



E D C T P



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EDCTP Secretariat The Hague

Postal address:

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

Visiting address:

Laan van Nieuw Oost Indië 300
The Hague, The Netherlands
Phone: +31 70 344 0880/0897
Fax: +31 70 344 0899
E-mail: info@edctp.org
Internet: www.edctp.org

Editors Simon Belcher, Ilona van den Brink, Charles Mgone

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European & Developing Countries Clinical Trials Partnership

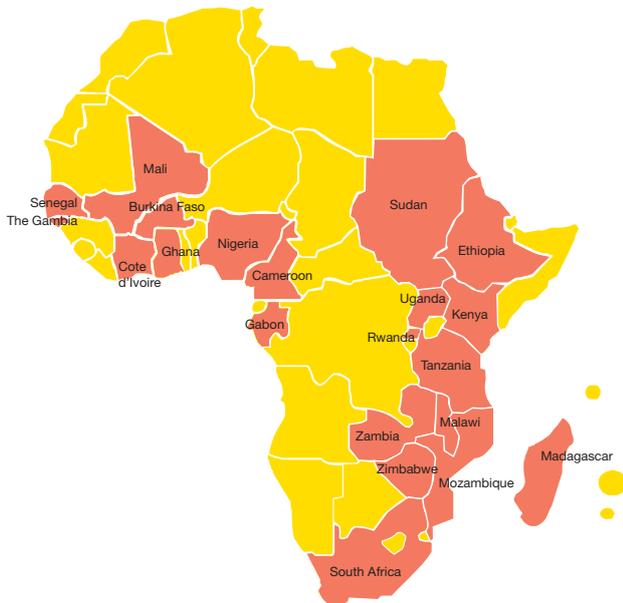


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About EDCTP

The European & Developing Countries Clinical Trials Partnership (EDCTP) was created in 2003 as a European response to the global health crisis caused by the three main poverty-related diseases of HIV/AIDS, malaria and tuberculosis. These diseases account for around 7 million deaths each year. Sub-Saharan Africa is the world's worst-affected region where besides ravaging lives, they impede development and cause poverty.



74 EDCTP-funded projects in 21 countries

Who we are

EDCTP is a partnership between European and sub-Saharan countries, aiming to reduce poverty by developing new or improved drugs, vaccines, diagnostics and microbicides to fight HIV/AIDS, malaria and tuberculosis. It unites 14 European Union (EU) Member States plus Norway and Switzerland with sub-Saharan African countries in a partnership. This partnership helps EU Member States to integrate and coordinate their national research programmes and form partnerships with their African counterparts.

What we do

The focus of EDCTP funded projects is on phase II and III clinical trials in sub-Saharan Africa. EDCTP supports multicentre projects which combine clinical trials, capacity building and networking. The aim of integrating these three components is to ensure that the developed capacity is utilised to successfully conduct the clinical trials using best practices. The utilisation of capacity and networking encourages capacity retention and proliferation, and thus ensures that sustainability for self-supported clinical trial research within Africa is most likely to be attained in the longer term.

EDCTP publications include

- Annual reports
- Forum reports
- Investigator's meeting report
- Joint Programme: EDCTP strategic plan for 2004-2008
- Corporate brochure 'Sharing the power of science: A strategy to do more and better'

All reports are available in PDF at www.edctp.org or in print through info@edctp.org

Partnership and networking

Many EU Member States and their partners in the developing countries have substantial research activities into HIV/AIDS, malaria and tuberculosis. By forming true partnerships, we can substantially improve coordination and efficiency of these activities, and create a win-win situation for all parties involved.



Responsibility

Forming partnerships means sharing responsibility. EDCTP strongly promotes sharing responsibility of both European and sub-Saharan African stakeholders, at all levels.



Best practices

EDCTP believes that joint effort is the most efficient and effective way to fight the three poverty-related diseases. Joint effort increases efficiency and avoids duplication. As a part of EDCTP's support of stakeholders of this joint effort, best practices will be made available to the public.



Mutual trust

Research into the three poverty-related diseases may increasingly operate as joint programmes with pooling of resources. Mutual trust between all parties involved at political, institutional and project level forms the basis for this joint effort.



Our values

Innovation

Relieving poverty calls for innovative action. On the one hand, joining research activities is an innovative way of encountering public health problems in sub-Saharan Africa. On the other hand, tools for the control of poverty-related diseases are few in number and often not adapted for use in resource-poor settings. Therefore, development of these tools should be accelerated.



Empowerment

Researchers in sub-Saharan Africa are faced with the need for multicentre protocols, a demanding regulatory environment and universal ethical standards. With the right resources and training, sub-Saharan African countries have the opportunity to take leadership and create a sustainable environment for conducting high-quality medical research.



Transparency

All stakeholders should be aware of the achievements of EDCTP and of the work of the EDCTP Secretariat.

EDCTP activities and findings arising from EDCTP projects will therefore increasingly be made public and available to everyone.

Word from Chair of General Assembly

During 2007, EDCTP has shown that our vision – a reduction of poverty in Africa through a unique partnership between European and African scientists and institutions including better coordination and integration of the national programmes of EU Member States aimed at developing and improving drugs, vaccines and diagnostics to fight HIV/AIDS, Malaria and TB – is achievable. New approaches to identifying key topics in each of the disease areas and ensuring other stakeholders are appropriately involved have been developed and implemented.

One example is the call for proposals for capacity development for clinical trial sites for HIV vaccines. This was set up and delivered in partnership with the Bill & Melinda Gates Foundation. EDCTP, the BMGF and the Member States each provided about € 7 M for the awards. Other subsequent calls in all three disease areas include funding from other partners – PPPs, PDPs and biotech companies – as well as the funding from EDCTP and the Member States.



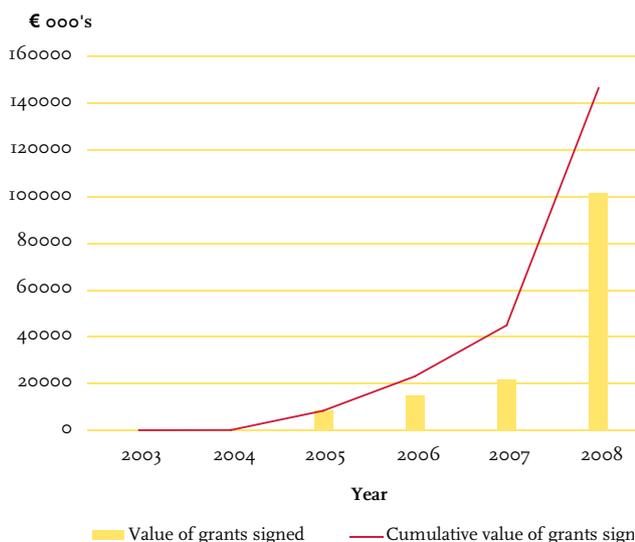
The partnership with African scientists and institutions has progressed well and our thanks for this achievement must go to all those involved with the Developing Countries Coordinating Committee (DCCC), the members of the Secretariat (especially those in the Cape Town office) and Pascoal Mocumbi. In fact the key to the progress made in 2007 is the real commitment and collaboration of all the components of EDCTP – the work done by members of the General Assembly, the Partnership Board, the DCCC, the Member States Networking Officers and most of all the Secretariat in both The Hague and Cape Town is greatly appreciated. In particular the leadership of our new Executive

Director, Charles Mgone, has been exemplary and has transformed EDCTP.

If we continue to progress in 2008 and beyond at the pace we have set in 2007, and I believe we will, then the future for EDCTP and the delivery of our aims is bright.

Diana Dunstan

Value of grants signed



Message from Executive Director

While closing the year 2006 and looking forward to the new year, we pledged that in 2007 EDCTP would Deliver More and Faster. Living true to that motto, EDCTP launched 11 calls totalling around € 90 M which is expected to be matched with an equal amount from European Member States and an additional sum from third parties. The calls covered various themes on the three major poverty-related diseases including drugs, vaccines, microbicides, capacity development, networking, ethics and regulatory issues.

In order to deliver more and faster efficiently, we started to offer integrated grants in which clinical trials are the core work package. The grants include capacity development, networking and project management as facilitating packages to ensure that the clinical trials are successfully conducted using the best practices. Additionally, this approach allows the developed capacity to be utilised appropriately and to be retained, and thus encourages both capacity retention and programme sustainability. Moreover, this way, capacity development offers an opportunity for practical training in conducting clinical trials.

2007 was also the year that we introduced yet another innovative approach by involving all stakeholders in deciding on the nature of calls and grants through stakeholder meetings. Based on the EDCTP Joint Programme, the Partnership Board (EDCTP's scientific and strategic advisory committee) developed a strategic plan and prioritised activities for the development of new or improved drugs, vaccines, microbicides and diagnostics for HIV/AIDS, malaria and tuberculosis. Using this strategic plan and priority list, each call was preceded by a stakeholder meeting to deliberate and decide on priorities and needs as well as to recommend on how to proceed with the call. The meetings involved all interested parties including members of the scientific community from sub-Saharan Africa, European Member States, private industry, like-minded organisations, policy makers, philanthropic organisations and other third parties.



The involvement and participation of the different stakeholders was very useful in harnessing the diverse expertise and contributions as well as fostering wide ownership of the partnership. This approach was very successful and it is now a norm in the EDCTP grant awarding process.

Among the highlights of 2007 was the Fourth EDCTP Forum that was held in October in Ouagadougou, Burkina Faso. The Forum has now established itself as a major event and perhaps the most prestigious and important platform for discussing poverty-related diseases in Africa. In view of this, it has been suggested that in the future the event

should always be held in Africa. Forum participants presented and discussed scientific papers, and discussed the future strategy of EDCTP. Participants suggested broadening the scope of EDCTP to include selected neglected diseases, public health services research, all phases of clinical trials (i.e. including phase I and IV) and expansion beyond sub-Saharan countries. These possibilities will be fully discussed in 2008.

There is no doubt that 2007 was a very eventful year for EDCTP. As 2006 was the year of strengthening African ownership and leadership, 2007 was the year of enhancing programme delivery and preparing for the future. As we look forward to 2008 and to the future, the strategy for 2008 will be to consolidate on the gains of 2007 and to start in earnest to prepare for the future. There is no doubt that the future looks very good for the Partnership.

Charles S. Mgone

Word from High Representative

The year 2007 was the year that EDCTP consolidated its partnership model. The Partnership forms the basis for sharing science to empower African research institutions and scientists to respond to their health needs. The EDCTP model of regional Networks of Excellence (NoE) was the flagship for my activities to advocate for and raise visibility of the Partnership. Nodes of Excellence are a powerful tool to engage health scientists and political leaders in Africa and in Europe to step up implementation of the Joint Programme and to mobilise additional support to scale up preparation of research centres to respond to the urgent need of developing clinical tools to effectively control the three major poverty-related diseases of HIV/AIDS, tuberculosis and malaria.

During visits to research centres in Ethiopia, Gabon, Kenya, Mozambique and Zimbabwe it was encouraging to note the support to EDCTP initiative expressed by high officials and political leaders. They were engaged in the preparation or implementation of their respective national science and technology strategies, and more importantly, support in kind or in funds was already channeled to most of the research sites visited.

My role as a World Health Organization Goodwill Ambassador for Maternal Newborn and Child Health, member of the Commission for Social Determinants of Health (CSDH), board member of the International Clinical Trials Registry Platform (ICTRP), the Alliance for Health Policy and Systems Research (AHPSR), the GHIV Vaccine Enterprise Coordinating Committee and other organisations offered valuable opportunities to reinforce continued collaboration of these organisations with the EDCTP Joint Programme. Specific progress was made in the interaction between EDCTP and WHO at its headquarters and in the African region (WHO/Afro), which helps strengthening the regulatory framework for clinical trials and the harmonisation of national regulatory authorities as well as in regulatory authorities' capacity strengthening.



Further highlights were a number of meetings that offered a platform for exploring synergies and complementarities. The INDEPTH/Malaria Clinical Trials Alliance (MCTA) Management Board meeting (Accra, Ghana, 10-11 January) presented the opportunity to encourage collaboration between EDCTP and INDEPTH/MCTA in research strategies to prevent and treat malaria by accelerating the development of effective and affordable malaria clinical tools. During the MRC-UK Strategic Review Meeting (London, 19 March) EDCTP Member States were encouraged to strengthen their commitment to improve funding to

the Partnership activities. The Council on Health Research for Development (COHRED) Board and Global Forum for Health Research Board joint meetings (Geneva/Chexbres, Switzerland, 23-25 April and Dublin, 12-14 December) resulted in a recommendation to strengthen collaboration between COHRED and EDCTP in view of the first ever Global Forum for Health Research in Africa, planned to take place in Bamako, Mali, November 2008. At the Lisbon meeting on "Health Dimensions of the EU-Africa Strategy" adopted at the Lisbon EU/AFRICA Summit 2007, EDCTP was identified as one of the implementation strategy priority areas under Science and Technology.

The year 2007 saw the expansion of EDCTP supported projects and acceleration of EDCTP operations capacity that greatly facilitated my advocacy activities. The environment is favourable for strengthening collaborative relations. It gives me great pleasure that in 2008 we can and will seize all the valuable opportunities to explore joint advocacy, synergy and complementarity with stakeholders and mobilisation of additional resources for fighting HIV/AIDS, tuberculosis and malaria.

