

The Annual Report 2005

the power of sharing science



EDCTP

*European and Developing Countries
Clinical Trials Partnership*



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ABBREVIATIONS

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ANR	National Agency for Research
ARV	Anti-retrovirals
AU	African Union
CIT	Corporate Income Tax
DC	Developing Country
DCCC	Developing Counties Co-ordinating Committee
EC	European Commission
EEC	European Economic Community
ED	Executive Director
EDCTP	European and Developing Countries Clinical Trial Partnership
EEIG	European Economic Interest Group
EFQM	European Foundation on Quality Management
ENNP	European Network of National Programmes
ENO	European Networking Officer
ES	EDCTP Secretariat
EU	European Union
ESDH	EDCTP Office The Hague
ICRH-K	International Centre for Reproductive Health – Kenya
JPA	Joint Programme A
JPB	Joint Programme B
KEMRI	Kenya Medical Research Institute
FO	Financial Officer
FM	Finance Manager
FS	Financial Supervisor
GA	General Assembly
GCP	Good Clinical Practice
HR	High Representative
IAS	International Accounting Standards
IHRDC	Ifakara Health Research & Development Centre
IED	Interim Executive Director
IPR	Intellectual Property Rights

LoI	Letter of intent
LSTM	Liverpool School of Tropical Medicine
MIS	Management Information System
MMV	Medicines for Malaria Venture
MoU	Memorandum of Understanding
MRC	Medical Research Council
MS	Member States
NACCAP	Netherlands-African Partnership for Capacity Development and Clinical Interventions Against Poverty-Related Diseases
NEPAD	New Partnership for Africa's Development
NGO	Non-governmental organisation
NWO	Netherlands Organisation for Scientific Research
N-NNM	North-North Networking Manager
N-NNO	North-North Networking Officer
NP	National Programme
PABIN	Pan-African Bioethics Initiative
PB	Partnership Board
PI	Principal Investigator
QMS	Quality Management System
SATVI	South African Tuberculosis Vaccine Initiative
SIDA	Swedish International Development Co-operation Agency
SO	Scientific Officer
SOPA	Statement of Financial Activities
SOP	Standard Operation Procedure
SRC	Selection Review Committee
S-SNM	South-South Networking Manager
UK	United Kingdom
VAT	Value Added Tax
WHO	World Health Organisation
WHO AFRO	World Health Organisation African Region Office
ZonMW	The Netherlands Organisation for Health Research & Development



GOVERNANCE



‘Diffused knowledge immortalises itself’

SIR JAMES MACKINTOSH. 1765-1832.

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The legal, operational and financial structure of the European and Developing Countries Clinical Trials Partnership (EDCTP) is provided by the European Economic Interest Group (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, while the Secretariat, headed by the Executive Director is responsible for the day-to-day running. The EEIG Assembly is assisted by the Partnership structure, which is the strategic planning arm comprising the scientific and regional expertise necessary for steering the EDCTP programme. Constituents of the Partnership include the Partnership Board (PB), the European Network of National Programmes (ENNP) and the Developing Countries Co-ordinating Committee (DCCC).

LEGAL STATUS

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

THE EEIG ASSEMBLY:

Peter Lange	Germany (Chair up to June 2005)
Diana Dunstan	United Kingdom (Chair since June 2005)
Bruno Gryseels	Belgium (Vice-Chair)
Hanna Akuffo	Sweden (Vice-Chair)
Hans-Georg Eichler	Austria

Søren Jepsen	Denmark
Jean-François Girard	France
Antonis Antoniadis	Greece
Teresa Maguire	Ireland
Antonio Chiesi	Italy
Bjorn Guldvåg	Norway
Sophie Couffignal	Luxembourg
Maria de Fatima Bravo	Portugal
Mercedes Diaz	Spain
Sacra Tomisawa	Switzerland (since December 2005)
Renée van Kessel	The Netherlands

THE EXECUTIVE SECRETARIAT:

Bernt Lindtjörn	Interim Executive Director (January-June 2005)
Odile Leroy	Executive Director (since July 2005)
Charles Mgone	(Head of Africa Office, appointed September 2005)
Simon Belcher	(Financial Manager)
Cynthia Naus	(Project Manager)

THE PARTNERSHIP BOARD:

Fred Binka	Ghana (Chair)
Patrice Debré	France (Vice-Chair)

THE DEVELOPING COUNTRIES CO-ORDINATING COMMITTEE

Bartholomew Akanmori	Ghana (Chair)
Francine Ntoumi	RD Congo (Vice-Chair)

THE EUROPEAN NETWORK OF NATIONAL PROGRAMMES

Laura Brum	Portugal (Chair)
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A full list of all members of the above bodies can be found on the EDCTP web site www.edctp.org

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AFRICA OFFICE

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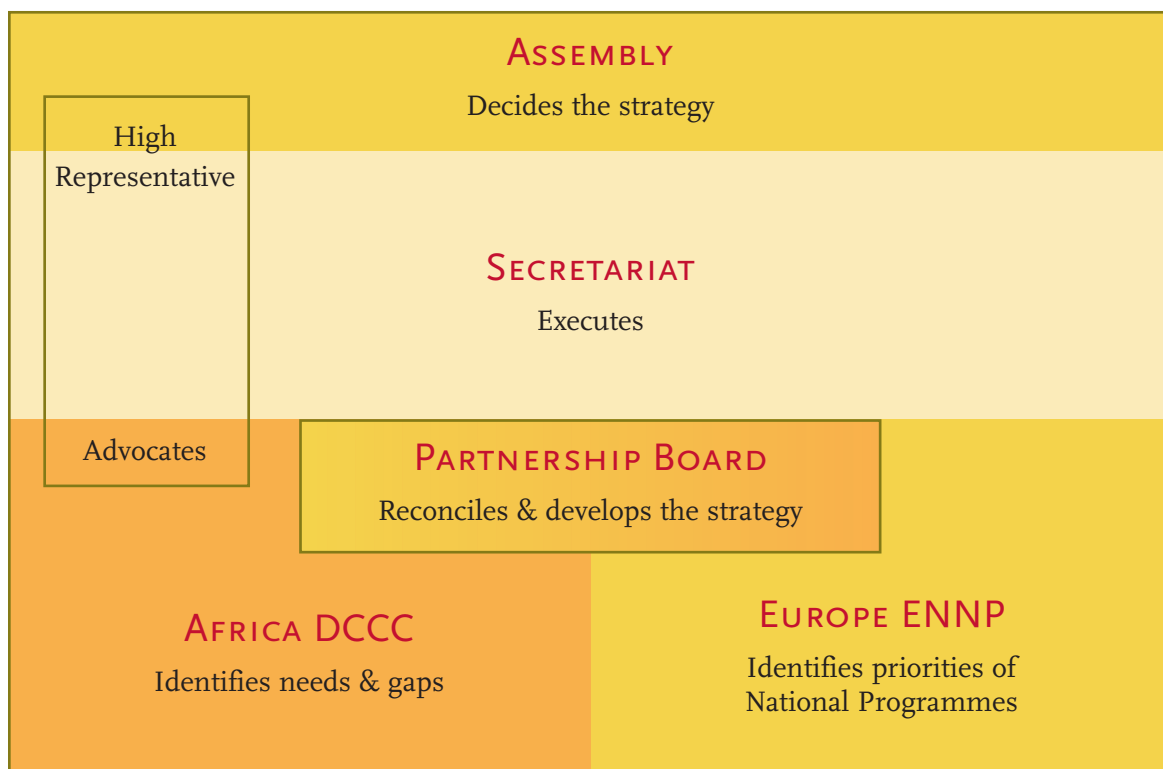
BANKERS

