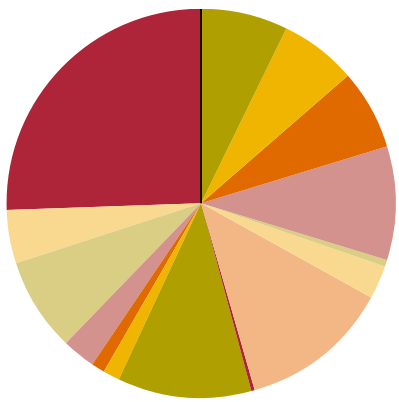
Funding contribution (expenditures and future commitment) to EDCTP supported projects: € 355.77 million



European Commission	€ 142.49M *
EDCTP Member States	€ 132.04M
Third parties	€ 81.24M

* Note: This figure includes a € 2.08 million FP7 contribution.

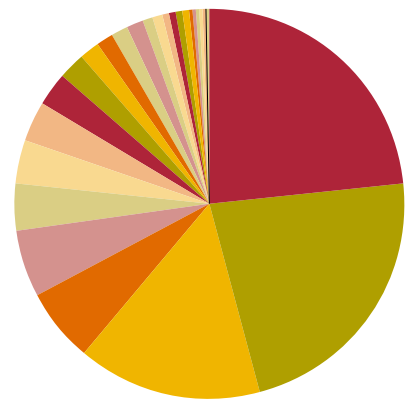
Member State total funding for research within the scope of the EDCTP programme, including cofunding of EDCTP projects, 2003-2011 (€ '000)



Austria	1,483
Belgium	50,897
Denmark	46,677
France	48,047
Germany	68,219
Greece	3,453
Ireland	19,972
Italy	90,302
Luxembourg	2,195
Netherlands	80,504
Norway	9,751
Portugal	7,584
Spain	19,260
Sweden	56,020
Switzerland	33,531
United Kingdom	182,309

Note: Amounts as reported by the Member States

Third-party funding to EDCTP activities for all types of contributions 2003-2011 (€ '000)



Bill & Melinda Gates Foundation (BMGF)	16,606
Global TB Alliance	15,948
Aeras Global TB Vaccine Foundation	10,642
Medicines for Malaria Venture	4,513
Sequella	3,876
Sanofi Pasteur & EuroVacc Foundation	2,800
Wellcome Trust	2,444
Foundation for Innovative New Diagnostics	2,375
European Vaccine Initiative (former EMVI)	1,975
International Partnership for Microbicides (IPM)	1,487
Bayer AG	1,200
FHI360	1,028
Jomaa Pharma GmbH	1,000
International AIDS Vaccine Initiative (IAVI)	920
Foundation for the National Institutes of Health	641
World Health Organization	631
Sanofi Aventis	376
Chiracon GmbH	355
CIPLA India	350
Delft Imaging Systems	300
Vecura Company	200
Walter Reed Army Institute of Research	178
Heidelberg Pharma	165
Merck Investigator Studies Program (MISP)	133
Okairos	110
Novo Nordisk	81
Other	350

Third-party funding

From the start of the EDCTP programme in 2003 to 31 December 2011, third parties have contributed € 46.2 million and committed an additional € 24.5 million to EDCTP-funded projects. The largest third-party funder is the Bill & Melinda Gates Foundation. The Foundation has contributed over € 11.3 million in cash to EDCTP projects involving research and capacity building in HIV vaccines, tuberculosis treatment and diagnostics in sub-Saharan Africa.

Networks of Excellence

TESA: Second annual meeting

The Trials of Excellence in Southern Africa (TESA) held its second Annual Meeting at the Centro de Investigação em Saúde da Manhiça (CISM) in Maputo, Mozambique from 23 to 25 February 2011. TESA is the first project of the Southern African Consortium. It is a collaborative effort of ten southern African research institutes and universities involved in clinical trials of HIV/AIDS, tuberculosis and malaria. The aim of the project is to build clinical trials capacity and infrastructure by mentoring and training the researchers, clinicians and laboratory technicians to conduct trials in line with ethical guidelines and Good Clinical Practices.