Pascoal Mocumbi



Constituencies Joint Report

Partnership Board (PB)

The Partnership Board (PB) is a scientifically independent expert panel responsible for the strategic planning of EDCTP. The PB advises the General Assembly on technical and scientific matters relating to the EDCTP programme.

During the year 2007, the PB held a total of three meetings. As in the previous years' meetings, the PB advised on the design of various calls for proposals, discussed the results of proposal and project evaluation and the EDCTP roadmap. The meetings took place in The Hague (6 February and 22 June) and in Ouagadougou (24-25 October). At the Ouagadougou meeting, the PB brainstormed on the future of EDCTP under Framework Programme 7. One of the most specific activities of the year 2007 was the holding of the stakeholder meetings. The Board representatives attended all eight stakeholder meetings (two on malaria, two on TB, three on HIV, and one on Networks of Excellence).

At the end of June 2007, the contracts expired for PB members Dr Britta Wahren (Sweden), Dr Michel Klein (Canada) and Dr Bruno Kubata (Kenya). Following an advertised call for new members, EDCTP welcomed four new PB members in July 2007: Dr Christian Burri (Switzerland), Dr Eric Gunnar Sandström (Sweden), Dr Rosemary Mubanga Musonda (Zambia) and Dr Shabbar Jaffar (United Kingdom). At the GA meeting held on 28 June, the decision was made to reduce the PB to nine members from the end of 2007. In December 2007, the contracts of Prof. Patrice Debré (former Chair), Prof.

Souleymane Mboup (former Vice-chair) and Prof. Peter Smith (former Vice-chair) expired. Dr Sodiomon Sirima was appointed the new Chair. The new Vice-chairs Dr Eric Gunnar Sandström and Prof. Richard Adegbola were subsequently to be elected by the PB in January 2008.

Developing Countries Coordinating Committee (DCCC)

The Developing Countries Coordinating Committee (DCCC) is an independent advisory body of prominent African scientists and health professionals. The DCCC ensures the input and commitment from the African countries and researchers in the EDCTP programme.

In 2007, the DCCC held meetings in The Gambia, Cameroon, Cape Town, and Burkina Faso, and held two joint DCCC/ENNP meetings in Cameroon and Burkina Faso. The DCCC made great strides in ensuring the involvement and ownership of EDCTP by the scientific community and leadership from developing countries (DCs), especially from sub-Saharan Africa. A number of activities led to deliverables of which most will show their impact in the coming year. DCCC members participated actively in the organisation of the stakeholder meetings and the Fourth EDCTP Forum in Ouagadougou, where they presented and chaired several sessions and participated in making recommendations at these meetings.

DCCC members made significant input to call texts through the stakeholder meetings for malaria, HIV and tuberculosis



Prof. Patrice Debré

PB future outlooks

Following the progress made by EDCTP in 2007, the PB is set on monitoring the progress made by the individual projects. We want to see activity, and will therefore be closely involved in ensuring this will happen. The PB is also looking forward to the challenge of assessing applications for



Dr Sodiomon Sirima

Networks of Excellence. The concept of NoEs relating to EDCTP calls for proposals is a relatively new one, involving African multi-country applications. The success of Networks of Excellence is core to sustainability of conducting clinical trials in Africa. The PB therefore considers the NoEs as one of its primary goals for 2008.

as well as the Regional Networks of Excellence which were all released in 2007. The DCCC contributed significantly to capacity building, networking and ethics strategy, which were built into the encompassing strategy of Regional Networks of Excellence. Furthermore, DCCC members developed within this strategy sustainability of activities beyond EDCTP funding. The strategy is to develop both human and infrastructural capacity across Africa so that at the end of the programme, we will have sites that are fully functional and that can compete favourably for other funding opportunities. Regional Networks of Excellence are also envisaged to be a platform for conducting clinical trials, networking, mentorship, African ownership and cofunding.

The DCCC provided significant input to the PB strategy on various aspects of EDCTP. With respect to networking, the DCCC worked closely with the ENNP to ensure that North-South collaboration is strong and works to help realise the goals of EDCTP. The constant dialogue with all constituencies continues to add value to the contributions DCCC is making.

During the General Assembly meeting on 28 June, four DCCC members were appointed: Dr Christopher Kuaban (Cameroon), Dr J. Johnstone Kumwenda (Malawi), Dr Mecky Isaac Matte (Tanzania) and Dr Steven Velabo Shongwe (Swaziland).

European Network of National Programmes (ENNP)

The European Network of National Programmes (ENNP) consists of representatives of the European national programmes (European Networking Officers or ENOs). The ENNP develops proposals to coordinate and join the national programmes of the EDCTP Member States into a joint programme.

The ENNP met five times in 2007 and held two joint ENNP/DCCC meetings. European Networking Officers (ENOs) presented their respective national programme priorities and activities, and discussed possibilities of providing cofunding to the EDCTP calls for proposals and of enhancing Joint Programme Activities. The two joint ENNP-DCCC meetings held in 2007 were good opportunities to discuss the development, strengthening and sustainability of North-South Networking. In particular, the members of the two constituencies exchanged their views on the support of four Nodes of Excellence in Africa and the means by which African and European researchers can benefit from EDCTP grants to create, expand and maintain genuine sustainable partnerships.

The ENNP chair Laura Brum (Portugal) was re-elected for two years and a second vice chair was requested from the ENNP and approved by the GA. Claudia Herok (Germany) was elected and joined Dirk van der Roost (Belgium) as Vice Chair of the ENNP.



Dr Simon Agwale

DCCC Future outlooks

More avenues are required for the DCCC to source extra funding for EDCTP. This continues to be the indispensable pursuit of the Committee from other stakeholders including African national programmes or health budgets. A premise of hope is the fact that the African Health ministers have agreed to contribute 2% of their

national budgets to health research. A significant amount of money will therefore be available in Africa annually for health research. Some countries have started to implement this agreement, but there is a need to advocate that these funds are properly utilised.



Laura Brum

ENNP Future outlooks

The ENNP will continue to promote European Member States' commitment to EDCTP and to reinforce researchers' participation in the calls for proposals. The increase of Member State support in 2007 is very encouraging and provides a firm basis for further integration of European national programmes in 2008.



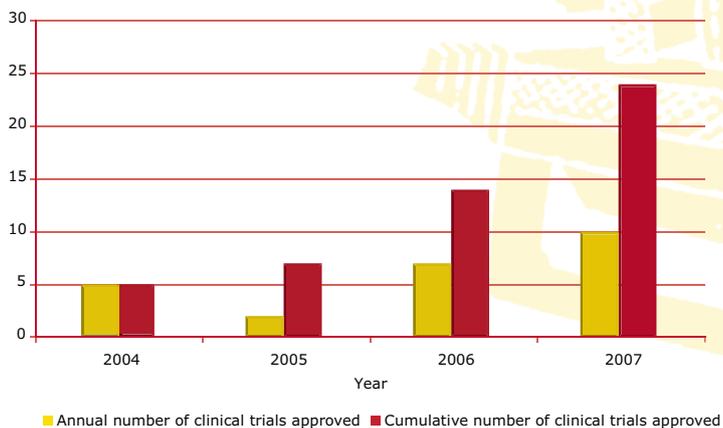
Calls of 2007

EDCTP successfully launched eleven calls for proposals in 2007 (listed in the table below). The launch of these calls was significant as it was the first time that EDCTP implemented its new design for project proposals: the “integrated proposals”. Previously all calls were launched separately by programme area. For example: clinical trials and networking were separate calls. Now integrated proposals are used to better achieve the EDCTP goals of accelerating the development of effective tools to fight HIV/AIDS, tuberculosis and malaria and of creating a sustainable research environment in Africa. These proposals have a clinical trial at the core of the project, and complement it with capacity building, networking and project management activities to support the implementation of the clinical trial and to create a sustainable environment for conducting future clinical trials.

Prior to the launch of the calls, several thematic stakeholder meetings were held with Member States, pharmaceutical industry and scientific experts. In these meetings EDCTP stakeholders informed on the current and future scientific directions, developments in the field of HIV/AIDS, tuberculosis and malaria, and made recommendations on research strategies.

Of the eleven calls that were launched, eight were calls for integrated proposals and three were on capacity building. The table on page 12 indicates the programme area, advertised budget, deadlines, number of applications received and the status of the review procedure.

Number of clinical trials approved



EDCTP calls for proposals 2007

Subject	Advertised Budget	Cofunding requirement	Deadline	Number of applications received	Status of review on 31 December 2007
Tuberculosis Vaccines	€ 9,000,000	EDCTP-MS are expected to at least match the EDCTP contribution for each call	5 November 2007	4	Scientific Review Committee (SRC) to be convened in January 2008
Tuberculosis Treatment (Brokering)	€ 14,000,000		Brokering meeting held in December 2007. Final proposal due March 2008	5	SRC to be convened in second quarter 2008
Malaria Vaccines	€ 14,000,000		19 November 2007	2	SRC to be convened in January 2008
Malaria Treatment	€ 9,000,000		19 November 2007	3	SRC to be convened in January 2008
Malaria in Pregnancy	€ 9,000,000		26 November 2007	3	SRC to be convened in January 2008
HIV Treatment	€ 6,500,000		1 April 2008	TBD	TBD
HIV Microbicide	€ 6,000,000		1 May 2008	TBD	TBD
HIV Vaccines	€ 7,000,000		31 May 2008	TBD	TBD
Senior Fellowships	€ 1,200,000		N/A	5 November 2007	19
Ethics and Regulatory Affairs	€ 450,000	N/A	5 November 2007	17	SRC to be convened in January 2008
Networks of Excellence	€ 10,000,000	N/A	5 December 2007	8	SRC to be convened in February 2008

Grant contracts signed in 2007

In 2007, eleven contracts were signed to a total of around € 20 M. The projects are on the following subjects:

- Capacity building in preparation for conducting preventive HIV vaccine trials
- Prevention of Mother-To-Child-Transmission (PMTCT) of HIV, including prevention of transmission during breast feeding
- Capacity building for the conduct of phase I/II and phase III trials of vaginal microbicides against sexual transmission of HIV

- Identification of safe and efficacious ARV in combination with tuberculosis drugs in tuberculosis patients with HIV infection
- Capacity building and site development for the conduct of phase III trials of TB vaccines in children under 1 year of age
- Capacity building and site development for the conduct of phase III trials of TB vaccines in high-risk populations (the last two calls were merged).

Below is a full overview of contracts that were signed in 2007, and their status as per 31 December 2007.

Grant contracts signed in 2007

Disease	Grantee	Project Title	Total Budget	EDCTP Funding	African and European Collaborator Countries	Clinical Trial Sponsor	Investigational Product	Status
HIV/ PMTCT	Katzenstein	Back-up with AZT/3TC or single dose FTC/TDF in order to avoid NNRTI resistance after single dose NVP for PMTCT	€ 1,270,988	€ 418,648	Tanzania, Denmark, Sweden	Copenhagen University Hospital, Rigshospitalet, Denmark	Zidovudine/ Lamivudine, FTC/TDF	To start in 2008
	Kisanga	Improving the balance between efficacy and development of resistance in women receiving single dose nevirapine	€ 1,508,335	€ 507,732	Tanzania, Zambia, United Kingdom, Netherlands	United Kingdom, Netherlands Radboud University Nijmegen Medical Center, Netherlands	Nevirapine, Carbamezapine	To start in 2008
	Newell	Impact of HAART during pregnancy and breastfeeding on MTCT and Mothers Health: The Kesho Bora Study	€ 2,711,378	€ 1,303,062	Kenya, South Africa, Burkina Faso, United Kingdom, France, Sweden	WHO's Department of Reproductive Health and Research, Switzerland	Nevirapine, Zidovudine, Lopinavir/ Ritonavir, Zidovudine/ Lamivudine	Ongoing

Grant contracts signed in 2007

Disease	Grantee	Project Title	Total Budget	EDCTP Funding	African and European Collaborator Countries	Clinical Trial Sponsor	Investigational Product	Status
HIV/BMGF	Kaleebu	Strengthening long term clinical and lab research capacity, cohort development and collection of baseline data in Uganda and Malawi for future vaccine trials	€ 4,312,814	€ 3,035,532	Uganda, Malawi, Netherlands, United Kingdom, Sweden, Ireland	Not applicable	Not applicable	To start in 2008
HIV/Microbicides	Van de Wijgert	Preparing for Phase II vaginal microbicide trials in Rwanda and Kenya: Preparedness studies, capacity building and strengthening of medical referral systems	€ 4,178,443	€ 2,000,000	Rwanda, Kenya, Belgium, Italy, Netherlands	Not applicable	Not applicable	Ongoing
	Hayes	Site preparation and capacity strengthening for trials of vaginal microbicides in Tanzania and Uganda	€ 5,138,534	€ 2,435,071	Tanzania, Uganda, Netherlands, United Kingdom	Not applicable	Not applicable	Ongoing
	Mc Cormack	Establishing HIV microbicides clinical trial capacity in Mozambique and expanding an existing site in South Africa	€ 6,716,810	€ 2,436,622	Mozambique, South Africa, United Kingdom, Spain	United Kingdom Medical Research Council	Not applicable	Ongoing

Grant contracts signed in 2007

Disease	Grantee	Project Title	Total Budget	EDCTP Funding	African and European Collaborator Countries	Clinical Trial Sponsor	Investigational Product	Status
TB	Bertilsson	Optimisation of tuberculosis and HIV co-treatment in Africa: Pharmacokinetic and pharmacogenetic aspects on drug-drug interactions between rifampicin and efavirenz	€ 2,086,052	€ 907,052	Ethiopia, Tanzania, Zimbabwe, Sweden, Germany	Karolinska Institute, Sweden	Rifampicin and Efavirenz	Ongoing
	van 't Hoog	Prospective epidemiological studies of TB in neonates and adolescents in Karemo Division, Siaya district, Western Kenya, in preparation for future vaccine trials	€ 32,628,120	€ 1,678,216	Kenya, Austria, Netherlands, Italy, South Africa	Kenya Medical Research Institute, Kenya	Not applicable	Ongoing
	Musoke	Toward conducting phase III trials of novel TB vaccines in Ugandan infants and adolescents	€ 5,599,287	€ 1,850,000	Uganda, South Africa, Sweden, Belgium, Netherlands	Not applicable	Not applicable	Ongoing
	Engers	Capacity building for the conduct of ICH-GCP level TB vaccine trials in high risk populations in Ethiopia and East Africa	€ 2,989,681 (SSI-project) € 2,175,425 (SSI-project)	€ 988,856 (SSI) € 203,400 (GSK)	Ethiopia, Madagascar, Denmark, Netherlands, Belgium, Tanzania	SSI GSK	ESAT-6/Ag85B (Statens Serum Institut), Mtb72F/ASo2A (GlaxoSmith-Kline)	Ongoing

Grant contracts signed before 2007

All projects for which contracts were signed before 2007 are ongoing. The projects relate to:

- Trials assessing the effectiveness and safety of simplified anti-retroviral drug regimens and monitoring in HIV
- Trials of studies of surrogate markers of drug efficacy emphasising non-clinical predictors and relapse following anti-tuberculosis therapy
- Phase II-III of drug regimens that shorten or simplify current treatment options in tuberculosis

- Phase II-III drug trials for the treatment of severe malaria using artemisinin compounds
- Phase II-III drug trials for the treatment of uncomplicated malaria using artemisinin compounds.