Fortis Bank, Coolingsingel 93 –3012 AE Rotterdam, The Netherlands

AUDITORS

KPMG, Churchillplein 6,2517 JW, Den Haag, The Netherlands

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FOREWORD

2005 proved to be a turning point for EDCTP. My predecessor as Chair of the Assembly, Dr Peter Lange, referred in his foreword to the annual report last year about the challenges and difficulties that EDCTP had faced as the first European initiative based on Article 169 of the European treaty. I am pleased to say that during the last year we have been able to put these difficulties behind us and to rise to the challenge of leading a co-ordinated European research agenda for clinical trials and capacity building in partnership with our colleagues in Africa. We acknowledge that there is still work to do to fully deliver the promises of the partnership, but writing this in the Spring of 2006 I am confident that we are now well on track and that the hard work of last year has paid off.

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*Dr Odile Leroy
Executive Director*



*Dr Diana Dunstan
Chair of the EEIG*

We are very grateful to the work of the interim director, Professor Bernt Lindtjørn of the University of Bergen, in reviewing our procedures and advising the assembly on improved operational and management arrangements. Bernt agreed to stay with us until June when a new Executive Director of EDCTP was appointed. We were all delighted that Dr Odile Leroy was able to accept the position of Executive Director. Odile has worked tirelessly ever since to revitalise EDCTP and to motivate member states to take a full and active part in EDCTP activities as required under article 169. On behalf of my colleagues on the General Assembly I would also like to express our deep thanks to all staff in the secretariat who have worked extremely hard, particularly through a difficult transition time, to support and deliver EDCTP activities. The revised peer review and operating procedures have been well received by the research community and this has helped to restore confidence in EDCTP's ability to work effectively with scientists and research institutions.

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One of the highlights of 2005 was the second EDCTP forum held in Durban, South Africa. This was an excellent opportunity for the various constituents of EDCTP to meet with scientists and stakeholders from 20 African countries and we had a packed agenda of scientific presentations. The diseases that EDCTP is targeting, HIV, TB and Malaria continue to have a disproportionately high mortality rate in Sub-Saharan Africa and it is only by working together, sharing our experiences and knowledge, breaking down the old barriers to co-ordinated research and research funding that we can hope to make an impact on prevention and treatment. As the EDCTP message is more widely disseminated so support for our activities is increasing. It will undoubtedly take time to build on last years developments and to see the outcomes of current clinical trials and capacity building initiatives, but the activities described in this report have all contributed to EDCTP's renewed commitment to prove the 'power of sharing science'.

Dr Diana Dunstan

EXECUTIVE SUMMARY

This annual report covers EDCTP activities during 2005. It highlights activities that were undertaken in the seven areas of the core functions of EDCTP namely:

(1) supporting of relevant clinical trials; (2) capacity building and strengthening; (3) networking and co-ordination of European national programmes together with their partners in the south; (4) networking and co-ordination of African national programmes; (5) advocacy and fundraising; (6) management; and (7) information management.

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During 2005 the co-ordination of the national programmes and activities of Member States (MS) was given top priority. To achieve this, a North-North Networking Manager (N-NNM) was appointed in January. Together with the European Networking Officers (ENOs) the N-NNM proceeded to develop a strategy for implementing and co-ordinating of the MS national programmes. To tackle this challenge EDCTP used the top-down approach through which member states (MS) co-fund EDCTP. In September 2005, the co-funding was implemented for the calls for clinical trials and large capacity building grants. Furthermore, a procedure for co-funding of EDCTP calls to facilitate co-ordination of Member State National Programmes and channelling of their €200 M contribution to EDCTP was developed and implemented.

The south-south networking and inputs from the African scientific community were spearheaded by the South-South Networking Manager (S-SNM), the Developing Countries Co-ordinating Committee (DCCC) and the High Representative (HR). Among the activities that were undertaken to strengthen the African involvement in the programme include collection of information on clinical trial sites in Africa; establishment the EDCTP Listserv for providing updates and a discussion forum; strategic and scientific input from DCCC; and advocacy. The DCCC met three times and contributed significantly to the programme. The High Representative, Dr Pascoal Mocumbi, dynamically engaged himself in advocacy activities, which among others resulted in the recognition of EDCTP as a promising venture by stakeholders, particularly the African Union (AU), the New Partnership for Africa's Development



(NEPAD) and the African leadership. Through these efforts a Memorandum of Understanding (MoU) was signed between EDCTP and NEPAD.

In September 2005, EDCTP launched a new set of calls for proposals. These were under four different grant schemes namely Clinical Trials, Capacity Building, Training Awards and Fellowships, and Networking. The Clinical Trials Grant Scheme was introduced to support both the capacity of clinical trial sites and to actually conduct clinical trials, while the Capacity Building Grant Scheme is for the general capacity building on clinical trials related issues including ethics review and regulatory issues. The Training Awards and Fellowships are for the support for Senior and Career Development Fellowships, PhD scholarships and MSc studentships. Networking Grants are for the promotion of collaboration and co-ordination of activities among researchers and their institutions at national and regional levels in order to enhance co-operation, ownerships and sustainable capacity.

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In order to improve its efficiency, in 2005 EDCTP introduced several measures. These include self-assessments which were performed by its constituencies; introduction of standard operating procedures (SOPs) and guidelines for all critical activities; review of internal regulations; introduction of a Quality Management System (QMS) and Quality Assurance (QA); review of the information and communication strategy; and the restructuring of its organisation scheme. These measures have greatly enhanced efficiency, transparency and adherence to the best practices of EDCTP in the performance of its activities including the processing of grants.