Participants from nine sites in six Southern African countries, namely Botswana, Malawi, Mozambique, South Africa, Zambia and Zimbabwe, were present. Some of the achievements of the first year of TESA were highlighted. TESA made remarkable steps forward in terms of human resources capacity development in 2011. During the two day meeting TESA partners made considerable progress in exploring new areas for research and clinical trials. For each disease a baseline study was defined and the supervision and training of Master's and PhD students were put in place. Strategies were established to seek regional and international funding; the network's sustainability was the focus of most discussions.

EACCR: Second annual meeting

The East African Consortium for Clinical Research (EACCR) convened its second Annual Meeting at the Kilimanjaro Christian Medical Centre (KCMC) in Moshi, Tanzania on 18 and 19 April 2011. The meeting was attended by 87 regional participants.

The objective of EACCR is is to strengthen the capacity to conduct clinical trials and other health research on malaria, tuberculosis and HIV/AIDS. The consortium currently focuses on training and mentoring as well as on upgrading research infrastructure. Thirty-four institutions in Ethiopia, Kenya, Sudan, Tanzania and Uganda are involved in the consortium. Its European partner institutions are in Germany, the Netherlands, Norway, Sweden and the United Kingdom. The Secretariat is located at the Uganda Virus Research Institute (UVRI) providing support to the four coordinating nodes for training (KCMC, Tanzania), malaria (KEMRI-Kilifi, Kenya), tuberculosis (NIMR-Muhimbili, Tanzania) and HIV (UVRI, Uganda).

EACCR secured four EDCTP Senior Fellowships and supported more than 20 Master's degree studentships in regional universities and long distance courses in the United Kingdom. Ultimately, the network aspires to provide a career platform for scientists funded and trained beyond the EDCTP programme. In June 2011, EACCR received three scientists who graduated with PhDs from the London School of Hygiene and Tropical Medicine (United Kingdom).

The Networks of Excellence at the Sixth Forum

In October 2011, the achievements, foreseeable challenges and potential solutions were discussed at the Sixth EDCTP Forum following updates from the four Networks of Excellence. These networks vary in their aims and mode of operation as well as in size. They encounter different problems, for example challenges attributed to language differences between the regions and level of existing capacity to support clinical trials activities. All presenters stressed their network's concerns to achieve long-term sustainability. The session involved considerable roundtable discussion. Many comments were made inter alia on the factors that hamper progress in both research and training/career development; the need to critically monitor success and progress in capacity building; and the challenge of networks sustainability. Questions were asked on several issues including the evaluation of the networks and maintenance of the networks beyond the grant period; and the value of networking. Despite the concerns expressed, it was universally agreed that the Networks of Excellence are a valuable part of EDCTP's strategy and should be further developed.

Networks of Excellence: next steps

As capacity development and partnerships in research networks are long-term endeavours, a joint meeting of the four Networks of Excellence was arranged during the Forum on 11 October 2011. The aim of this meeting was to facilitate the exchange of experiences and to discuss future priorities and conditions.
EDCTP will continue to support the Networks of Excellence in line with revised terms and conditions as part of the Coordination and Support Action Grant, part of the Seventh Framework Programme (FP7).The future plans of the Networks of Excellence are specific to the particular network and others are cross-cutting. Common to all the networks is the essential challenge to sustain what has been built so far, and to further strengthening these networks. Sustainability of the regional research capacity will have to be secured through new grants and support from different sources including the countries in which the networks are rooted. All four networks have invested in developing grant writing capacity, are in the process of developing sustainability strategies and exploring different fundraising approaches. Other activities prioritised are: improvement of communication among the network partners; systematic development of laboratories aiming at future accreditation; 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; continued investment in research infrastructure; and professional training.

Research funding

ESSENCE: harmonising research funding

EDCTP is an active member in the research funding platform ESSENCE (Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts), a new initiative to harmonise internationally funded research programmes. Harmonisation of donor practices and the prevention of unmanageable funding systems will benefit policy makers and researchers in sub-Saharan countries and will give them a stronger voice in determining the priorities of internationally-funded global health programmes.
ESSENCE made its first major step with the development of a framework document. A first pilot study in Tanzania will facilitate the dialogue between international donors and representatives from all Tanzanian health research institutes on how to harmonise international research funding to the country. In March 2011, ESSENCE joined the new Medical Education Partnership Initiative (MEPI) for Africa.
(Website: www.who.int/tdr/partnerships/initiatives/essence/en/)