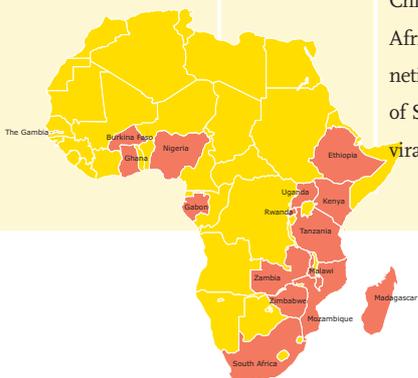
The table below provides an overview of these projects and their status as per 31 December 2007.

Grant contracts signed before 2007

Disease	Grantee	Project Title	Total Budget	EDCTP Funding	African and European Collaborator Countries	Clinical Trial Sponsor	Investigational Product	Status
TB	van Helden	Surrogate markers to predict the outcome of anti-tuberculosis therapy	€ 973,033	€ 973,033	South Africa, United Kingdom	Not applicable	Not applicable	Ongoing
	Gillespie	Rapid Evaluation of Moxifloxacin in the treatment of sputum smear positive tuberculosis: REMoxTB	€ 90,407,240	€ 3,157,240	South Africa, Tanzania, Zambia United Kingdom	University College London, United Kingdom	Moxifloxacin, Rifampicin, Pyrazinamide, Ethambutol, Isoniazid	Ongoing
	Jindani	A controlled clinical trial to evaluate high dose rifapentine and moxifloxacin in the treatment of pulmonary tuberculosis	€ 4,782,134	€ 4,251,991	Mozambique, Zambia, South Africa, United Kingdom, Tanzania	St. George's University of London, United Kingdom	Moxifloxacin, Rifapentin	Ongoing

Grant contracts signed before 2007

Disease	Grantee	Project Title	Total Budget	EDCTP Funding	African and European Collaborator Countries	Clinical Trial Sponsor	Investigational Product	Status
TB	Merry	Determining the optimal doses of antiretroviral and anti-tuberculous medications when used in combination for the treatment of HIV/TB in co-infected patients	€ 1,026,952	€ 1,026,952	South Africa, Uganda, United Kingdom, Ireland	University of Cape Town, South Africa	Efavirenz (EFV), nevirapine (NVP), lopinavir (LPV; with ritonavir) and ritonavir (RTV; with lopinavir) with rifampicin-based anti-TB therapy	Ongoing
Malaria	D'Alessandro	Evaluation of 4 artemisinin-based combinations for treating uncomplicated malaria in African children	€ 5,710,824	€ 2,111,714	Uganda, Nigeria, Mozambique, Burkina Faso, Gambia, Zambia, Rwanda, United Kingdom, Spain, Belgium, France, Denmark,	Institute for Tropical Medicine, Antwerp, Belgium	Amodiaquine / Artesunate, Dihydroartemisinin / Piperaquine (Artekin), Artemether / Lumefantrine (Coartem), Chlorproguanil-dapsone (Lapdap) / Artesunate	Ongoing
	Kremsner	Artesunate for severe malaria in African children	€ 6,736,620	€ 5,365,420	Gambia, Malawi, Ghana, Gabon, Kenya, United Kingdom, Austria, Germany	Not applicable	cGMP Intravenous Artesunic Acid	Ongoing
HIV	Chintu	CHAPAS Trials: Children with HIV in Africa: Pharmacokinetics and Adherence of Simple Antiretroviral Regimens	€ 1,280,333	€ 1,280,333	Zambia, Netherlands, United Kingdom, Italy	Medical Research Council, London, UK	Nevirapine / Stavudine / Lamivudine (Pedimune)	Ongoing



Countries with EDCTP supported clinical trials



Networking grants

In light of the change of the funding strategy of EDCTP the networking component will from 2008 be one of the four major sections in the application for integrated projects and will not be granted separately. Seven out of ten networking grants that EDCTP awarded in 2006 were completed in 2007. Financial and technical reports were received for those projects that were completed. Two projects will be carried over to 2008 and one grant on a distance learning MSc course in clinical trials is continuous. On page 21 is a table indicating the status of the networking grants that have been awarded until now.

South-South networking

DCCC meetings

The thirteenth DCCC meeting was conducted in Banjul (The Gambia) from 9 to 10 February. Among the important resolutions was an agreement to draft a position paper of how EDCTP should fund African Nodes of Excellence. DCCC members agreed that regional nodes had to be developed as a platform to accelerate clinical trials and capacity building in Africa. A stakeholder meeting to discuss this strategy took place in Cameroon on 8 May. Other issues discussed in Banjul included the DCCC contribution to an independent external review of EDCTP, the importance of stimulating African cofunding to the partnership and a compilation of an inventory of clinical trial sites in Africa.

The fourteenth DCCC meeting took place in Douala, Cameroon soon after the stakeholder meeting on Nodes of

Excellence on 10 May. At this meeting the DCCC resolved to work with PABIN on improving training on ethics in Africa, to request the GA to support their participation at African regional meetings where they will lobby for political support for the EDCTP programme, and to work with bodies like the Global Forum for Health Research and COHRED in demonstrating documented African contributions in research into three PRDs.

The fifteenth DCCC meeting, which took place on 21 September in Cape Town, South Africa, followed a networking meeting of potential applicants to the Networks of Excellence call. At this meeting the DCCC members discussed ways of encouraging scientists to group and apply for the NoE call for proposals. They also shared their vision on EDCTP's future and expressed the need to write a story of how EDCTP has moved from infancy to a unique organisation that is likely to deliver on building capacity and conduct of successful trials.

The sixteenth DCCC meeting took place during the Fourth EDCTP Forum on 25 October in Ouagadougou, Burkina Faso. At this meeting the DCCC resolved to encourage PABIN to conduct transparent election to gain confidence of African scientists. The second joint DCCC/ENNP meeting took place in Douala. Several issues ranging from improving understanding of cofunding issues among scientists and the importance of close collaboration between the two committees in shaping the EDCTP strategy were discussed. At the third joint meeting which took place at the Ouagadougou Forum the ENNP and DCCC agreed to work together in demonstrating Member State funding in African sites and producing a draft call for networking Member State projects funded outside the EDCTP channels.

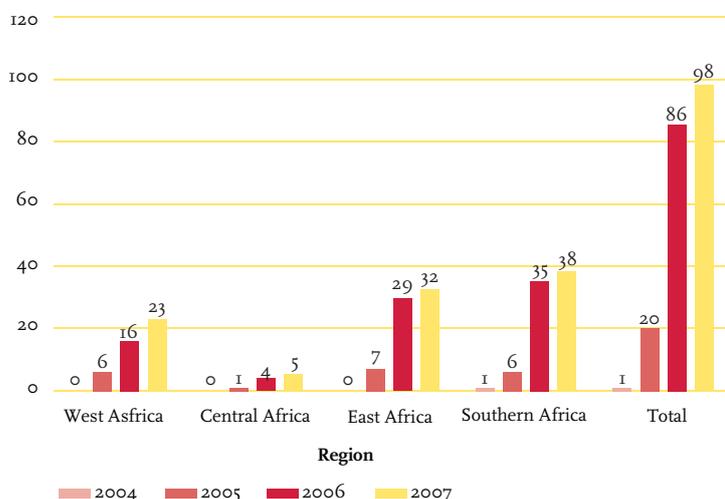
Support to the High Representative in South Africa

In October 2007, EDCTP's High Representative Dr Pascoal Mocumbi relocated to South Africa. This move reinforces the focus on engaging African leadership in the EDCTP programme. The HR's activities are supported by the Africa Office staff.

Stakeholder meetings on funding Nodes of Excellence

The stakeholder meeting on Nodes of Excellence (NoEs) took place in Douala, Cameroon, on 8 May. The meeting that was

African Institutes involved in EDCTP activities



chaired by Professor Nkrumah from Ghana and was attended by 38 participants, including PB members, European Networking Officers (ENOs), DCCC members, scientific experts, and Member State development agency or government representatives. The Duovala meeting recommended that EDCTP provide seed funding to enable potential African applicants to network and start writing joint proposals. A consecutive meeting took place at the EDCTP Africa Office on 20 September. EDCTP through the DCCC drew representatives from 29 participating institutions from all regions of Africa to this meeting. Other participants were members of the secretariat and representatives of the Wellcome Trust. The call for establishing Networks of Excellence worth € 10 M was launched on 1 August 2007 with a deadline of 3 December 2007.

Other meetings and highlights

Other highlights included a meeting on the acceleration of TB drug development organised by Médecins Sans Frontières in New York from 10 to 12 January. EDCTP also joined an INTERTB network meeting of investigators and other scientists held in Durban from 5 to 7 March. INTERTB is a consortium that received a networking grant. Its aim is to link scientists in sub-Saharan Africa to facilitate conduct of trials in TB treatment. Other meetings included the NEPAD meeting on Science, Technology and Innovations for public health in Entebbe from 23 to 24 July, the Wellcome Trust meeting on capacity building in African institutions in Cape Town from 14 to 16 November and the Fourth Forum of the African AIDS Vaccine Programme (AAVP) in Abuja from 26 to 30 November. EDCTP will continue to be involved in the meetings and activities of stakeholders and related organisations as a part of enhancing the network that can ensure a sustainable research environment in Africa.

North-North networking

ENNP meetings

The ENNP met five times in 2007 and held two joint ENNP-DCCC meetings. European Networking Officers (ENOs) presented their respective national programme priorities and activities, and discussed possibilities of providing cofunding to the EDCTP calls for proposals and of enhancing Joint Programme Activities. The two joint ENNP-DCCC meetings held in 2007 were good opportunities to discuss the development, strengthening and sustainability of North-South Networking. In particular, the members of the two constituencies exchanged their views on the support of four

Networks of Excellence in Africa and the means by which African and European researchers can benefit from EDCTP grants to create, expand and maintain genuine sustainable partnerships.

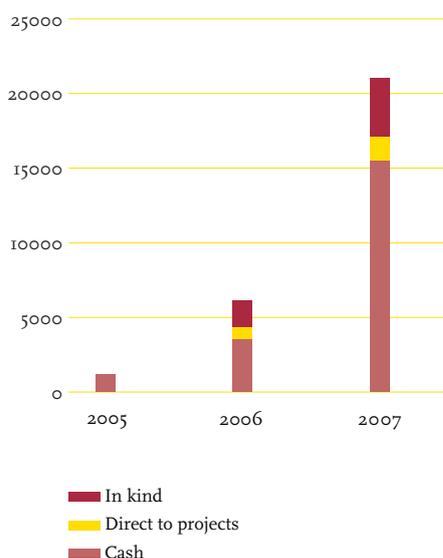
Visits to MS

To help promote a common European approach to EDCTP activities and its cofunding, the GA Chair, the Executive Director and the Joint Programme Manager accompanied by Member States' representatives have an ongoing programme of visits to Ministers and senior officials in the EDCTP-EEIG Member States. In 2007 EDCTP visited Austria, Germany, Spain, Sweden, and UK. The aim of these visits is to seek Member States' continued commitment and input on the future direction of the EDCTP programme, and to follow up on the letter that was sent to them by the EC Commissioner for Research in October 2007, encouraging the renewal of Member State political and financial commitment to EDCTP.