CONSTITUTION AND OBJECTS



With the overall goal to reduce poverty in developing countries by improving the health of the populations, the European and Developing Countries Clinical Trials Partnership aims through European research integration and in partnership with African countries to develop new clinical interventions to fight HIV/AIDS, malaria and tuberculosis. The Partnership is a venture between 14 European Union (EU) countries, Norway and Switzerland on one hand, and African countries on the other hand. 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 that allows the European Commission (EC) and the member states to co-fund the Programme. EDCTP has therefore a very important pilot function as a first institution to apply Article 169 which is the most advanced instrument for the integration of European research.

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The *context* of the programme is the dramatic health situation in many developing countries, and the concerted action of the EU to fight the poverty-related diseases 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 *activities* of the EDCTP include:

1. Networking and co-ordination of European national programmes in collaboration with their partners in the south
2. Networking and co-ordination of African national programmes
3. Supporting relevant clinical trials
4. Strengthening the African capacity in this field
5. Advocacy and fundraising
6. Management
7. Information management

The *European National Programmes* are defined as publicly funded activities within one country that can contribute to the 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 the EDCTP and to maintain the levels of support at minimally equal levels throughout the programme.

The *budget* of the EDCTP is €400 M for five 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 co-funding is sought from other sources, whether public or private.

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

The principal objectives of the 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 DCs.

Principal policies to achieve objectives

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

SCIENTIFIC EXCELLENCE AND QUALITY MANAGEMENT

STANDARD OPERATING PROCEDURES AND GUIDELINES

16 In January 2005, after taking the position as the Interim Executive Director (IED), Prof. Bernt Lindtjørn initiated the development of standard operation procedures (SOPs) for processing EDCTP grants. To archive this, the IED invited to The Hague, Dr Mark Palmer from the Medical Research Council (MRC), UK and Dr Eivind Hovden from the Research Council of Norway to come to work together with the EDCTP Secretariat (ES) to develop the SOPs. Following their visit and consultations with various constituents the ES finalised the first set of SOPs in June 2005. At this stage the new Executive Director (ED), Dr Odile Leroy had already taken up her position at EDCTP and in addition to the SOPs had introduced a quality assurance and control system for calls and grant processing.

Currently all SOPs and Guidelines are to be cleared by the ED as well as the Chair of the General Assembly (GA). For the final approval collaboration was set up with the Dutch Medical Research Council (ZonMW) with the Quality Manager of ZonMW taking the responsibility of reviewing and approving all procedures that received clearance of the ED and Chair of the GA. From the initial focus on granting procedures, in 2006 SOPs and Guideline will be expanded to include all procedures that are undertaken by the ES.

QUALITY MANAGEMENT

Furthermore, to ensure that EDCTP remains focussed, Quality Management System (QMS) was also introduced with the aim of making certain that all members of the EDCTP constituencies know what is expected of them and that all stakeholders are aware of the aims and direction of EDCTP. This is to ensure that EDCTP carry out its activities in a transparent, accountable and efficient manner. After assessing various alternatives the choice was made to implement the method that had been developed by the European Foundation for Quality Management (EFQM). The introduction of



the EFQM system was presented to the GA during its meeting of 28 September and the first step towards implementation of the method explained to the ES staff at its Staff Educational meeting of 1 December 2005. As a second step the ED developed an organogram for the ES which is based on a matrix structure in which QA plays a very prominent role as shown on page 22.

SELF-ASSESSMENT

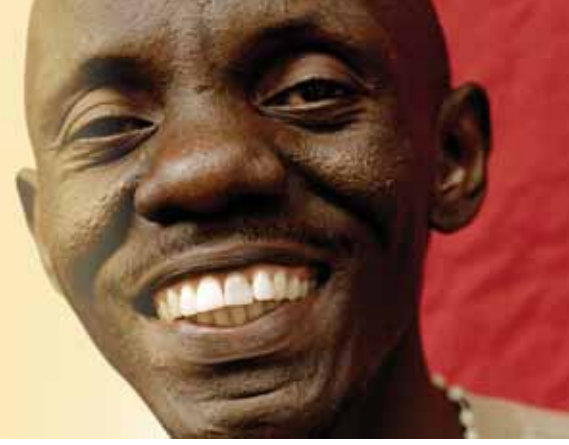
To evaluate the difficulties that EDCTP had faced in 2004, the constituencies that were involved during this period namely the ES, PB and DCCC were asked by the GA in January 2005 to conduct self-assessments. Although ENNP was formed after 2004 and was therefore not required to do a self-assessment, this constituency nevertheless decided to conduct one. To meet this requirement, the PB discussed its role in its meeting of March 2005 and subsequently submitted its self-assessment to the GA. Similarly, the ES and DCCC also conducted self-assessments that were submitted to the GA. These self-assessments were first discussed during the GA meeting of 30 March. In the GA meeting of 14 June a working group was formed comprising the GA representative from Sweden as the Chair and representatives from Denmark, Germany, Netherlands and Norway as well as Chairs of the PB, DCCC, and ENNP, the ED and the Scientific Officer (SO) as members. The working group held its first face-to-face meeting on 28 September and thereafter continued discussions via email and telephone. The committee had a final meeting on 18 December before presenting its report to the GA on 19 December. A general discussion on this issue is scheduled to take place at the GA meeting of 8 March 2006.

OUR AIMS ARE TO MAINTAIN BEST PRACTICES AND TRANSPARENCY

REVISION OF THE METHOD FOR PROCESSING CALLS FOR PROPOSALS

18 Prior to 2005, there was some dissatisfaction in the way calls were handled at EDCTP. To improve this and ensure scientific excellence and integrity of the review process, the EDCTP-EEIG GA during 2005 asked the IED to investigate the quality of the review of the proposals that were submitted in response to the first and second calls launched in February 2004 and June 2005 respectively, as well as the call for the support of Senior Fellowships that was launched in May 2004. Regarding the status of these calls as of January 2005; nine projects were already approved for funding under the first call and the review of pre-proposals for the second call had been completed and applicants informed of the outcome. Additionally, six senior fellowships had been approved and contract negotiations were taking place along with those for nine projects that were approved from the first call.

As early as July 2004, questions were raised regarding the procedures that were used to review and approve the proposals from the first call. However, it was not until December 2004 and early 2005 during the project contract negotiations that more questions came to the surface. Problems were also noted by the European Court of Auditors during its visit to the EDCTP ES in March 2005 when several issues with respect to the procedures used to review the applications were raised. In view of this the GA decided to suspend contract negotiations and appoint a working group to investigate these issues. This working group which comprised the IED, two representatives from the EC and one from NWO, the hosting institution in the Netherlands, presented its findings and recommendations to the GA during their meeting of 14 June. These recommendations were accepted and contract negotiations of five of the projects were allowed to resume while the remaining four were to be re-reviewed along with new projects. This review took place in August 2005 and the results were presented to the PB for their recommendation during the PB meeting of



5 September. During the GA meeting of 28 September, three projects were eventually approved for funding; none of them were among those that were re-evaluated.