Regional collaborations and policy meetings in Africa

EDCTP site visit to Malawi

As part of the ongoing advocacy activities as well as project follow up in the field, an EDCTP site visit to Malawi was conducted from 15-19 March 2011. The visit included a high level meeting with honourable Professor David Mphande, Minister of Health, and Dr Felicitas Zawaira, WHO Country Representative, and targeted EDCTP funded projects. The latter involved the College of Medicine of the University of Malawi in Blantyre and its peripheral research health centres in Mangochi and Chikwawa. The College of Medicine is the focal institution for the nine EDCTP funded projects with majority of them utilising the laboratories, clinical and teaching facilities of the Queen Elizabeth Central Hospital in Blantyre.

Research management at the College of Medicine is centralised and coordinated by a Research Support Centre. This collaborative set up is favourable as it ensures optimal use of research capacity and clearly contributes to the centre's success. Good collaboration exists between the College and research affiliates of northern institutions, especially the Malawi-Liverpool-Wellcome Trust which shares laboratory infrastructure and complements the training requirements of the College. The John Hopkins Research Programme facilities at the College are also part of the TESA Network of Excellence.

EAC Health Ministers sixth annual meeting in the Republic of Burundi

The Ministers of Health of the East African Community, Permanent Secretaries and senior government officials convened in Bujumbura, Burundi, for their sixth annual Sectoral Council meeting from 28 March-1 April 2011. EDCTP was represented at this meeting by Dr Michael Makanga, EDCTP Director of South-South Cooperation and Head of Africa Office and its programme discussed. The council advocated for stronger participation by the EAC Partner States in EDCTP projects and to enhance institutional capacity to conduct clinical trials under the East Africa Consortium for Clinical Research.

At April 2011, EDCTP funding for East Africa amounted to a total of € 45,291,404. The East African Community is an associated member of the EDCTP General Assembly and as such part of the governance of EDCTP.

EDCTP visit to Sierra Leone

Sierra Leone is one of the African countries where no EDCTP-funded projects take place. In June 2011, the EDCTP High Representative, Dr Pascoal Mocumbi, and Dr Michael Makanga visited Sierra Leone and held meetings with the Minister of Health and Sanitation, Honourable Zainab Hawa Bangura, the Deputy Minister and senior officials responsible for research and policy issues involving HIV/AIDS, malaria and tuberculosis. An additional meeting was held on the same day with the Minister of Education, Youth and Sports (also responsible for Science and Technology), Honourable Minkailu Bah, the Deputy Ministers, the Permanent Secretary and senior officials involved in health research training.

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 cooperation. 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 the EU funding programme FP7.

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, was one of the high level panel discussants.

Robert-Jan Smits, Director General for Research and Innovation, European Commission and Dr Michael Makanga, Head of the EDCTP Africa Office.

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

Robert-Jan Smits, EC Director General for Research and Innovation, visited an EDCTP funded field project on HIV/AIDS in South Africa 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 SASHA-project. At the Africa Office, the delegation met with Prof. Ali Dhansay, then acting President of the Medical Research Council of South Africa. 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, and to validate new technologies in clinical primary-care practice in Africa.

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 recognized 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. The aim is for the centres to form 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.

WHO-AFRO AACHRD meeting

From 17 to 19 November 2011 the African Advisory Committee on Health Research and Development (AACHRD) met in Brazzaville (Congo). EDCTP is one of the active partners of WHO-AFRO and was represented at the AACHRD meeting. The AACHRD was established by the World Health Organisation African Regional Office (WHO AFRO) in 1979 to advise the Regional Director on research related to health policies and development strategies. The main objectives of the meeting were to review the progress made on the implementation of the recommendations

of the Algiers and Ouagadougou declarations; to review the commitments of the Region within the context of the WHO Strategy for Health Research; and to review plans to attain the health research objectives of the WHO AFRO Strategic directions 2010-2015.

54th ECSA Health Ministers' Conference

The East, Central and Southern Africa Health Community (ECSA-HC) in collaboration with the Ministries of Public Health and Sanitation, and of Medical Services of the Republic of Kenya hosted the 54th ECSA Health Minister's Conference from 21-25 November 2011 in Mombasa, Kenya. Dr Thomas Nyirenda represented EDCTP and provided an update on EDCTP activities in ECSA-HC region. EDCTP has funded projects in ten of the fourteen member states of the ECSA Health Community to a total of almost € 102 million. The projects involve 80 research institutions, hospitals and clinics.