Cofunding

In 2007, the EDCTP-EEIG Member States participated in the EDCTP Programme by cash contributions to EDCTP (€ 15.3 M), direct cofunding of projects (€ 1.6 M) and in kind contributions to EDCTP projects (€ 3.9 M). In addition they also supported other national programme activities within the scope of EDCTP but not funded by EDCTP (€ 45.9 M). The Member States' total commitment for EDCTP projects that have started in 2007 accounts for an additional of € 30.8 M. Moreover, Member States have to date pledged a further € 35.9 M for cofunding of EDCTP calls being evaluated in 2008.

Member States Cofunding of EDCTP for the period 2005-2007

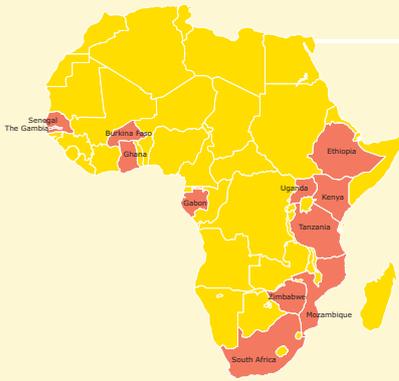


Status of networking projects per 31 December 2007

Grantee	Title	Budget	Location	Status per 31-12-2007
Colebunders, Institute of Tropical Medicine, Antwerp, Belgium	Workshop on Tuberculosis Immune Reactivation Inflammatory Syndrome (TB IRIS)	€ 19,450	Kampala (Uganda)	Completed
Hill, Liverpool School of Tropical Medicine, Liverpool, UK	A north-south working group to support the design integrated research proposals for malaria in pregnancy	€ 21,000	Liverpool (UK)	Completed
Temmerman, University of Ghent, Belgium	Strengthening laboratory capacity and nutrition skills in the context of an ICH GCP clinical trial for the prevention of mother-to-child transmission of HIV	€ 100,000	Mombasa (Kenya), Muraz (Burkina Faso)	To be completed in 2008
Navia, Fundació Clínic per a la Recerca Biomèdica, Spain	Ifakara-Lambarene-Manhiça Partnership	€ 99,000	Ifakara (Tanzania), Manhiça (Mozambique), Lamberene (Gabon)	Completed
Jindani St George's Medical College, London, UK	A proposal to establish a network of sites in sub-Saharan Africa to conduct clinical trials in tuberculosis and to build their capacity to participate in multicentre trials	€ 30,000	Durban (South Africa)	Completed
McCormack, MRC, UK	Identifying the common learning needs of investigators working in poverty-related diseases in African settings, and the materials to address these, notably in the areas of project and data management	€ 30,000	London (UK)	Completed
Kyabaynze, Regional Center For Quality of Health Care (RCQHC), Kampala, Uganda	KIDS-ART-LINC: network of clinical centres treating HIV-infected children with antiretroviral therapy in Africa to inform public health care and treatment programs	€ 30,000	Cape Town (South Africa)	To be completed in 2008
Merry Trinity College, Dublin, Ireland	Networking of European and sub-Saharan African research and capacity building in pharmacology	€ 32,770	Kampala (Uganda)	Completed

Status of networking projects per 31 December 2007

Grantee	Title	Budget	Location	Status per 31-12-2007
Aseffa, Armauer Hansen Research Institute (AHRI), Addis Ababa, Ethiopia	Strengthening the National Tuberculosis Research Network in Ethiopia	€ 26,150	Addis Ababa (Ethiopia)	Completed
Hall London School of Hygiene and Tropical Medicine	Masters courses in clinical trials for sub-Saharan Africa	€ 370,000	London (UK), Ouagadougou (Burkina Faso), Accra (Ghana)	Continuous



Countries with EDCTP supported networking activities



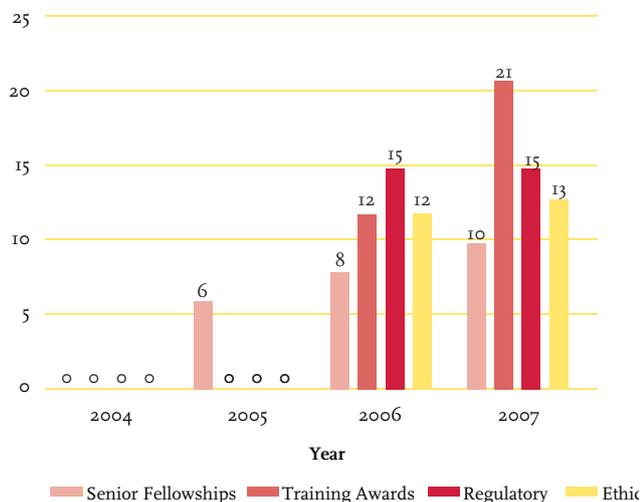


Site visits

EDCTP visited in 2007 Mozambique, Zimbabwe, Kenya, Uganda, Ethiopia and Gabon. The countries visited were selected by strategic importance and the number of EDCTP supported projects they have. Site visits are for advocacy, data collection and technical assessment on finance and capacity building. An integral part of the site visits are meetings with high officials of national Ministries, European Union country representatives, Member States ambassadors, national ethics committee chairs, directors of national regulatory authorities (NRAs) and WHO country representatives.

Lack of training in Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP) was repeatedly identified as a gap that needs to be bridged at a majority of the African sites with EDCTP supported projects. To help address these gaps EDCTP, in collaboration with the Swiss Tropical Institute and the UK Medical Research Council, organised a GCP training workshop for various research institutions in Africa with EDCTP supported projects. The training workshop took place from 7-11 May in Banjul, the Gambia and was attended by a total of 35 participants including study clinicians, data managers, laboratory scientists and technologists, and clinical trial nursing managers. The research institutions represented include Kigali National Malaria Control Programme (NMCP), Rwanda; Blantyre Malaria Programme (BMP), Malawi; Kilimanjaro Christian Medical Centre (KCMC) and Kibong'oto National TB Hospital, Kilimanjaro Tanzania; Centre Muraz, Bobo Dioulasso, Burkina Faso; University Teaching Hospital of Lusaka, Zambia; Tropical Disease Research Centre in Ndola, Zambia; and the University of Calabar, Nigeria.

Capacity building activities in Africa



To address the financial management gap that was identified during the site visits, EDCTP organised a two week financial training course between 3 and 14 December 2007. The course was attended by 16 African participants directly involved in producing budgets and annual reports on EDCTP grants from 12 different sub-Saharan countries. The course was designed and taught by Deloitte at their Gambia offices and practical examples were demonstrated at the Medical Research Council research site in Banjul, the Gambia. EDCTP is planning to continue this activity.

Regulatory affairs capacity development

EDCTP in collaboration with the World Health Organization (WHO) continued their joint activities to facilitate assessment and strengthening capacity of the national regulatory environment of various African countries through training and support of the development of a common regulatory framework. Funding from EDCTP and NACCAP amounting € 360,000 was used to support national regulatory authorities' (NRA) activities involving 15 African countries (Tanzania, Kenya, Uganda, Rwanda, Mozambique, Malawi, Zambia, Gabon, Ghana, Nigeria, Burkina Faso, The Gambia, Cote d'Ivoire, Mali, and Ethiopia). Regulatory activities that took place in 2007 include:

- A joint inspection of a clinical trial using a WHO supported Meningitis A conjugate vaccine trial*
The inspection was conducted on 17-19 January in Bamako, Mali. It involved both regulators and ethics committee members. The participating countries were: Gambia, Mali, Ghana, Burkina Faso, and Ethiopia.
- Training workshop on clinical trial authorisation*
This workshop was held on 18-22 June in Harare, Zimbabwe. It involved both regulators and members of ethics committees from the Gambia, Ghana, Botswana, Ethiopia, Malawi, Uganda, Tanzania and Zimbabwe.
- Global Training Network on vaccine quality, Good Clinical Practice (GCP) inspection training course*
The training took place on 25-29 June in Harare, Zimbabwe. It covered a variety of subjects including:

 - Planning, coordination and conduct of a GCP inspection
 - Identification and classification of observations and deviations
 - Logical regulatory decision making in compliance of the study with GCP standards



Launch of Aids Registry at the Medical Research Council of South Africa

- Reporting of outcome to the sponsors and investigators at clinical trial site.

The participating countries included Botswana, Ethiopia, The Gambia, Ghana, Malawi, Nigeria, Tanzania, Uganda, Zimbabwe and Mozambique.

EDCTP regulatory consultative meeting

This meeting aimed at obtaining recommendations on how best EDCTP should proceed to support and further strengthen regulatory capacity in Africa. It was held in Geneva at the WHO headquarters on 11 June and brought together stakeholders including WHO, Development for Neglected Diseases Initiative (DNDi) and the International Partnership for Microbicides (IPM) among others. The full report of this meeting is accessible on the EDCTP website (www.edctp.org).

The initial 18 months contract with WHO for strengthening regulatory capacity in Africa ended at the end of October 2007. Continued collaboration in line with the recommendations of the Geneva consultative meeting is envisaged in 2008.

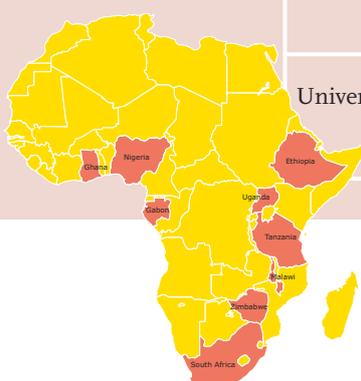
Ethics capacity development

In its aim to strengthen the African national ethics framework, EDCTP supports training and networking of institutional and national ethics committees (NECs). Where neither an NEC nor local institutional review boards exist, EDCTP will search appropriate bodies or scientists in each country to initiate the formation of an NEC. Part of the activities in the field of ethics capacity strengthening is described in the section on regulatory affairs in this chapter.

The majority of the EDCTP ethics grants that were awarded in 2006 started implementation in 2007. These included grants that support ethics courses and seminars, establishment or strengthening of national ethics committees and/ or Institutional Review Boards (IRBs) in sub-Saharan Africa. Additionally a grant to support an African regional coordinating office for ethics was awarded. Details of these projects are summarised in the table on page 27.

Status of ethics capacity development projects per 31 December 2007

Type of grant	Grantee	Title	Budget	Location	Status
Ethics Courses and Seminars	University of Stellenbosch	Enhancing Research Ethics Capacity and Compliance in Africa	€ 69,926	South Africa	Ongoing
	Medical Research Council, Zimbabwe	Proposal for Building National Capacities in Health Research Ethics, Ethical Review and Clinical Trial Monitoring in Zimbabwe	€ 98,700	Zimbabwe	Ongoing
	Africa Malaria Network Trust (AMANET)	Creating web-based research training courses in biomedical research ethics for Africans	€ 99,800	Tanzania	Ongoing
	University of Malawi	Proposal for Building and Strengthening National Capacities in Ethical Review and Clinical Trial Monitoring in Malawi	€ 98,123	Malawi	Ongoing
	Nigerian Institute for Medical Research (NIMR)	Capacity Strengthening of Nigerian researchers and ethics committee members on ethics	€ 78,000	Nigeria	Ongoing
	Cardiff University	Developing a distance learning research ethics course for East Africa	€ 94,800	United Kingdom	Ongoing
	Institut de Droit de la Santé	Training and Resources in Research Ethics Evaluation for Africa (TRREE for Africa)	€ 98,700	France	Ongoing
	Vienna School of Clinical Research	Training on Ethical Aspects of Clinical Research for Members of African National Ethics Committees and for African physicians/investigators	€ 100,000	Austria	Ongoing
	Establishment /Strengthening of NECs/IRBs	Medical Research Council, Zimbabwe	Proposal to strengthen the Medical Research Council of Zimbabwe	€ 48,400	Zimbabwe
Navrongo Health Research Centre		A Proposal for Strengthening Capacity of Six Research Ethics Committees in Ghana	€ 50,000	Ghana	Ongoing
University of Malawi		Proposal to Strengthen the National health Sciences Committee (NHSRC) and College of Medicine Ethics Committee (COMREC)	€ 50,000	Malawi	Ongoing
University of Ibadan		Strengthening the Capacity of Research Ethics Committees in Africa	€ 49,957	Nigeria	Ongoing



Countries with EDCTP supported ethics capacity development activities

Type of grant	Grantee	Title	Budget	Location	Status
Establishment /Strengthening of NECs/IRBs	Makerere University	Supporting research through enhancement of the IRB processes at Makerere Medical School	€ 50,048	Uganda	Ongoing
	Ministry of Public Health, Gabon	Establishment and support of a National Ethics Committee in Gabon	€ 50,000	Gabon	Ongoing
Coordinating office for Ethics	Pan African Bio-ethics Initiative (PABIN)	Establishing an African Coordinating Office for Ethics	€ 100,000	Ethiopia	Ongoing

Career development training awards

Senior Fellowships call for proposals 2007

On 6 July a call was launched for proposals for Senior Fellowships, worth € 1,2 M with a deadline of 12 November. For this prestigious award nineteen applications were received, to be reviewed early 2008.

Status of training awards granted before 2007

A total of ten EDCTP Senior Fellowship projects continued through in 2007. Six of these are from Kenya, South Africa, Sudan, Gambia, Ivory Coast and Mali presented their results at the Fourth EDCTP Forum in Burkina Faso. Two projects from Sudan and Ivory Coast were also successfully completed in 2007. Five Career Development Fellowships from Cameroon the Gambia, Mozambique, Uganda and South Africa continue to run smoothly. Two Masters and seven PhD projects progressed well in 2007. All PhD grantees presented the results of their work at the Fourth EDCTP Forum in Burkina Faso.