Following this, in January 2005 the IED recommended the suspension of the second call mainly due to lack of documentation on the selection procedure and inexperience of the ES personnel in processing calls. The IED also proposed to involve research councils in the implementation of the structures that were required for proper review procedures. This decision was endorsed by the GA which decided to cancel the call and agreed to use the funds that were reserved for the call to be used for a new call on similar subjects. The GA also agreed with the proposal of the IED to involve research councils in the improvement of the review procedures at the ES.

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On the other hand, since the quality of the review of applications received in response to the call for support of Senior Fellowships was considered to be satisfactory, contracts for all six applicants were signed.



The December assembly meeting First row from left to right: Patrice Debré (France), Sissy Kolyva (Greece), Dicky Akanmori (Ghana), Diana Dunstan (United Kingdom), Odile Leroy (ES), Mercedes Diez (Spain), Laura Brum (Portugal), Joanna Camillo (Portugal), Sophie Couffignal (Luxembourg), Jean François Girard (France) Second row:

Naus (ES), Stefano Vela (Italy), Peter Lange (Germany), Bruno Gryseels (Belgium), Christa Janko (Austria), Peter Dukes (United Kingdom), Soren Jepsen (Denmark), Antonie Egeland (Norway), Sacra Tomisawa (Switzerland), Coenraad Krijger (Netherlands)

NEW EDCTP CALLS LAUNCHED IN 2005

EDCTP launched a new set of calls for proposals in September 2005. These were in four different grant schemes namely:

- *Clinical Trials:*
Support for capacity building for clinical trial sites and/or conduct of clinical trials
- *Capacity Building:*
Support for general capacity building on clinical trials related issues such as ethics and regulatory issues
- *Training Awards:*
Support for Senior and Career Development Fellowships, PhD scholarships and MSc studentships
- *Networking:*
Grants for the promotion of collaboration, synergy and co-ordination of activities among researchers and their institutions at national and regional levels in order to enhance co-operation, ownerships and sustainable capacity.

All applications received in response to these calls are being reviewed according to the EDCTP SOPs for the relevant granting scheme.

OUR LEADERSHIP



EDCTP CONSTITUENCIES

GENERAL ASSEMBLY

The GA met five times during 2005. All meetings took place in The Hague. At each meeting members of the Assembly were updated of the state of affairs from each constituent by the ES and respective chairs of the GA, DCCC, PB and ENNP.

The main decisions taken during 2005 by the assembly were the following:

- Approval of Switzerland as an EDCTP associate member
- Implementation of a self-assessment working group to improve EDCTP efficiency
- Nomination of a new chair of the EEIG: Dr Diana Dunstan
- Nomination of a new Executive Director: Dr Odile Leroy
- Nomination of a new Head of the Africa Office: Prof. Charles Mgone
- Implementation of co-funding mechanisms
- Memorandum of Understanding with NEPAD and WHO
- Approval of Internal Regulations, standard operating procedures and guidelines
- Review of Hosting Agreements with the Medical Research Council of South Africa and NWO for hosting the EDCTP Secretariats at Cape Town and The Hague, respectively
- Approval of projects that were selected from the first call
- Approval of 2005 calls



During the staff retreat **First row:** Chris Bruinings (Netherlands)
Second row: Thomas Nyirenda (Malawi), Francine Ntoumi (Republic of Congo), Michael Makanga (Uganda), Marjolein Robijn (Netherlands), Stefan Wagener (Germany) **Third row:** Simon Belcher (United Kingdom), Marianna Karras (Greece, France), Charles Mgone (Tanzania), Rosemarie Veen-Oei (Netherlands), Vanessa de Oliveira (Brazil), Odile Leroy (France), Cynthia Naus (Netherlands)

- Approval of the second EDCTP Annual Forum programme, date and location; “From Knowledge to Implementation” held in Durban in October 2005.

EXECUTIVE SECRETARIAT

The EDCTP Secretariat had a high staff turnover during 2005. Besides the departure of seven staff members, seven new staff joined the ES.

The interaction of the ES with the hosting institution was also strengthened, particularly for legal services and quality assurance support.

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The new ED reorganised the secretariat to allow a better interface between the African and the European Offices, by creating three teams, i.e. capacity building team, clinical trial team and networking team, involving team members from both offices. This matrix structure was presented to the GA and approved during their meeting of 19 December.

	Team Leader	Project Officer	QA Officer	Archiving	Communication Officer
Capacity Building	M. Makanga	M. Karras V. de Oliveira	R. van der Veen-Oei	D. Abrahams L. Ramalakhan	M. Karras
Clinical Trial	F. Ntoumi	M. Robijn Vacant	R. van der Veen-Oei	D. Abrahams L. Ramalakhan	M. Robijn
Networking Team	T. Nyrienda S. Wagener	R. van der Veen-Oei	V. de Oliveira	D. Abrahams L. Ramalakhan	R. van der Veen-Oei

“I have joined EDCTP at an exciting period when European member states have shown genuine interest to work together through joint programmes and in partnership with their African counterparts. My mission in this is to mobilise and galvanise a strong African input to provide ownership and leadership for developing a genuine and sustainable partnership that will live well beyond the existence of the programme”



Professor Charles Mgone

Executive Director

The position of Executive Director was held by Prof. Bernt Lindtjørn as an Interim Executive Director from February until June 2005, and in July 2005 Dr Odile Leroy joined EDCTP as the new Executive Director.

Head of Africa Office

The appointment of Prof. Charles Mgone as Head of the Africa Office was approved by the GA in September 2005.

Legal Officer

In the hosting agreement with NWO, legal services were included, in order to benefit the expertise of their legal department, EDCTP supporting the cost of half FTE.

Communication Officer

The position of communication officer was suppressed, and all project officers have been give the task of communications under the supervision of the Head of Africa Office, Prof Charles Mgone.

Operation Manager

A new position has been created to manage all the operations of EDCTP, and supervision of the three teams. Dr Cynthia Naus, previously programme co-ordinator has been nominated to the position of Operation Manager.

Scientific Officer

Dr Francine Ntoumi has joined EDCTP in October 2005 as a Scientific Officer and also leader of the clinical trial team.