ICASA 2011

EDCTP participated in the 16th International Conference on AIDS and Sexually Transmitted Infections in Africa (ICASA) held in Addis Ababa, Ethiopia from 4-8 December 2011. EDCTP's model of funding HIV research and capacity development in Africa was presented. The session focused on the need for excellent biomedical research conducted in Africa for the African response to HIV and AIDS. EDCTP through its integrated clinical trials grants, integrates research, capacity development and networking. Moreover its regional Networks of Excellence are also contributing to this effort.


KCMC/DUKE/026/001

EDCTP Governance

EDCTP General Assembly meeting in November 2011.

In 2011 the EDCTP Secretariat welcomed five new members of staff including two new members of the management team. Mr Abdoulie Barry MBA (The Gambia) joined EDCTP as the new Director of Finance and Administration. He has extensive experience in financial management, auditing, installation of financial management systems and management of donor funded projects. Prior to joining EDCTP, Abdoulie Barry was Head of Finance and Procurement for the Medical Research Council (UK) The Gambia. He is a member of both the Chartered Association of Certified Accountants (ACCA) and Chartered Association of Management Accountants (ACMA).

Dr Pauline Beattie (United Kingdom) became the new EDCTP Operations Manager where she oversees the administrative process for EDCTP's core business, the funding of clinical trials. Prior to EDCTP, she was Science Portfolio Manager at the Wellcome Trust and gained extensive experience managing the funding, review and evaluation processes for research grants. She has an academic background in malaria research.

General Assembly in 2011: members and deputy members

Austria	Christiane Druml	Hemma Bauer
Belgium	Bruno Gryseels	Dirk van der Roost
Denmark	Søren Jepsen (Vice-Chair)	
France	Patrice Debré (Vice-Chair)	Bernadette Murgue
Germany	Joachim Krebser	Detlef Böcking
Greece	Evangelia Ntzani	Suzanne Kolyva
Ireland	Teresa Maguire	Diarmuid McClean
Italy	Stefano Vella	
Luxembourg	Carlo Duprel	
Netherlands	Marja Esveld (Vice-Chair)	Judith de Kroon
Norway	Arne-Petter Sanne	Kårstein Måseide
Portugal	Ana Maria Faisca	Catarina Resende
Spain	Rafael de Andres Medina	Tomaz-López-Peña Ordoñez
Sweden	Hannah Akuffo (Chair)	Olle Stendahl
Switzerland	Isabella Beretta	
United Kingdom	Mark Palmer	Morven Roberts

African Representation at the General Assembly in 2011

The African Union (AU) Commission of Social Affairs
Advocate Bience Gawanas, Commissioner Social Affairs of AU
(Alternate representative: Dr Olawale Maiyegun, Director for Social Affairs of AU)

The East African Community (EAC)
Ambassador Juma Mwapachu, Secretary General of EAC (replaced by Ambassador Dr Richard Sezibera, Secretary General of EAC)
(Alternate representative: Dr Stanley Sonoiya, Principal Health Officer of EAC)

The Economic Community of Central African States (ECCAS) and the Organisation for the Coordination of the Struggle Against Epidemics in Central Africa (OCEAC)
Dr Jean Jacques Moka, the Secretary General of OCEAC
(Alternate representative: Dr Marlyse Peyou Ndi, Head of Studies, Planning and Training Department of OCEAC)

The African Regional Committee of Health Ministers
Professor John Gyapong, Director Health Research Division, Ministry of Health, Ghana (now Pro-Vice-Chancellor (Research Innovation & Development) University of Ghana)
(Alternate representative: Dr Alasford M. Ngwengwe, Chairperson of the Zambian National Health Research Advisory Committee)

Partnership Board in 2011

Shabbar Jaffar (Chair)	United Kingdom (appointed in January 2011)
Martin Grobusch (Vice-Chair)	The Netherlands/Germany
Rosemary Musonda (Vice-Chair)	Botswana/Zambia
Christian Burri	Switzerland
Tumani Corrah	The Gambia
Opokua Ofori-Anyinam	Belgium
Eric Sandström	Sweden
Robert Sauerwein	The Netherlands