Distance learning MSc clinical trials course

In August 2007 EDCTP and the London School of Hygiene and Tropical Medicine (LSHTM) signed a contract to support African researchers for a distance learning Masters in Clinical Trials course. Twenty-one EDCTP studentships for African applicants are available for 2007, 2008 and 2009.

Training awards 2004-2007

Type of grant	Grantee	Title	Budget	Location	Status
Senior Fellowships (2004)	Ekouevi	Preventing per-partum transmission of HIV-1 in Africa: tenofovir based alternatives to single dose nevirapine in the light of future treatment options	€ 200,000	Ivory Coast	Completed
	Djimde	Assessment of the Public Health Benefit of artemisinin based combination therapies for uncomplicated malaria treatment in Mali	€ 300,000	Mali	Ongoing
	Nzila	Understanding the mechanism of piperaquine resistance	€ 300,000	Kenya	Ongoing

Training awards 2004-2007

Type of grant	Grantee	Title	Budget	Location	Status
Senior Fellowships (2004)	Alabi	Development and evaluation of high throughput, cheap and reliable assays for monitoring HIV-1 and HIV-2 viral loads in ARV programmes and clinical trials in developing countries	€ 300,000	The Gambia	Ongoing
	Mukthar	The burden of tuberculosis in eastern Sudan: epidemiology and drug resistance patterns of Mycobacterium tuberculosis isolates	€ 200,000	Sudan	Completed
	Hanekom	BCG-induced immune correlates of protection against tuberculosis	€ 300,000	South Africa	Ongoing
Fellowships (2005)	Talisuna	Safety of artemisinin derivatives-based combination therapy in children with uncomplicated malaria and population-based pharmacovigilance: a capacity strengthening proposal for pharmacovigilance of antimalarial drugs in Africa	€ 199,440	Uganda	Ongoing
	Nebie	Understanding the mechanisms underlying the difference in susceptibility to malaria in an area of hyper-endemic malaria in Burkina Faso: The potential role of regulatory T cells	€ 199,013	Burkina Faso	Ongoing
	Nwakanma	Evaluation and implementation of high throughput PCR-based method for diagnosis and measurement of <i>P. falciparum</i> parasitaemia in clinical trials	€ 181,320	The Gambia	Ongoing
	Cisse	A Pilot Study of the Implementation of seasonal intermittent preventive treatment with community participation in Senegal	€ 198,242	Senegal	Ongoing
Career Development Fellowship	Serwanga	Patterns of HIV-1 specific CD8+ T cell epitope recognition determining plasma viral load trajectory and set point following HIV-1 infection	€ 99,095	Uganda	Ongoing

Training awards 2004-2007

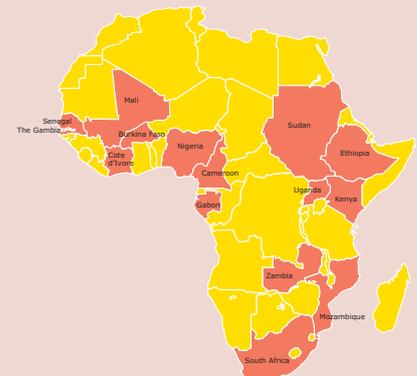
Type of grant	Grantee	Title	Budget	Location	Status
Career Development Fellowship	Carole Eboumbou Moukoko	Identification of <i>Plasmodium falciparum</i> parasite virulence markers for the evaluation of the impact of malaria control intervention according to the local parasite populations	€ 100,000	Cameroon	Ongoing
	Sevene	Intensive safety monitoring of antimalarial and antiretroviral drugs in pregnancy	€ 97,524	Mozambique	Ongoing
	Rangaka	Immunological investigation of the HIV-tuberculosis associated immune reconstitution	€ 87,960	South Africa	Ongoing
	Adetifa	A double blind, placebo controlled randomized trial of vitamin A supplementation for modulation of Mycobacterium tuberculosis immune responses in children aged 5-14 years with latent Tuberculosis	€ 96,624	The Gambia	Ongoing
PhD Scholarships	Arama	Host immunogenetic factors involved in the susceptibility to malaria in sympatric ethnic groups (Dogon and Fulani) in Mali	€ 75,000	Mali	Ongoing
	Yimer Ali	Anti tuberculosis-anti retroviral drugs induced Hepatotoxicity and interaction of these drugs at the level of CYP 450 metabolism	€ 75,000	Ethiopia	Ongoing
	Mwai	Understanding the mechanism of resistance to lumefantrine by <i>Plasmodium falciparum</i>	€ 75,000	Kenya	Ongoing
	Ramatoulie	Investigating the effects of inactive CYP2C19 alleles on chlorproguanil pharmacokinetics in adults and in children with mild malaria following Lapdap® treatment	€ 75,000	The Gambia	Ongoing
	Sikateyo	An assessment of the understanding of the informed consent process by participants in microbicide intervention trials in Zambia	€ 75,000	Zambia	Ongoing

Training awards 2004-2007

Type of grant	Grantee	Title	Budget	Location	Status
PhD Scholarships	Marie Yindom	The role of Human leukocyte antigen (HLA) and killer immunoglobulin-like receptor (KIR) in HIV-2 infection: a key component to HIV vaccine design and its evaluation in Africa	€ 75,000	The Gambia	Ongoing
	Mthiyane	Reconstitution of TB antigen specific IFN- γ responses in TB-HIV co-infected participants	€ 32,640	South Africa	Ongoing
MSc Studentships	Oyakhirome	Masters in Public Health Training	€ 21,000	Gabon	Ongoing
	Jobe	Masters in Reproductive and Sexual Health Research	€ 21,000	The Gambia	Completed
	Ngure	Masters in Clinical Trials	€ 13,522	Kenya	Ongoing
	Omungo		€ 13,522	Kenya	Ongoing
	Ansah		€ 13,522	Ghana	Ongoing
	Veena		€ 13,522	Kenya	Ongoing
	Aiku		€ 13,522	Nigeria	Ongoing
	Muturi		€ 13,522	Kenya	Ongoing
	Obuku		€ 13,522	Uganda	Ongoing

HIV/AIDS, Tuberculosis and Malaria (ATM) Clinical Trials Registry in sub-Saharan Africa

EDCTP funded the HIV/AIDS, tuberculosis and malaria (ATM) Registry (www.atmregistry.org) run by the Cochrane Centre at the MRC South Africa. The registry was officially launched on 22 May during the African Cochrane Contributors' Meeting (ACCM) that was hosted by the South African Cochrane Centre in Cape Town. The launch was well received and generated much interest (both locally and in other African countries) in clinical trial registration.



Countries with EDCTP supported training activities



Fourth EDCTP Forum

The Fourth EDCTP Forum was held from 22 to 24 October in Ouagadougou, Burkina Faso. During the Forum, scientists from both Europe and sub-Saharan Africa presented an overview of ongoing clinical trials on the three poverty-related diseases of HIV/AIDS, malaria and tuberculosis in Africa. They also identified future priorities, particularly with respect to promoting networking and capacity development activities. Highlights of the scientific sessions included the presentation of the data that led to the tentative approval by the FDA of Triomune (a fixed-dose anti-HIV drug specifically formulated for paediatric use), and the presentation of unpublished data concerning prevention of mother-to-child transmission of HIV/AIDS through a combination of tenofovir and emtricitabine. The Forum concluded with a look into EDCTP's future and perspectives.

The Forum was officially opened by the Minister of Social Affairs in Burkina Faso, Pascaline Tamini, and was hosted by the Centre de Recherche et de Formation sur le Paludisme (CNRFP). The Forum's theme, 'Building Bridges for Better Health', gained meaning when Charles Mgone said that the partnership between Europe and Africa in fighting HIV/AIDS, malaria and tuberculosis is "nearly or already a reality". In his keynote speech, Manuel Romarís from the European Commission's Research Directorate said that "2007 was the year in which EDCTP went on the right track".

All presentations are currently available on the Forum's website: <http://www.edctp.org/forum2007>.

The recommendations of the forum are published in a report that will be made available in 2008.

EDCTP Key Performance Indicators

In its quest for transparency and involvement of its stakeholders, EDCTP in 2007 identified a set of Key Performance Indicators (KPIs). A selection of these KPIs are included in this annual report. The KPIs provide an insight into EDCTP's progress and performance, and are updated on a quarterly basis. They are taken across the range of EDCTP activities, from the number of clinical trials approved to the number of African institutions involved in EDCTP funded projects, and from the value of grants signed to actual expenditure breakdown. The KPIs cover all areas of activity for EDCTP, and are divided into four categories: grants, partnership, donors and governance. All KPIs are included in a chronological table, and have their own chart or graph which present them in a visual manner and often add details or cumulative information.

EDCTP created the KPIs both for internal and external monitoring. As EDCTP recognises that numbers require interpretation, the KPIs will be developed over time and will where necessary be elaborated on by providing explanation and links to information relevant to a specific KPI. EDCTP invites all stakeholders to familiarise themselves with and monitor EDCTP's progress by visiting the KPIs webpage on the EDCTP website.



Fourth EDCTP Forum official opening



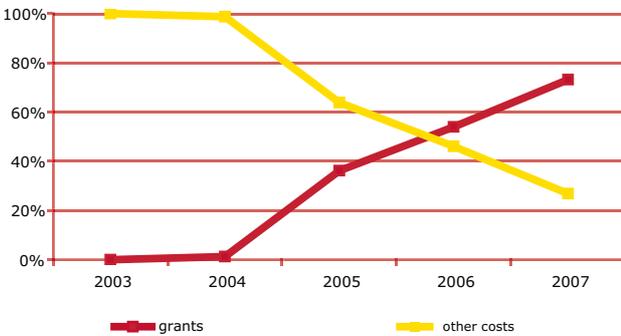
- **Financial summary**
- **Auditor's letter**
- **Accounts**

Financial Summary

Continuing the rise of 2006, grant funding provided by EDCTP increased by 85% in 2007 rising to € 28.8 M from € 15.6 M in the previous year. From this total of € 28.8 M, € 12.4 M was provided by cofunding from EEIG-EDCTP Member States. This is an increase of € 12.2 M compared to 2006 and it is the major contributing factor behind the overall increase. EDCTP core funding provided directly to grants from the European Commission (EC) was 6.4% higher at € 16.4 M (€ 15.4 M 2006). This brings the total of EDCTP, third party and Member States' grant expenditure to € 52.6 M since the start of the project.

The rapid pace of increase seen in 2007/6 in the value of grants signed is expected to continue. The calls launched in 2007 totalled € 68 M with further calls for € 19.5 M on HIV/AIDS slated for 2008. Therefore this increase in the value of the grants signed in 2008 is achievable.

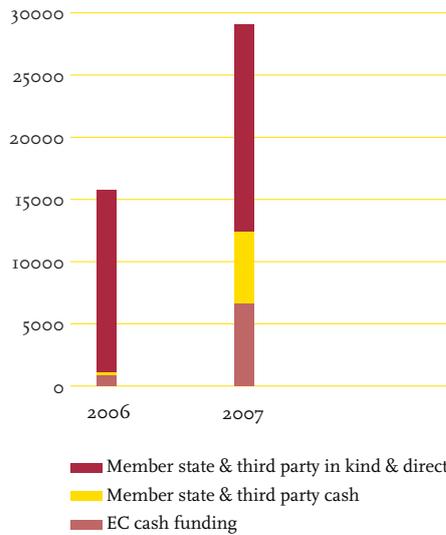
Grants vs other capenture



The € 28.8 M of grants signed in the year 2007 were funded from the following sources:

	€000
European Commission	16,379
Member States	9,609
Third Parties	2,794
Total	28,782

Allocation of EDCTP grant funding apportione between category and provider (EUR 000)



With the split of funding between the categories of in kind and cash as shown above, there was a high percentage of cash in Member State and third party cofunding which attests to the fact that EDCTP is stimulating new rather than reclassified funding from donors.

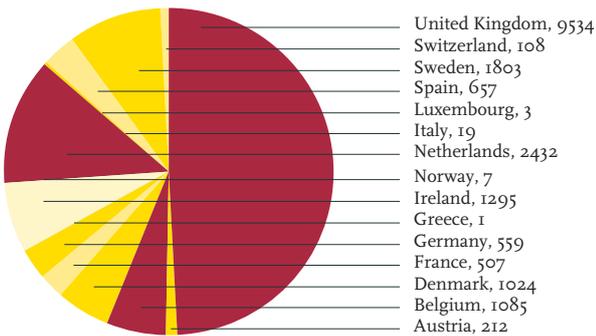
Principal funding sources

The growth in the provision of funding from Member States and third parties of € 13.8 M in cash plus € 0.5 M in interest received, helped boost the available unallocated non-EC funding cash balances to € 21.4 M, compared to € 13.2 M at the end of 2006. Third party cofunding in terms of low cost or free vaccines and drugs for the clinical trials is likely to be understated and under-reported. Efforts are being made to encourage projects to fuller reporting by grantees on these areas.

The EC funded EDCTP to the tune of € 37.8 M during the year as it released the payment in respect of forecast expenditure for 2007/(1/2)8. When combined with the deposits held on behalf of non EC donors the cash balances reached € 63.8 M at the year end compared to € 22.6 M for the previous year. EDCTP therefore has a very strong cash position at the year end and is able to comfortably disburse large amounts to grants during the course of 2008.