EDCTP principles of the partnership

1. Decide on the objectives together
2. Build up mutual trust
3. Share information; develop networks
4. Share responsibility
5. Create transparency
6. Monitor and evaluate the collaboration
7. Disseminate the results
8. Apply the results
9. Share contributions and profits equitably
10. Increase research capacity
11. Build on achievements

Project officers

Four project officers were appointed to the Operations. Ms Rosemarie van der Veen Oei who was originally recruited as the Assistant to the Programme Co-ordinator was the first person to fill this position. Due to the increased workload of the ES two additional project officers, Ms Vanessa de Oliveira and Dr Marianna Karras were recruited in October and November, respectively and Ms Marjolein Robijn joined on a temporary basis from November 2005. In December Germany proposed a seconded project officer to take the position of north-north network officer.

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Support staff

Ms Janice Chittick took the position of financial assistant in February 2005. In June 2005 Ms La Toya Ramlakhan joined EDCTP as an administrative assistant.

PARTNERSHIP BOARD

During 2005, the PB held five face-to-face meetings and two teleconferences. Three of the face-to-face meetings took place in The Hague and the other two in Accra, Ghana and Durban, South Africa. At these meetings the PB reviewed the text and content of various proposal calls and discussed several issues including input on the Second EDCTP Annual Forum that was held in Durban, South Africa. The PB had also participated in the self-assessment process.

Following expiry of their term of office on 31 December 2005, Prof. Fred Binka (Chair), Prof. Thomas Egwang, Dr Pedro Alonso, Dr Bernard Fourie and Dr Alwyn Mwinga resigned from the Partnership Board.

DEVELOPING COUNTRIES CO-ORDINATING COMMITTEE

In 2005, the DCCC held three meetings which took place in Ghana, Kenya and South Africa. Two of these meetings included visits to nearby clinical trial sites, which enabled members of DCCC to raise awareness and the visibility of both EDCTP and DCCC.

DCCC meeting in Durban in October
First row: Cynthia Naus (Netherlands)
Second Row: from left to right
 Thomas Nyirenda (Malawi), Simon Agwale (Nigeria), Aderaye Getachew (Ethiopia),
 Kobus Herbst (South Africa), John Waitombi (Kenya), Pascoal Mocumbi (Mozambique), Joseph Odhiambo (Kenya), Vohangy Rasolofo (Madagascar), Akin Sowumni (Nigeria)



Among the needs and the gaps identified by the DCCC, the main ones included the following:

- Upgrading of clinical trials sites
- Call for institutions offering clinical trial methodology training
- Data management training
- Infrastructure strengthening
- Training of monitors
- Identification of means of effective collaboration with WHO AFRO
- Completing inventory of African National Programmes, institutions and clinical sites
- Proposal on DCCC regional meetings for networking
- Proposal of spread of expertise and competencies from well-established centres to new or less developed centres, the “sister approach”
- Proposal of a call for an integrated approach of nodes of excellence.

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DCCC members expressed the need for a common strategy between DCCC, PB and HR in addressing south-south networking and capacity building needs.

DCCC members strongly proposed that south-south networking and north-south networking should be in the hands of the Head of the Africa Office.

HR presented his on-going networking plans and the signed memorandum of understanding between NEPAD and EDCTP.

Following expiry of their term of office on 31 December 2005, DCCC members to step down and be replaced were Dicky Akanmori, Voahangy Rasolofo and John Waitumbi.

EUROPEAN NETWORK OF NATIONAL PROGRAMMES

One of the main priorities of EDCTP during 2005 was the co-ordination of the national programmes and activities of Member States.

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The European Networking Officers together with the ES continued with the development of a strategy for the implementation and co-ordination of MS national programmes. To tackle this challenge EDCTP is using both the top-down approach through which MS co-fund EDCTP, as well as the bottom-up where EDCTP co-funds MS. During 2005 the top-down approach was the most successful. In fact co-funding was implemented for large capacity building and clinical trial calls for proposals that were launched in September 2005. The bottom-up approach was also frequently discussed. The MS were encouraged to develop joint calls that could be co-funded by EDCTP. The ED discussed with the French ANRS how a joint call on mother-to-child transmission of HIV could be developed. It is expected that this approach will yield its first results in 2006.

The ENNP met five times. Prof. Laura Brum from Portugal was elected Chair of the ENNP in April 2005. The priorities from National Programmes were addressed through the inventory of the national funding structures and the already existing collaboration with African countries.

The role of ENOs was discussed and translated in the preparation of Internal Regulations for ENNP. The ENNP has also set up a working group on self-assessment.

The ES staff paid visits to Portugal, Germany, Norway, France, Netherlands, Switzerland and UK. The Interim Executive Director, Prof. Bernt Lindjorn and subsequently the Executive Director Dr Odile Leroy and the High Representative, Dr Pascoal Mocumbi also actively participated in the co-ordination of member state activities.

EDCTP MAIN ACTIVITY AREAS

NETWORKING

North-north networking activities

In the course of the year EDCTP constituency representatives and personnel proactively engaged with various agencies, institutions and representatives of member states to promote EDCTP activities. The EDCTP N-NNO attended a meeting of the NACCAP steering committee from the Netherlands and made a presentation on EDCTP. Similarly, the programme co-ordinator of the NACCAP met several times with the ES staff, including the ED to discuss matters of mutual interest.

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Co-funding

In 2005, a procedure for co-funding of EDCTP calls to facilitate the co-ordination of Member State National Programmes and their €200 M contribution to EDCTP was developed and implemented. Thus all applicants of proposals that were launched under the Clinical Trial Grant Scheme were asked to match the financial contribution of EDCTP with either cash or in-kind contributions from their EDCTP-EEIG MS National Programmes. Similarly, co-funding was also introduced for projects involving two or more European institutions for providing incentives for joint capacity building programmes in Africa. These calls were launched on 26 September under the Networking Grant Scheme.



Manual Barroso, president of the European Commission, encourages EDCTP Haut representative Dr Pacoal Mocumbi to pursue the EDCTP mission in Africa

South-south networking and African involvement

The south-south networking activities were spearheaded by the South-South Networking Manager (S-SNM) who through the year collected information on clinical trial sites in Africa. S-SNM was also responsible for establishing the EDCTP Listserv that was launched in 2005. The Listserv provides regular updates and serves as a discussion forum, especially for the African scientific community working on poverty-related diseases. The S-SNM also organised the three DCCC meetings that took place in 2005 and accompanied the HR to the meeting of the African Ministers of Health that was held on 10-14 October in Gaborone, Botswana.