Developing Countries Coordinating Committee in 2011

Alioune Dieye (Chair)	Senegal
Nkandu Luo (Vice-Chair)	Zambia
Veronique Nintchom Penlap (Vice-Chair)	Cameroon
Abraham Alabi	Nigeria
Martin Antonio	The Gambia
Omu Anzala	Kenya
Herman Awono Ambene	Cameroon
Saadou Issifou	Gabon
Josephine Kibaru Mbae	Tanzania/Kenya
Mecky Isaac Matee	Tanzania
Modest Mulenga	Zambia
Angelique Ndjovi Mbiguino	Gabon
David Ofori-Adjei	Kenya (left in May 2011)
Jasper Ogwal-Okeng	Uganda
Jean Bosco Ouedraogo	Burkina Faso (appointed in May 2011)
Issa Sanou	Republic of Congo (WHO-AFRO)
Hulda Swai	South Africa/Tanzania

EDCTP Secretariat staff in 2011

Charles Mgone	Executive Director
Pascoal Mocumbi	High Representative
Simon Belcher	Director of Finance and Administration (left in April 2011)
Abdoulie Barry	Director of Finance and Administration (appointed in September 2011)
Michael Makanga	Director South-South Cooperation and Head of Africa Office
Waley Salami	Operations Manager (left in May 2011)
Pauline Beattie	Operations Manager (appointed in August 2011)
Thomas Nyirenda	South-South Networking and Capacity Development Manager
Christa Janko	Private Sector Relations Coordinator
Sophie Mathewson	Networking Officer (appointed in January 2011)
Montserrat Blázquez Domingo	Project Officer
Hager Bassyouni	Project Officer
Nuraan Fakier	Project Officer
Jean Marie Habarugira	Project Officer
Pete Murphy	Project Officer
Monique Rijks-Surette	Project Officer
Gert Onne van de Klashorst	Communications Officer (appointed in March 2011)
Daniela Pereira-Lengkeek	Assistant Communications & IT Officer
Lidwien van der Valk	Legal Advisor
Suzanne Ignatia	Human Resources Advisor (appointed in December 2011)
Chris Bruinings	Senior Bookkeeper
Mary Jane Coloma-Egelink	Grants Financial Assistant
Emma Qi	Grants Financial Assistant
Jing Zhao	Grants Financial Assistant
Sayma Siddiqui	Financial Assistant
Suzanne Hoogervorst	Travel and Events co-ordinator
Sanne Zoun	Travel and Events co-ordinator (left in August 2011)
Gail Smith	Senior Administration Officer
Patricia Sáez	Administration Officer
Nancy Kensmil	Administration Officer & HR Assistant (appointed in May 2011)

Summary financial statements 2011 and auditor's report

Statement of comprehensive income for the year ended 31 December 2011

Expressed in thousands ('000) of Euro

	Restricted EC 2011	Restricted Donor 2011	Total 2011	Total 2010
Income				
Contributions	11 541	24 800	36 341	59 001
Finance income	340	410	750	1 086
Total income	11 881	25 210	37 091	60 087
Expenditure				
Grants expenditure	(8 156)	(28 557)	(36 713)	(56 049)
Other expenditure	(3 547)	(571)	(4 118)	(3 947)
Governance expenditure	(257)	(119)	(376)	(331)
Total expenditure	(11 960)	(29 247)	(41 207)	(60 327)
Total comprehensive income for the year	(79)	(4 037)	(4 116)	(240)

All income and expenditure relates to continuing activities.

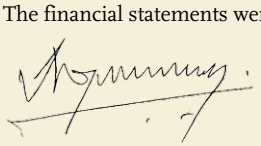
	2011 € 000	2010 € 000
Result attributable to:		
Restricted reserves EC	(79)	(49)
Restricted reserves Donor	(4 037)	(191)
	(4 116)	(240)