EDCTP now holds significant cash deposits on behalf of five Member State donors and one third party (the Bill & Melinda Gates Foundation), whilst also during the course of the year eight of the Member States made direct cash donations to sponsor bursaries attending the 2007 annual scientific forum in Burkina Faso.

EDCTP new funding received 2007 (cash & in kind € 000)



Resources expended

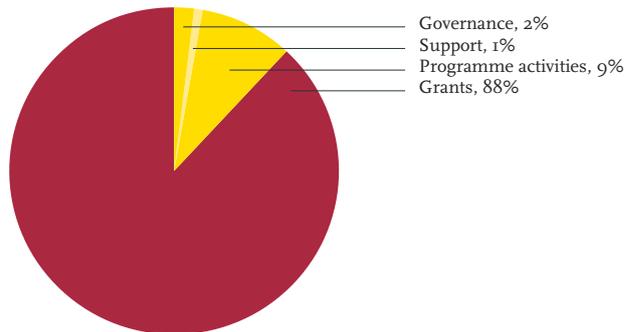
Non grant making costs came to € 4.2 M (2006: € 4 M) or 12.6% of total resources expended. The largest single component, accounting for € 1.5 M (2006 € 1.8 M), was employment costs, which were down on the previous year due to not replacing the Head of the African Office after Prof. Mgone became the Executive Director.

Costs which increased during the year included additional payments in respect of the 2006 and the 2007 forums. There were also costs of organising stakeholders meetings, which were held for the first time during 2007, and of organising regional training courses, further details can be seen in note 4 of the annual accounts.

Governance costs rose by € 0.3 M during 2007. This was largely due to the effect of Member States costing their contributions to attending the various constituency meetings rather than an increase in EDCTP paid for costs. Although the costs of organising DCCC meetings was up by € 96,000 due to an increase in the level of interaction, these costs were still below budget.

Support costs which cover the charges incurred by EDCTP with its hosting institutions in the Netherlands and South Africa were marginally lower compared to last year, with the waiver of the office rent by NWO being offset by the additional cost of half of the annual salary cost of the Communications officer over a full year for the first time.

Resources expended 2007 by cost category



To: the Assembly Board of EDCTP-EEIG

Auditor's report

We have audited the accompanying financial statements 2007 of EDCTP-EEIG, The Hague, which comprise the balance sheet as at 31 December 2007, the statement of recognized income and expenditure and cash flow statement for the year then ended and a summary of significant accounting policies and other explanatory notes.

Management's responsibility

The management board of EDCTP-EEIG is responsible for the preparation and fair presentation of the financial statements in accordance with International Financial Reporting Standards as adopted by the European Union. This responsibility includes: designing, implementing and maintaining internal control relevant to the preparation and fair presentation of the financial statements that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

Auditor's responsibility

Our responsibility is to express an opinion on the financial statements based on our audit. We conducted our audit in accordance with Dutch law. This law requires that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial

statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements give a true and fair view of the financial position of EDCTP-EEIG as at 31 December 2007, and of its result and its cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union.

The Hague, 13 May 2008

KPMG ACCOUNTANTS N.V.

W.A. Touw RA

Statement of financial activity 2007 (SOFA)

Incoming resources	Notes	Earmarked € 000	Restricted € 000	2007 Total € 000	2006 Total € 000
Incoming resources from generated funds:					
Voluntary & donor income	2	37,769	20,981	58,750	14,306
Investment income	3	1,246	485	1,731	630
Total incoming resources		39,015	21,466	60,481	14,936
Resources expended					
Activities in furtherance of EDCTP objects	4	(2,729)	(616)	(3,345)	(3,446)
Grants payable	5	(16,379)	(12,403)	(28,782)	(15,557)
Governance costs	6	(588)	(235)	(823)	(534)
Total resources expended		(19,696)	(13,254)	(32,950)	(19,537)
Net income (expenditure) for the year		19,319	8,212	27,531	(4,601)
Allocations					
Allocated to earmarked funds				19,319	(17,017)
Allocated to general funds				0	0
Allocated to restricted funds				8,212	12,416
				27,531	(4,601)

Statement of recognised Income & Expenditure 2007

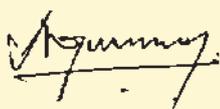
	Notes	Unrestricted € 000	Earmarked € 000	Restricted € 000	Total € 000
Balance as at 1 January 2006		0	18,708	736	19,444
Allocation of result for the year		0	(17,017)	12,416	(4,601)
Balance as at 31 December 2006		0	1,691	13,152	14,843
Previous period adjustment	23	0	273	0	273
Adjusted balance as at 31 December 2006		0	1,964	13,152	15,116
Allocation of result of the year		0	19,319	8,212	27,531
Balance as at 31 December 2007	14,15,16	0	21,283	21,364	42,647

The statement of financial activities includes all gains and losses recognised in the year.
All incoming resources and resources expended derive from continuing activities.

Balance Sheet as at 31 December 2007

	Notes	2007 € 000	2006 € 000
Assets			
<i>Non-current assets</i>			
Tangible assets	9	0	3
Total non-current assets		0	3
<i>Current assets</i>			
Debtors	10	8,146	9,257
Cash at bank and in hand	11	63,846	22,563
Total current assets		71,992	31,820
Total assets		71,992	31,823
Liabilities and reserves			
<i>Liabilities</i>			
<i>Current liabilities</i>			
Creditors: amounts falling due within one year	12	16,709	8,958
<i>Non-current liabilities</i>			
Creditors: amounts falling due over one year	13	12,636	8,022
Total liabilities		29,345	16,980
<i>Reserves</i>			
<i>Unrestricted reserves</i>			
General funds	14	0	0
Earmarked funds	15	21,283	1,691
Total unrestricted reserves		21,283	1,691
<i>Restricted reserves</i>			
Restricted funds	16	21,364	13,152
Total reserves		42,647	14,843
Total liabilities and reserves		71,992	31,823

Approved by the EDCTP Secretariat on behalf of EEIG General Assembly



Prof. Charles Mgone
Dated 15th May 2008

Statement of Cash Flow for the year ended 31 December 2007

	Notes	2007 € 000	2006 € 000
Net cash inflow from operating activities	17	39,552	(4,355)
Returns on investments and servicing of finance			
Deposit income received		1,808	630
Capital expenditure and financial investment			
Payments to acquire tangible fixed assets		(0)	(0)
Effect of foreign exchange differences		(77)	(0)
Increase/(Decrease) in cash in the year		41,283	(3,725)
Net cash resources at 01 January		22,563	26,288
Increase/(Decrease) in cash in the year		41,283	(3,725)
Net cash resources at 31 December		63,846	22,563

Notes forming part of the financial statements for the year ended 31 December 2007

Note 1 Principal accounting Policies

(a) Basis of accounting

The accounts for 2007 have been prepared under international financial reporting standards and are fully compliant with requirements.

(b) Grants receivable

Grants receivable are credited to the Statement of Financial Activities (SOFA) in the year for which they are receivable. Earmarked and restricted funds represents amounts received for future periods and are released to incoming resources in the period for which it has been received.

Restricted funds are to be used for specific purposes as laid down by the donor. Expenditure which meets these criteria is charged to the fund.

(c) Cofunding and other income receivable

Other voluntary income including donations is recognised when there is a certainty of receipt and the amount can be measured with sufficient reliability. Cofunding is included from member states where the contribution is either directly to EDCTP or to an EDCTP project and can be either cash or in kind. The value of the direct cash to grantee and in kind contributions are taken from the annual signed certificates sent to EDCTP after the year end. The effect on the financial statements is neutral as the income is offset by an equal charge for the relevant category of cost concerned. (See note 2b below).

(d) Grants payable

In accordance with guideline 640 the full amounts of all grants awarded by EDCTP are charged to the SOFA in the year in which the grant contract is signed. Amounts payable in respect of future accounting periods are included as liabilities within the balance sheet.

The costs of grants awarded are included within activities in furtherance of EDCTP objects and are separately analysed in note 5 below.

(e) Investment income and interest receivable

Interest received on bank deposits is included in the SOFA in the year in which it is receivable.

(f) Expenditure

All expenditure is included on an accruals basis, inclusive of any VAT which cannot be recovered, and is recognised when there is a legal or constructive obligation to pay for expenditure. All costs have been directly attributed to one of the functional categories of resources expended in the SOFA.

(g) Support costs

In undertaking activities EDCTP incurs support costs under the hosting agreements signed with NWO and MRC; these are detailed in note 7 below. Support costs are those costs incurred directly in support of expenditure on the objects of the EDCTP.

(h) Costs in furtherance of EDCTP object activities

These are costs which are incurred by EDCTP directly in carrying out its programme and comprise all costs except those of governance and grants. They include both direct and support costs (see note 4 below).

(i) Costs of governance

These represent the costs attributable to the strategic planning bodies of EDCTP; the assembly, the partnership board (PB), the developing countries collaborating committee (DCCC) and the European network of national programmes (ENNP). These costs are not part of the direct management function which is executed by the secretariat, but are derived from the strategic planning exercises for the future development of the EDCTP.

Also included are the costs of generating information required for public accountability such as external audit fees. No support costs are attributed to the costs of governance.

(j) Capitalisation and depreciation of tangible fixed assets

Individual fixed assets costing 5000 Euro or more are capitalised at cost.

Tangible fixed assets are depreciated on a straight line basis over their useful economic lives as set out below:

Computing equipment	3 years
Racking	2 years

(k) Funds accounting

Funds held by EDCTP are either:

- Unrestricted general funds – these are funds which can be used in accordance with the scientific research objects of the EEIG, which can be used at the discretion of the EDCTP executive management.
- Earmarked funds – these are funds set aside from the unrestricted funds for specific eligible expenditures and grants covered by the EC grant agreement with EDCTP.
- Restricted funds – these are funds received from other parties which can only be used for particular restricted purposes within the object of EDCTP. Restrictions arise when specified by the donor or when funds are raised for particular restricted purposes.

Further explanation of the nature and purpose of each fund is included in the notes to the financial statements.

(l) Foreign currencies

Transactions in foreign currencies are translated into Euro at rates prevailing at the date of the transaction. Monetary assets and liabilities are retranslated at the rate of exchange ruling at the balance sheet date and any differences taken to the SOFA.

There were two foreign currency assets as at 31 December 2007 which were the grants receivable in US dollars from BMGF and in Swedish Kroner from SIDA. Under the terms of the contract with BMGF their contribution (€ 6.7mn) is fixed in Euro so there is no exchange risk involved, on the second grant from SIDA the contribution is set as SEK 30 M over 3 years receivable in tranches of SEK 10 M per annum. Grant expenditure for this will be managed so that the grants awarded from this contribution will, so far as is possible, not exceed the Euro value of Swedish the kroner donations. All non Euro currency receipts are translated into Euro as soon as they are received on the EDCTP bank account. Any exchange differences are recognised through the SOFA.

(m) Pension scheme

EDCTP does not contribute into any defined benefit schemes for any of its international staff employees; instead a defined contribution is operated.

For the local seconded staff from NWO who are members of a defined benefit scheme the liabilities are the responsibility of the employer, NWO, therefore there is no need for EDCTP to account for pension payments on anything other than a defined contribution basis.

Note 2(a) Incoming resources from voluntary and donor income

	Earmarked €000	Restricted €000	2007 Total €000	2006 Total €000
Cash cofunding to EDCTP				
EC for p 4 of the grant agreement	37,764		37,764	0
Member state & third party cofunding re grant contributions (2b)		13,573	13,573	12,961
Member state & third party cofunding re programme activities (2b)		181	181	33
Member state EC ineligible cost reimbursement		20	20	0
Registration fees for annual forum	5		5	6
Total cash cofunding	37,769	13,774	51,543	13,000
In kind & direct cofunding to EDCTP & grantees				
Member state & third party cofunding grant contributions (2c)		6,576	6,576	877
Member state & third party cofunding re programme activities (2c)		405	405	397
Member state & third party cofunding re governance (2c)		226	226	32
Total cash & in kind and direct cofunding	0	7,207	7,207	1,306
Total cofunding	37,769	20,981	58,750	14,306

Note 2(b) Incoming resources from member state & third party cofunding (cash cofunding only)

	Grants €000	Programme activities €000	Support €000	Governance €000	2007 Total €000	2006 Total €000
BMGF					0	6,667
Austria	17	4			21	
Belgium		40			40	
Ireland	1,250	40			1,290	
Italy		12			12	
Netherlands	1,412	28			1,440	184
Spain					0	2,003
Sweden	1,581	17			1,598	3,284
United Kingdom	9,313	40			9,353	857
Total	13,573	181	0	0	13,754	12,994

Note 2(c) Incoming resources from member state & third party cofunding (In kind and direct cofunding to grantees only)

	Programme		Support	Governance	2007 Total	2006 Total
	Grants	activities				
	€000	€000	€000	€000	€000	€000
Third Party	1,685	10			1,695	0
Austria	133	31		26	190	0
Belgium	1,025	3		16	1,044	31
Denmark	967	9		48	1,024	0
France	504				504	2
Germany	585			11	596	830
Greece				1	1	2
Ireland		3		1	4	3
Italy				4	4	0
Luxembourg				3	3	0
Netherlands	782	209			991	210
Norway		2		4	6	1
Spain	634	3		18	655	34
Sweden	196			8	204	3
Switzerland	65	29		14	108	72
United Kingdom		106		72	178	118
Total	6,576	405	0	226	7,207	1,306