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African leadership in EDCTP

Acknowledging that the African commitment and leadership is essential for the success and sustainability of the programme, EDCTP had right from the start fostered and embraced the involvement and representation of the African scientific community. This is underpinned by the African presence at all levels. For instance, the Partnership Board which is responsible for determining the EDCTP strategy is composed of African and European experts in an equal representation. The Developing Countries Co-ordinating Committee comprising 15 experts from sub-Saharan African countries, ensuring balance in experience, expertise and regional representation, serves as the advisory committee on south-south networking and capacity building.

The High Representative Dr Pascoal Mocumbi dynamically engaged himself in advocacy activities, which among others resulted in the recognition of EDCTP as a promising venture by stakeholders, particularly the African Union (AU), NEPAD and African leaders. This involvement of African leadership will further strengthen the partnership.

Additionally, during 2005 grant agreements were signed for six African EDCTP Senior Fellowships. These include Dr Didier Ekouevi from Côte d'Ivoire, Dr Willem Hanekom from South African, Prof. Maowia Mukhtar from Sudan, Dr Abdoulaye Djimde from Mali, Dr Alexis Nzila from Congo Brazzavillie and Dr Abraham Alabi from The Gambia. African involvement is also prominent at the EDCTP Executive Secretariat which has several staff members of African nationalities including Prof. Charles Mgone who has accepted the position of the Head of the Africa Office, Dr Michael Makanga (Capacity Building Manager), Dr Thomas Nyirenda (South-South Networking Manager) and Dr Francine Ntoumi (Scientific Officer).

During 2005, eight clinical trials were approved for funding, four of which are already up and running including those of Prof. van Helden, Prof. Chintu, Prof. D'Alessandro and Prof. Gillespie. Three of these grants are managed by Principal Investigators (PIs) of African origin (Prof. Chintu, Prof. van Helden and Dr Jindani) two of whom are based in Africa (Prof. Chintu and Prof. van Helden). Due to other commitments, unfortunately one grantee who is African withdrew his request for funding after it had been awarded. In total 64 African residents were involved in the capacity of either PIs or co-applicants of the EDCTP grants that were approved for funding in 2005. These projects are taking place in 17 different African countries including Burkina Faso, Côte d'Ivoire, Gabon, Gambia, Ghana, Kenya, Malawi, Mali, Mozambique, Nigeria, Rwanda, South Africa, Sudan, Tanzania, Uganda, Zambia and Zimbabwe.

Sites that are involved in EDCTP funded projects

AFRICAN SITES THAT HAVE BEEN APPROVED FOR EDCTP FUNDING		
<i>Country</i>	<i>Site</i>	<i>Location</i>
Burkina Faso	Centre Muraz	Bobo Dioulasso
Côte d'Ivoire	Yopougon University Hospital Programme PACCI	Abijan
Gabon	Albert Schweitzer Hospital	Lambaréné
Gambia	MRC laboratories	Banjul
Ghana	University of Science and Technology	Kumasi
Kenya	ICRH-K KEMRI/Wellcome Trust laboratories KEMRI	Mombassa Kilifi Nairobi
Malawi	Queen Elisabeth Central Hospital	Blantyre
Mali	Malaria Research and Training Centre	Bamako
Mozambique	Mahnicá Health Research Centre Ministerio de Saude	Maputo
Nigeria	University of Calabar	Calabar
Rwanda	Programme de Lutte contre le Paludisme	Kigali

table continued on next page

<i>Country</i>	<i>Site</i>	<i>Location</i>
South Africa	University of Stellenbosch _____ Groote Schuur Hospital _____ University of Cape Town _____ SATVI _____ Medical Research Council _____ University of Pretoria	Cape Town _____ Durban _____ Pretoria
Sudan	University of Khartoum _____ Federal Ministry of Health	Khartoum
Tanzania	IHRDC _____ Muheza Teule Hospital _____ Kilimanjaro Christian Medical College	Ifakara _____ Muheza _____ Moshi
Uganda	Mbarara University of Science and Technology _____ Uganda Malaria Surveillance Project _____ Epicentre	Mbarara _____ Kampala
Zambia	University Teaching Hospital _____ Ndola Central Hospital _____ Tropical Diseases Research Centre	Lusaka _____ Ndola
Zimbabwe	LSHTM Biomedical Training Institute	Harare

Networking grants

A call for proposals for a €30,000 networking grant supported by the south-south budget was launched on 26 September. The call is open only for applications that will involve EDCTP grantees and/or DCCC members. However, since no applications were received the deadline for submission of applications for this had been extended to 1 Feb 2006.

CAPACITY BUILDING IN SUB-SAHARAN AFRICA

EDCTP training awards

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The call for Senior Fellowships was first launched in 2004. In 2005, this was expanded to support Career Development Fellowships, PhD Scholarships and MSc Studentships. The senior fellowship awards are ongoing and the first instalments of €90,000 have already been awarded to all six fellows. This is summarised in the following table.

**TRAINING AWARDS – SENIOR FELLOWSHIP –
TOTAL BUDGET €200,000 – MAY 2004**

<i>Grantee</i>	<i>Location</i>	<i>Title</i>
Dr Ekouevi	Côte d'Ivoire	Preventing per-partum transmission of HIV-1 in Africa: tenofovir-based alternatives to single dose nevirapine in the light of future treatment options
Dr Djimde	Mali	Assessment of the Public Health Benefit of artemisine based combination therapies for uncomplicated malaria treatment in Mali
Dr Nzila	Kenya	Understanding the mechanism of piperazine resistance
Dr Alabi	Gambia	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
Prof. Mukthar	Sudan	The burden of tuberculosis in eastern Sudan: epidemiology and drug resistance patterns of Mycobacterium tuberculosis isolates
Dr Hanekom	South Africa	BCG-induced immune correlates of protection against tuberculosis

TRAINING AWARDS – SEPTEMBER 2005 (TITLES: TO BE DETERMINED)		
<i>Type/Budget</i>	<i>Location</i>	<i>Remarks</i>
Senior Fellowship	Proposals were received from applicants based in Burkina Faso, Congo, Gambia, Nigeria, Senegal, Tanzania and Zimbabwe	A total of 10 eligible applications were received in response to the call that was launched on 26 September 2005 with a deadline of 28 November 2005. These are currently under review. These applications included 7 malaria projects, 1 project on TB, and 2 HIV projects.
Career Development Fellowships €100,000	Proposals were received from applicants based in Cameroon, Congo, Ethiopia, Malawi, Mozambique, Nigeria, South Africa and Uganda	A total of 9 eligible applications were received in response to the call that was launched on 26 September 2005 with a deadline of 28 November 2005. These are currently under review. These applications included 2 malaria projects, 1 TB project, 3 HIV projects, 2 projects on TB/HIV and 1 project on HIV/malaria.
PhD Scholarships €75,000	Proposals were received from applicants based in Burkina Faso, Ethiopia, Gabon, Gambia, Kenya, Mali, Mozambique, South Africa, Tanzania, Uganda and Zambia	A total of 27 eligible applications were received in response to the call that was launched on 26 September 2005 with a deadline of 21 November 2005. These are currently under review. These projects include 14 malaria projects, 4 TB projects and 9 HIV projects.
MSc Studentships €21,000	Proposals were received from applicants based in Gabon, Gambia, South Africa and Uganda	A total of 6 eligible applications were received in response to the call that was launched on 26 September 2005 with a deadline of 21 November 2005. These are currently under review. These projects include 2 malaria projects, 1 TB, 2 HIV and 1 general.