Statement of financial position as at 31 December 2011

Expressed in thousands ('000) of Euro

Assets	31 December 2011	31 December 2010
Non-current assets		
Property, Plant & Equipment	–	–
Debtors	7 714	17 272
Total non-current assets	7 714	17 272
Current assets		
Debtors and other receivables	21 046	22 244
Cash and cash equivalents	38 416	50 405
Total current assets	59 462	72 649
Total assets	67 176	89 921
Equity		
Restricted reserve: EC	(207)	(128)
Restricted reserve: Donors	3 917	7 954
Total equity	3 710	7 826
Non-current liabilities		
Grant payables	26 473	39 918
Total non-current liabilities	26 473	39 918
Current liabilities		
Grant payables	36 702	42 009
Other payables	291	168
Total current liabilities	36 993	42 177
Total equity and liabilities	67 176	89 921

The financial statements were approved by the Executive Secretariat on behalf of the EDCTP-EEIG General Assembly by:



Professor Charles Mgone

Dated 14 May 2012

Statement of Changes in Equity

Expressed in thousands ('000) of Euro

	Restricted reserve: EC	Restricted reserve: Donor	Total
Balance as at 1 January 2010	(79)	8 145	8 066
Total comprehensive income for the year	(49)	(191)	(240)
Balance as at 31 December 2010	(128)	7 954	7 826
Total comprehensive income for the year	(79)	(4 037)	(4 116)
Balance as at 31 December 2011	(207)	3 917	3 710

EDCTP has no unrestricted reserves.

Statement of cash flows for the year ended 31 December 2011

Expressed in thousands ('000) of Euro

	Note	2011	2010
Cash flows from operating activities			
Result for the year		(4 116)	(240)
Adjustment for:			
Depreciation		0	0
Finance income		(750)	(1 086)
		(750)	(1 086)
(Increase) decrease in debtors and other receivables		10 756	(16 094)
Increase (decrease) in grant and other payables		(18 629)	2 125
Net cash flows from operating activities		(12 739)	(15 295)
Cash flows from investing activities			
Interest received		792	991
Net cash flows from investing activities		792	991
Net increase (decrease) in cash and cash equivalents		(11 947)	(14 304)
Cash and cash equivalents at 1 January		50 405	64 614
Exchange rate effects		(42)	95
Cash and cash equivalents at 31 December		38 416	50 405

Notes to the summary financial statements

Basis for preparation

The summary financial statements, including the 2010 comparative figures, comprising the statement of comprehensive income for the year ended 31 December 2011, the statement of financial position as at 31 December 2011, statement of changes in equity and statement of cash flows for the year then ended, have been extracted from the annual financial statements of EDCTP-EEIG for the year ended 31 December 2011. These financial statements have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union (hereafter EU-IFRS).

The summary financial statements omit the notes comprising the significant accounting policies and other explanatory information as required by EU-IFRS. Therefore, to obtain a full understanding of the financial statements, the summary financial statements should be read in conjunction with the annual financial statements from which the summary financial statements were extracted.

The annual financial statements can be obtained from the EDCTP website (www.edctp.org).

Independent auditor's report

To: the General Assembly of EDCTP-EEIG

The accompanying financial statements, which comprise the statement of comprehensive income as at 31 December 2011, the statement of financial position as at 31 December 2011, statement of changes in equity and statement of cash flows for the year then ended are derived from the audited annual financial statements of EDCTP-EEIG for the year ended 31 December 2011. We expressed an unqualified audit opinion on those annual financial statements in our report dated 14 May 2012. Those annual financial statements, and the summary financial statements, do not reflect the effects of events that occurred subsequent to the date of our report on those annual financial statements.

The summary financial statements do not contain the significant accounting policies and disclosures required by International Financial Reporting Standards as adopted by the European Union. Reading the summary financial statements, therefore, is not a substitute for reading the audited annual financial statements of EDCTP-EEIG.

Management's responsibility

Management is responsible for the preparation of a summary financial statements on the basis described in the basis of preparation.

Auditor's responsibility

Our responsibility is to express an opinion on the summary financial statements based on our procedures, which were conducted in accordance with Dutch Law, including the Dutch Standard on Auditing 810 "Engagements to report on summary financial statements".

Opinion

In our opinion, the summary financial statements derived from the audited annual financial statements of EDCTP-EEIG for the year ended 31 December 2011 are consistent, in all material respects, with those annual financial statements, as described in the basis of preparation note.

The Hague, 29 June 2012
KPMG ACCOUNTANTS N.V.

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European & Developing Countries Clinical Trials Partnership

Photo acknowledgement

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