Note 3 Investment income

	2007	2006
	€000	€000
Foreign exchange gain/(loss)	(77)	0
Deposit interest	1,808	630
Total	1,731	630

Note 4 Programme Activities

	2007 Total €000	2006 Total €000
Staff costs (see note 8)	1,545	1,701
Temporary staff costs	6	146
Depreciation	3	12
Recruitment	33	7
Travel & subsistence	333	330
Annual scientific forum & bursaries	406	174
Advertising in scientific & other media	21	25
Scientific review committee meetings	14	126
Principal investigators & stakeholders meeting	179	80
Ineligible EC Costs	23	
Naccap cofunded secretariat costs	207	192
Document management system	0	108
Connecting the chain forum costs	0	34
Mobile telecommunications	25	23
GCP & financial training courses	181	
Other	77	30
Total direct costs	3,053	3,135
Support costs (see note 7)	292	311
Total research activities	3,345	3,446

Note 5 Grants payable

The amount paid in respect of grants in the year comprises:

Note 5(a) EDCTP Grant Funding

Value (€) of grants signed in 2007		Networking, training, fellowships, PhD, MSc,	Clinical trials by disease			Grand Total
Country	Site	All 3 PRDs	HIV/ AIDS	Malaria	TB	
Austria	Vienna School of Clinical Research			16,940	190,350	207,290
Austria total				16,940	190,350	207,290
Belgium	Institute of Tropical Medicine		290,231	285,000		575,231
	University of Ghent		172,942			172,942
Belgium total			463,173	285,000		748,173
Denmark	SSI Copenhagen				49,680	49,680
	University Hospital Copenhagen		14,400			14,400
Denmark total			14,400		49,680	64,080

Value (€) of grants signed in 2007		Networking, training, fellowships, PhD, MSc, All 3 PRDs	Clinical trials by disease			Grand Total
Country	Site		HIV/ AIDS	Malaria	TB	
Ethiopia	Armauer Hansen Research Institute (AHRI)				467,738	467,738
	University of Addis Ababa				276,737	276,737
Ethiopia total					744,475	744,475
France	Immuno Vac Consulting				48,600	48,600
France total					48,600	48,600
Gabon	Ministry of Public Health Gabon	49,960				49,960
Gabon total		49,960				49,960
Gambia	Medical Research Council Gambia		99,950		96,624	196,574
Gambia total			99,950		96,624	196,574
Germany	University of Heidelberg				115,457	115,457
Germany total					115,457	115,457
Holland	University of Amsterdam		743,232			743,232
	AMC Medical Research Amsterdam				56,160	56,160
	KNCV TB Foundation The Hague				24,000	24,000
	Leiden University Medical Centre				49,440	49,440
	University of Nijmegen		412,800			412,800
	IAVI		247,178			247,178
Holland total			1,403,210		129,600	1,532,810
Italy	Fondazione cCentro San Raffaele del Monte Tabor via Olgettina Milan				44,730	44,730
Italy total					44,730	44,730
Ivory Coast	NGO Aconda Ivory Coast		-5,378			-5,378
Ivory Coast total			-5,378			-5,378
Kenya	Wellcome-KEMRI Collaborative Programme			100,000		100,000
	International Centre For Reproductive Health		622,576			622,576
	CDC/Kemri Kenya				2,362,976	2,362,976
Kenya total			622,576	100,000	2,362,976	3,085,552

Value (€) of grants signed in 2007		Networking, training, fellowships, PhD, MSc,	Clinical trials by disease			
Country	Site	All 3 PRDs	HIV/ AIDS	Malaria	TB	Grand Total
Madagascar	Institute Pasteur Madagascar				89,940	89,940
Madagascar total					89,940	89,940
Malawi	Malawi Liverpool Welcome Trust		968,218			968,218
Malawi total					968,218	968,218
Mali	University of Bamako			99,201		99,201
	Faculty of Medicine Bamako Mali			75,000		75,000
Mali total					174,201	174,201
Mozambique	Eduardo Mondlane Univertsity Mozambique			97,524		97,524
	Instituto Nacionale Saude Mozambique		1,712,234			1,712,234
Mozambique total					1,712,234	1,809,758
Rwanda	Project Ubuzima Kigali		519,592			519,592
Rwanda total					519,592	519,592
Senegal	University of Dakar			198,242		198,242
Senegal total					198,242	198,242
South Africa	University of Cape Town				92,216	92,216
	Reproductive Health & HIV Unt (RHRU)		500,985			500,985
	Africa Centre For Health & Population Studies South Africa		839,491			839,491
	University of Kwa Zulu Natal		250,963			250,963
South Africa total					92,216	1,683,655
Spain	University of Barcelona		150,912			150,912
Spain total					150,912	150,912
Sweden	Karolinska Institute				369,397	369,397
Sweden total					369,397	369,397
Tanzania	Kilimanjaro Christian Medical College		594,634		90,060	684,694
	University of Muhimbili				276,737	276,737
	National Institure of Medical Research		1,774,785			1,774,785
Tanzania total					366,797	2,736,216

Value (€) of grants signed in 2007		Networking, training, fellowships, PhD, MSc,	Clinical trials by disease			Grand Total
Country	Site		All 3 PRDs	HIV/ AIDS	Malaria	
Uganda	Medical Research Council Uganda		710,688			710,688
	Uganda Malaria Surveillance Project			199,440		199,440
	Infectious Diseases Institute (IDI) Makerere Uni, Uganda	28,520			2,722,800	2,751,320
	Uganda Virus Research Institute		1,609,601			1,609,601
Uganda total		28,520	2,320,289	199,440	2,722,800	5,271,049
United kingdom	Liverpool School of Tropical Medicine		210,535			210,535
	London School of Hygiene & Tropical Medicine	315,000	110,105			425,105
	Medical Research Council UK		311,509			311,509
United kingdom total		315,000	632,149			947,149
Zambia	University Teaching Hospital Lusaka		369,660			369,660
	Ministry of Health Zambia		24,000			24,000
Zambia total			393,660			393,660
Zimbabwe	African Institute of Bio Medical Science & Technology (AIBST)				62,116	62,116
Zimbabwe total					62,116	62,116
Grand Total		393,480	13,255,842	1,071,347	7,485,758	22,206,427

Note 5(b) Member State & third party in kind and direct cofunding of grants

Cofunding Member State	Networking, training, ethics	Clinical Trials			Total
		HIV/AIDS	Malaria	TB	
Third Party	23,690	1,489,933		171,220	1,684,843
Austria	34,900		7,940	90,100	132,940
Belgium		263,487	649,224	112,241	1,024,952
Denmark		309,439		657,342	966,781
France	199,341	304,795			504,136
Germany		491,353		93,600	584,953
Netherlands		515,597		266,391	781,988
Spain		397,879	235,639		633,518
Sweden		4,302		191,874	196,176
Switzerland	64,968				64,968
Total	322,899	3,776,785	892,803	1,582,768	6,575,255
Combined MS/third party/EDCTP grant funding	716,379	17,032,627	1,964,150	9,068,526	28,781,682

Note 6 Governance costs

	Total 2007 Earmarked €000	Total 2006 Earmarked €000
Assembly	123	75
Partnership Board	253	232
European Network of National Programmes	171	49
Developing Countries Collaborating Committee	253	157
Audit fees	23	21
Total governance costs	823	534

Note 7 Support costs from third parties

	NWO €000	MRC SA €000	Total 2007 €000	Total 2006 €000
Telephones	24	6	30	30
Catering	8		8	9
IT maintenance	68		68	35
Rent	30	15	45	126
Office Cleaning	12		12	11
Postage	0		0	6
Photocopies	14		14	11
Travel	13	5	18	0
Recruitment	2		2	0
Legal/Personnel Prof & Fin Services	93	2	95	83
Total	264	28	292	311

Note 8 Staff costs and numbers

Total staff costs comprised:

	2007 €000	2006 €000
Wages and salaries	1,451	1,603
Social security costs	22	20
Pension costs	72	78
Total	1,545	1,701

The average number of full time equivalent employees (including casual and part time staff) was as follows:

	2007	2006
Secretariat (EDCTP international contract)	6	6.25
Secretariat (Seconded from NWO)	15.5	11.5
Total	21.5	17.75

Note 9 Tangible fixed assets

As at 31/12/07 Computing Equipment
€000

Cost	
At 31 December 2006	31
Additions	0
At 31 December 2007	31
Depreciation	
At 31 December 2006	(28)
Charge for the year	(3)
At 31 December 2007	(31)
Net Book Value	
At 31 December 2006	3
At 31 December 2007	0

Note 10 Debtors

	2007 €000	2006 €000
Other Debtors	8,144	9,247
Prepayments	2	10
Total	8,146	9,257

Other debtors includes € 5.8 M due from the BMGF under the terms of the joint call for capacity development in HIV clinical trials for sub Saharan-Africa and € 1 M from, SIDA re an agreed Member State national contribution to EDCTP payable over 3 years.

Note 11 Cash at bank and in hand

	2007	2006
	€000	€000
Bank balances	63,823	22,559
Cash in hand	23	4
Total	63,846	22,563

Note 12 Creditors: amounts falling due within one year

	2007	2006
	€000	€000
Other creditors	0	0
Grant creditors	16,616	8,847
Accruals	93	111
Total	16,709	8,958

Note 13 Creditors: amounts falling due over one year

	2007	2006
	€000	€000
Grant creditors	12,636	8,022
Total	12,636	8,022

Note 14 Unrestricted funds of the EEIG general fund

	€000
Balance at 31 December 2006	0
Movement in funds for the year	0
Balance at 31 December 2007	0

Note 15 Earmarked funds

	€000
Balance at 31 December 2006	1,691
Previous period adjustment	273
Adjusted balance as at 31 December 2006	1,964
EC Grant funds received	37,764
Released to statement of financial activities	(18,445)
Balance at 31 December 2007	21,283

Note 16 Restricted funds

	At 31/12/06 €000	Incoming resources €000	Outgoing resources €000	At 31/12/07 €000
MRC UK Capacity Development	550	24	(394)	180
Investment income	25	20		45
Medical Research Council (MRC) UK HIV trials contribution to joint call with BMGF	575	1,588	(370)	1,793
Investment income	14	79	0	93
Medical Research Council (MRC) UK future calls	0	7,415	(688)	6,727
Investment income	0	274	0	274
Medical Research Council (MRC) UK re “Evaluation of 4 artemisinin based treatments for treating uncomplicated malaria in African children”	0	285	(285)	0
Bill & Melinda Gates Foundation (BMGF)	6,667	0	(1,109)	5,558
Investment income	2	32	0	34
Swedish International Development Cooperation Agency (SIDA)	3,284	1,598	(1,321)	3,561
Investment income	5	46	0	51
Foreign exchange adjustment	0	0	(77)	(77)
Spanish ministry of Health & Consumer Affairs (ISC)	1,750	0	(17)	1,733
Investment income	30	78	0	108
Spanish ministry of Health & Consumer Affairs (ISC) RE BMGF Joint Call HIV Vaccines	250	0	0	250
Irish Aid contribution to EDCTP calls	0	1,250	(250)	1,000
Investment Income	0	11	0	11
NACCAP contribution to EDCTP calls	0	1,412	(1,412)	0
Investment Income	0	23	0	23
Total	13,152	14,135	(5,923)	21,364

The funding received from the MRC UK re the capacity development is to be used in respect of capacity building and training for staff and infrastructure at the MRC Uganda and MRC Gambia sites. MRC UK has also supplied funding to be used on the joint call with BMGF and for all of the calls to be launched in 2007/8.

The SIDA, ISC and Irish Aid grants are for clinical trials and capacity building grants awarded within the EDCTP programme including the joint call with BMGF.

The BMGF grant is to be used as part of the joint call for capacity building in clinical trials of HIV vaccines in sub-Saharan Africa announced 1/12/06

Note 17 Notes to cash flow statement

(a) Reconciliation of income to net cash inflow from operating activities			
		2007	2006
		€000	€000
Net movement in funds for the year		27,531	(4,601)
Investment income		(1,731)	(630)
Decrease in debtors		1,110	(9,022)
Increase in creditors		12,366	9,886
Previous period adjustment		273	0
Depreciation		3	12
Net cash inflow from operating activities		39,552	(4,355)
(b) Analysis of net cash resources			
	31 Dec 07	Cash flow	31 Dec 06
Deposits with no notice & cash	63,846	41,283	22,563

Note 18 Related parties

The EEIG has signed a hosting arrangement contract with NWO and MRC SA which includes secondment of personnel, rent of office space. Transactions under the hosting agreement, including the cost of seconded staff wages, amounted to € 807,716 in 2007, € 792,602 (2006) for NWO and € 41,776 in 2007, € 22,371 (2006) for MRC SA.

Note 19 Taxation

EDCTP itself is exempt from Dutch corporate income tax "CIT" as laid down in article 40 of the EEC Council regulation adopted in 1985, as clarified in a ruling from the Dutch Secretary of Finance issued 1 March 1990. However it is liable for all wages and social security taxes in Holland.

A special VAT exemption has been granted by the Dutch Ministry of Finance for all invoices which have a gross value in excess of € 250. This results in an amount of irrecoverable Dutch VAT every year which is ineligible expenditure under the terms of the EC agreement and is therefore repayable by the members.

EDCTP is also exempt from paying VAT in South Africa following a ruling from South African Revenue Service (SARS) in 2007. An application will also be made for exemption from income taxes on EDCTP in 2008 although the effect of this will be minimal even if granted as EDCTP has no taxable income or profits in South Africa.