Capacity building calls on ethics review

On 26 September 2005 three calls for proposals to support courses and seminars on ethics and the establishment of national or institutional review boards were made. These calls whose deadline was December and launched under the Capacity Building Grant Scheme require no co-funding. They are summarised in the following table.

<i>Subject</i>	<i>Budget</i>	<i>Number of applications received</i>	<i>African Countries involved</i>	<i>EDCTP EEIG MS involved</i>
Support of an African Co-ordinating Office for Ethics	€1,800,000 available/ €1,800,000 maximal budget per project	One application is currently under review	Cameroon Ethiopia Tanzania	Austria Belgium France Italy Norway Switzerland
Support for Courses and Seminars on Ethics	€700,000 available/ €100,000 maximal budget per project	Three applications are currently under review	Cameroon Malawi Senegal South Africa Tanzania Zambia Zimbabwe	Belgium Norway Switzerland
Support for the establishment of African National or Institutional Ethical Review Committees	€500,000 available/ €50,000 maximal budget per project	Three applications are currently under review	Ghana Malawi Nigeria Rwanda	Norway



Dr Merry's team in Cape Town

SUPPORT OF CLINICAL TRIALS

Among calls that were made in 2004, eight proposals were approved. These calls are partly being paid from the clinical trials budget. The capacity building aspects of the studies are being paid from the Capacity Building budget. The table below shows the current status of these grants:

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UPDATE ON THE CLINICAL TRIAL GRANTS THAT WERE SUBMITTED IN RESPONSE TO THE CALL OF FEBRUARY 2004				
<i>Disease</i>	<i>Grantee</i>	<i>Title</i>	<i>Budget</i>	<i>Update</i>
TB	Van Helden	Surrogate markers to predict the outcome of anti-tuberculosis therapy	€973,033	First payment was made on 27 Sep 2005
	Gillespie	Rapid evaluation of Moxifloxacin in the treatment of sputum smear positive tuberculosis: REMoxTB	€2,987,874	First payment was made on 21 Oct 2005
	Jindani	A controlled clinical trial to evaluate high dose rifapentine and moxifloxacin in the treatment of pulmonary tuberculosis	€4,013,000	Negotiations are ongoing
	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	Negotiations are ongoing

table continued on next page

<i>Disease</i>	<i>Grantee</i>	<i>Title</i>	<i>Budget</i>	<i>Update</i>
Malaria	D'Alessandro	Evaluation of 4 artemisinin-based combinations for treating uncomplicated malaria in African children	€1,999,990	Negotiations are ongoing
HIV	Mutabingwa	An open-label randomised controlled trial of piperazine-dihydroartemisinin, azithromycin-artemunate and arthemeter-lumefantrine for the treatment on non-severe Falciparum malaria in children	€350,000	PI unable to undertake the project
	Kremsner	Artemunate for severe malaria in African children	€5,000,000	Negotiations are ongoing
	Chintu	CHAPAS Trials: Children with HIV in Africa: pharmacokinetics and adherence of simple antiretroviral regimens	€1,100,070	First payment was made on 4 November

On 26 September 2005, four more calls for proposals under the Clinical Trials Grant Scheme were launched. Similar to the calls that were launched in 2004, the capacity building component of the studies will be funded under the Capacity Building budget. The table below summarises current status of these calls whose deadlines were 12 December 2005.

<i>Subject</i>	<i>Budget</i>	<i>Co-funding requirement</i>	<i>Number of applications received</i>	<i>African countries involved</i>	<i>EDCTP-EEIG MS involved</i>
Identification of safe and efficacious ARV in combination with tuberculosis drugs in tuberculosis patients with HIV infection	€1,833,333 available/ €1,000,000 maximal budget per project	50% from EDCTP-EEIG MS NP	Five applications are currently under review	Ethiopia Malawi Mozambique South Africa Tanzania Uganda Zimbabwe	Belgium France Germany Ireland Netherlands Sweden UK
Capacity building and site development for the conduct of phase III trials of TB vaccines in high-risk populations	€2,350,000 available/ €2,000,000 maximal budget per project	50% from EDCTP-EEIG MS NP	Four applications are currently under review	Cape Verde Ethiopia Gabon Kenya Madagascar Mozambique South Africa Tanzania Uganda Zambia	Belgium Denmark Germany Netherlands Portugal Spain Sweden UK

table continued on next page

<i>Subject</i>	<i>Budget</i>	<i>Co-funding requirement</i>	<i>Number of applications received</i>	<i>African countries involved</i>	<i>EDCTP-EEIG MS involved</i>
Capacity building and site development for the conduct of phase III trials of TB vaccines in children under 1 year of age	€2,350,000 available/ €2,000,000 maximal budget per project	50% from EDCTP-EEIG MS NP	Three applications are currently under review	Kenya South Africa Uganda	Belgium Denmark Netherlands Sweden UK
Capacity building for the conduct of phase I/II and Phase III trials of vaginal microbicides against sexual transmission of HIV	€7,000,000 available/ €2,500,000 maximal budget per project	50% from EDCTP-EEIG MS NP	Three applications are currently under review	Kenya Mozambique Rwanda South Africa Tanzania Uganda	Belgium Italy Netherlands Spain UK



The first meeting of ED with Jose Esparza to set up a close collaboration between EDCTP and the Bill and Melinda Gates Foundation on HIV vaccine capacity building in Africa From left to right: Marianna Karras (EDCTP), Odile Leroy (EDCTP), Jose Esparza (BMGF), Nina Russel (BMGF), Siobhan Malone (BMGF)

ADVOCACY AND FUNDRAISING

Communication

The ED started work on communication strategy during 2005. The development of a communication strategy was instigated with the aid of representatives of the Dutch hosting organisations NWO and ZonMW. It is expected that the new EDCTP communication strategy will be presented to the GA during their first meeting in 2006.