Note 20 Conditional asset

The grant agreement signed between the EC and EDCTP stipulates that a total sum of € 200 million is receivable by EDCTP over seven years commencing on the 15 September 2003. The receipt of the full amount is contingent on the members states contributing an equal amount either to EDCTP directly or to EDCTP focused projects.

EDCTP has received (€ 000) 70,374 as at 31/12/07 resulting in a contingent asset of (€ 000) 129,626 which has not been recognised in the accounts.

Note 21 Supplementary data

It is proposed to add the net income for the year to the earmarked funds (€ 000's) 20,251 and general funds € 0. This proposal has been incorporated in the financial statements.

Note 22 Remuneration of governing bodies

The Assembly is not paid any honorariums nor per diems in respect of attending meetings in 2007. Member States are encouraged to pay for their own travel costs and only reimbursed where this is not possible.

The Partnership Board members are paid an annual honorarium of € 10,000 per member with € 20,000 to the Chair for attending four (or three prorated) meetings annually, in addition to this they are also entitled to a supplementary honorarium of € 1,665 for each two day meeting (up to a maximum of six meetings per year) attended pro rated down if less than the full session is attended. In 2007 the total payments to the Partnership Board in respect of honorariums amounted to € 103,767 (2006 € 130,798).

The Developing Countries Coordinating Committee members were paid no annual honorarium, but they are entitled to a daily honorarium of € 200 for each meeting (up to a maximum of four meetings per year) attended. In 2007 the total payments to the DCCC in respect of honorariums amounted to € 51,801 (2006 € 43,634)

Note 23 Prior year adjustment

The prior year adjustment relates to the correction for the understatement in 2006 of outgoing resources from the MRC UK capacity development restricted fund in respect of amounts committed for grants which had been signed but not yet paid.





With the overall goal to reduce poverty in developing countries by improving the health of the populations, the European & Developing Countries Clinical Trials Partnership (EDCTP) aims through European research integration and in partnership with African countries to develop new clinical interventions to fight HIV/AIDS, malaria and tuberculosis.

The European & Developing Countries Clinical Trials Partnership is a partnership between 14 EU countries, Norway, Switzerland and sub-Saharan African countries. It aims to join relevant European national research programmes and their African partnerships to develop new clinical tools against HIV/AIDS, malaria and tuberculosis. The Joint Programme is based on Article 169 of the European Treaty. The European Commission (EC) will cofund this Joint Programme. EDCTP has a very important pilot function as a first application of Article 169, the most advanced instrument for the integration of European research.

The context of the programme is the dramatic health situation in many developing countries, and the concerted action of the European Union to fight the poverty-related diseases HIV/AIDS, malaria and tuberculosis.

The programme objective is to accelerate the development of new or improved drugs and vaccines against these diseases, with a focus on phase II and III clinical trials and on sub-Saharan Africa.

The principal objectives of EDCTP are:

- To accelerate the development of new clinical interventions, in particular drugs and vaccines, to fight HIV/AIDS, malaria and tuberculosis in developing countries and generally to improve the quality of research in relation to these diseases
- To advance the integration of the national scientific health research programmes of the Member States
- To strengthen related research and development capacity within the developing countries.

Principal policies to achieve objectives

- Direct funding by the EC through EDCTP under Article 169 of the Treaty of the European Union.
- Direct funding from the Member States national programmes from the individual countries' annual core funding budgets for scientific research and capacity building to fight the three main poverty related diseases in developing countries

- Encouraging the participation and mobilisation of funds from the private sector, both profit and not-for-profit organisations
- Closer coordination of European and developing countries research programmes, through improved networking and government-based support in developing countries
- Technology transfer to developing countries
- Capacity building within the developing countries to generally strengthen clinical trial research capacity
- Training of clinical research personnel in developing countries
- Promoting prevention, encouraging treatment and making essential medicinal products more affordable in developing countries.

The activities of EDCTP include:

1. Networking and coordination of European national programmes and with their partners in sub-Saharan Africa
2. Networking and coordination of African national programmes
3. Supporting relevant clinical trials
4. Strengthening the African capacity in conducting clinical trials
5. Advocacy and fundraising
6. Management
7. Information management.

Specific strategies and action plans have been developed for each of the seven activity areas.

The budget of EDCTP is € 400 M for 7 years. The national participation of the Member States towards the Joint Programme is estimated at least € 200 M. A financial contribution of the European Commission in the sum of € 200 M will be made to increase the impact of EDCTP. Additional cofunding is sought from other sources, whether public or private.

The European National Programmes are defined as publicly funded activities within one country that can contribute to EDCTP. The application of Article 169 implies the national commitment of each Member State to mobilise their publicly funded organisations active in the field of EDCTP, and to maintain the levels of support at minimally equal levels throughout the programme.

Grant making policy

EDCTP invites applications for funding of projects through advertising on the EDCTP website and relevant scientific and medical journals. Grants are available for supporting multicentre projects which combine clinical trials with capacity building and networking. These components should be closely integrated in such a way that they ensure the capacity development and networking developed are utilised to successfully conduct the clinical trials under the best practices and to promote sustainability in Africa. The maximum duration of a project is 5 years.

Proposals are reviewed by a Scientific Review Committee drawn from a pool of pre-selected experts, as well as by independent experts. Following recommendation from the Partnership Board, funding for recommended projects is approved by the General Assembly and applicants who are not selected are notified with the reasons why their application was unsuccessful.

Annual and final scientific and financial reports are required to be submitted and accepted by EDCTP for the grant to qualify for funding over the course of its term.

Details of all grants awarded are published on the EDCTP website.

Organisational structure and governance

Legal Status

EDCTP is established as a European Economic Interest Grouping (EEIG) in the Hague the Netherlands. As such, it is registered with the chamber of commerce of "Haaglanden" in 2003, the Netherlands (no. 27259980).

Governance

The legal, operational and financial structure of EDCTP is provided by the European Economic Interest Grouping (EEIG) through its two organs namely the EEIG Assembly and the Secretariat. The EEIG Assembly is the final decision-making authority in which all participating European states are represented, whilst the Secretariat, headed by the Executive Director is responsible for the day to day running of the organisation. The EEIG Assembly is assisted by the Partnership structure, which is the scientific strategic planning arm comprising of the scientific and regional expertise necessary for the effective steering of the EDCTP programme and its funding. Constituents of the Partnership include:

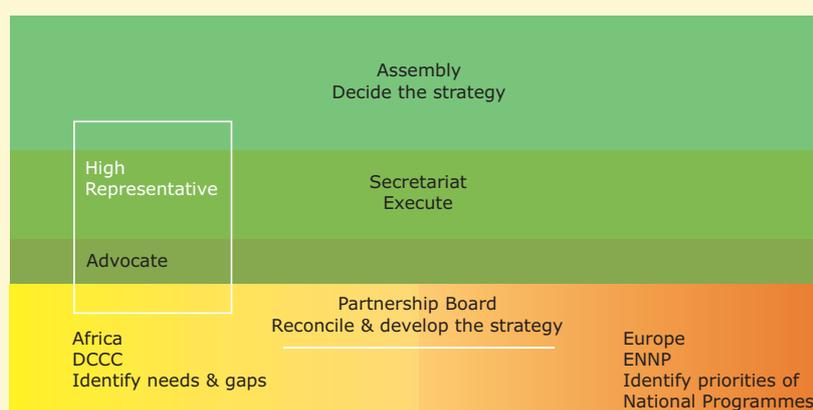
The Partnership Board (PB), a scientifically independent expert panel that develops the strategic planning of EDCTP

The Developing Countries Coordinating Committee (DCCC), which consists of representative African scientists and ensures the input and commitment of the African countries and researchers

The European Network of National Programmes (ENNP), which consists of representatives of the European national programmes and develops proposals to coordinate and joint national activities and funding.

The Partnership structures and the EC hold permanent seats in the EEIG Assembly.

The role and operations of each body are determined in the EEIG statutes and the Internal Regulations.





The EEIG General Assembly (GA)

Diana Dunstan (Chair)

Bruno Gryseels

Stefano Vella

Jean-Francois Girard

Patrice Debré (Vice Chair)

Hannah Akuffo

Christiane Druml

Gabriele Hausdorf

Søren Jepsen

Antonis Antoniadis

Teresa Maguire

Antonio Chiesi

Bjorn Guldvåg

Maria de Fatima Bravo

Carmen Audera Lopez (Vice Chair)

Isabel Noguer

Sacra Tomisawa

Edvard Beem

United Kingdom

Belgium

Italy

France (Resigned November 2007)

France (Appointed/Elected November 2007)

Sweden

Austria

Germany (Appointed January 2007)

Denmark

Greece

Ireland

Italy

Norway

Portugal

Spain (Elected November 2007)

Spain

Switzerland

The Netherlands

The Partnership Board (PB)

Patrice Debré (Chair)	France (Resigned October 2007)
Peter Smith (Vice-Chair)	United Kingdom (Resigned October 2007)
Souleymane Mboup (Vice-Chair)	Senegal (Resigned October 2007)
Sodiomon Sirima (Chair)	Burkina Faso (Appointed November 2007)

The Developing Countries Co-ordinating Committee (DCCC)

Simon Agwale (Chair)	Nigeria
Christine Manyando (Vice-Chair)	Zambia
Peter Ndumbe (Vice-Chair)	Cameroon

The European Network of National Programmes (ENNP)

Laura Brum (Chair)	Portugal
Dirk van der Roost (Vice-Chair)	Belgium

Secretariat's responsibility for financial reporting

In accordance with the internal regulations, the Secretariat is obliged to prepare financial statements for each financial year, which give a true and fair view of the state of affairs of EDCTP as at the balance sheet date and of its incoming resources and application of resources, including income and expenditure. In preparing those financial statements, the Secretariat is required to follow best practice and:

- Select suitable accounting policies and apply them consistently
- Make judgements and estimates that are reasonable and prudent
- State whether applicable accounting standards have been followed, subject to any material departures disclosed and explained in the financial statements
- Prepare the financial statements on the going concern basis unless it is inappropriate to presume that EDCTP will continue in operation.

The Secretariat are responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of EDCTP and which enable them to ensure that the financial statements comply with statutory regulations. They are also responsible for safeguarding the assets of EDCTP and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

Investment Policy

Unused funds are held on deposit with instant access at Fortis bank. From 2007 onwards and based on cash-flow forecasting, money will be invested in deposits of up to 1 year, also with Fortis, to earn higher returns. Interest received on these funds is declared to the EC or the donor agency which has deposited funds with EDCTP and either added to the donor balances or, in the case of the EC, deducted from the next years funding in line with the regulations stated in the grant agreement between EC and EDCTP.

EDCTP is not allowed to, and has not taken up any loans under Article 14 of the deed of incorporation.

Appendix 2: Glossary of Abbreviations

AAVP African AIDS Vaccine Programme	IFN Interferon
AMANET Africa Malaria Network Trust	IPM International Partnership for Microbicides
ARV Anti-retrovirals	IRB Institutional Review Board
ATM Registry HIV/AIDS, Tuberculosis and Malaria clinical trials Registry	ISC(III) Instituto de Salud Carlos III
AU African Union	KEMRI Kenya Medical Research Institute
BCG Bacillus of Calmette and Guérin	KPL Key Performance Indicator
BMGF Bill & Melinda Gates Foundation	LSHTM London School of Hygiene and Tropical Medicine
CDC Centers for Disease Control and Prevention	MRC (SA/UK) Medical Research Council (South Africa/ United Kingdom)
CD8 Cluster of Differentiation 8	MS Member State
cGMP Current Good Manufacturing Practice	MSc Master of Science
CNRFP Centre de Recherche et de Formation sur le Paludisme	NACCAP Netherlands-African Partnership for Capacity Development and Clinical Interventions Against Poverty-Related Diseases
COHRED Council on Health Research for Development	NEC National Ethics Committee
CIT Corporate Income Tax	NEPAD New Partnership for Africa's Development
CYP 450 Cytochrome P-450 isoenzymes	NGO Non-governmental organisation
DC Developing Country	NoE Network of Excellence
DCCC Developing Countries Coordinating Committee	NWO Netherlands Organisation for Scientific Research
DNDI Development for Neglected Diseases Initiative	NRA National Regulatory Affairs
EC European Commission	PABIN Pan. African Bio-ethics Initiative
EEC European Economic Community	PCR Polymerase Chain Reaction
EDCTP European & Developing Countries Clinical Trials Partnership	PhD Doctor of Philosophy
EEIG European Economic Interest Group	PB Partnership Board
ENNP European Network of National Programmes	PDP Product Development Partnership
ENO European Networking Officer	PMD Provincial Medical Directorate
EU European Union	PPP Public Private Partnership
FDA Food and Drug Administration	PRD Poverty-Related Disease
FP6 The European Commission's Sixth Framework Programme	SIDA Swedish International Development Co-operation Agency
GA General Assembly	SOFA Statement of Financial Activities
GAAP Generally Accepted Accounting Principles	SOP Standard Operation Procedure
GCLP Good Clinical Laboratory Practice	SSI Statens Serum Institut
GCP Good Clinical Practice	TB Tuberculosis
GMP Good Manufacturing Practice	UK United Kingdom
IAVI International AIDS Vaccine Initiative	USA United States of America
ICH International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use	VAT Value Added Tax
	WHO World Health Organization