Meetings with the EC

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A meeting between the HR, the IED, the Chair of the GA (Dr Peter Lange) and the EU Research Commissioner, Dr Janez Potočanik, took place on June 13. Dr Potočanik's main message was that a more concerted co-ordinated action of EDCTP was urgently needed. He stressed the need for EDCTP to further improve its strategic and administrative management. The commission acknowledged that the Article 169 principle has interesting prospects and the EDCTP goals are commendable but very difficult to be realised.

On September 30 the HR, ED and the Chair of the GA (Dr Diana Dunstan) were invited to a meeting with EU President José Manuel Barroso. Again EDCTP was strongly encouraged to concentrate on its mission.

Meetings with African policy makers

The HR attended several high level political meetings in Africa. These included the African Ministers of Health Meeting that was held in Gaborone, Botswana in October 2005.

Meetings with the European policy makers

Visits were made to the following countries: France, Germany, Netherlands, Norway, Portugal, Switzerland and the United Kingdom.



The Cochrane Centre team and the EDCTP African Office staff in Cape Town

INFORMATION MANAGEMENT

The main activities for the area of information management included the negotiations with the Cochrane centre for the establishment of a Clinical Trial Register and the selection of a Document Management System (DMS). With respect to the clinical trial register, negotiations focussed on the collaboration with WHO, who are also establishing an International Clinical Trials Registry. The co-ordinator of the project that EDCTP is funding at the Cochrane Centre in South Africa is part of the committee that advises WHO on their registry and both project agreed to have a close collaboration. EDCTP HR is also a member of the Steering Committee of the WHO International Clinical Trials Registry.

ACCOUNTS

AUDITORS' LETTER

Introduction

We have audited the financial statements which are part of the annual report of EDCTP-EEIG in The Hague, The Netherlands, for the year 2005 as set out on pages 43 to 56. These financial statements are the responsibility of the management of EDCTP-EEIG. Our responsibility is to express an opinion on these financial statements based on our audit.

Scope

We conducted our audit in accordance with auditing standards generally accepted in the Netherlands. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our 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 2005 and of the result for the year then ended in accordance with accounting principles generally accepted in the Netherlands.

Furthermore we have established to the extent of our competence that the annual report is consistent with the financial statements.

The Hague, 7 June 2006
KPMG ACCOUNTANTS N.V.
W.A. Touw RA

STATEMENT OF FINANCIAL ACTIVITIES

FOR THE YEAR ENDED 31 DECEMBER 2005

STATEMENT OF FINANCIAL ACTIVITY 2005 (SOFA)

Incoming resources	Notes	Restricted €000	Unrestricted €000	2005 Total €000	2004 Total €000
<i>Incoming resources from generated funds:</i>					
Voluntary & donor income	2	728	4,664	5,392	8,027
Investment income	3	8	452	460	366
Total incoming resources		736	5,116	5,852	8,393
<i>Resources expended</i>					
Activities in furtherance of EDCTP objects	4		(2,340)	(2,340)	(2,640)
Grants payable	5		(8,276)	(8,276)	(46)
Governance costs	6		(589)	(589)	(591)
Total resources expended		0	(11,205)	(11,205)	(3,277)
<i>Net income (expenditure) for the year</i>		736	(6,089)	(5,353)	5,116
<i>Net movement in funds</i>					
Total funds as at 31/12/04		0	24,797	24,797	19,681
Net income for the year		736	(6,089)	(5,353)	5,116
Total funds at 31/12/05		736	18,708	19,444	24,797
<i>Appropriation of funds</i>					
Earmarked funds			18,708	18,708	24,765
Allocated to general funds			0	0	32
Allocated to restricted funds		736		736	
Total funds		736	18,708	19,444	24,797

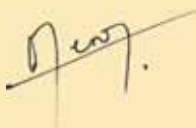
The statement of financial activities includes all gains and losses recognised in the year. All incoming resources and resources expended derive from continuing activities.

BALANCE SHEET AS AT 31 DECEMBER 2005

	Notes	2005 €000	2004 €000
<i>Fixed assets</i>			
Tangible assets	9	15	17
<i>Current assets</i>			
Debtors	10	235	8,234
Cash at bank and in hand	11	26,288	16,869
		26,523	25,103
Creditors: amounts falling due within one year	12	(4,694)	(323)
Net current assets		21,829	24,780
Creditors: amounts falling due over 1 year	13	(2,400)	0
Net assets		19,444	24,797
<i>Funds</i>			
<i>Unrestricted funds</i>			
General funds	14	0	0
Earmarked funds	15	18,708	24,797
		18,708	24,797
<i>Restricted funds</i>	16	736	
Total funds carried forward		19,444	24,797

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Approved by the EDCTP Secretariat



Dr. Odile Leroy

Dated 07 June 2006

STATEMENT OF CASH FLOW FOR THE YEAR ENDED 31 DECEMBER 2005

	Notes	2005 €000	2004 €000
<i>Net cash inflow from operating activities</i>	17	8,969	(3,477)
<i>Returns on investments and servicing of finance</i>			
Deposit income received		460	366
<i>Capital expenditure and financial investment</i>			
Payments to acquire tangible fixed assets		(10)	(21)
Increase/(decrease) in cash in the year		(9,419)	(3,132)
Net cash resources at 01 January		16,869	20,001
Increase/(Decrease) in cash in the year		9,419	(3,132)
Net cash resources at 31 December		26,288	16,869

NOTES FORMING PART OF THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2005

NOTE 1

PRINCIPAL ACCOUNTING POLICIES

(a) Basis of accounting

The accounts have been prepared under the historical cost convention and are in accordance with applicable accounting principles generally accepted in the Netherlands.

(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 is 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) 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.

(c) Investment income and interest receivable

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

(d) 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.

(e) 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.

(f) Costs of 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).

(g) Costs of governance

These represent the costs attributable to the strategic planning bodies of the EDCTP; the assembly the partnership board (PB) and the developing countries collaborating committee (DCCC). 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.

(h) Capitalisation and depreciation of tangible fixed assets

Individual fixed assets costing €5000 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

(i) 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 EEG, which can be used at the discretion of the EDCTP executive management.
- Earmarked funds – these are funds set aside 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 the 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.

(j) Foreign currencies

Transactions in foreign currencies are translated 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 no foreign currency assets or liabilities as at 31 December 2005.

(k) 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

Incoming resources from voluntary and donor income	Earmarked €000	Restricted €000	2005 Total €000	2004 Total €000
EC for period of 3 of the grant agreement	4,614		4,614	7,995
Member state payments for pre 15-09-2003 expenditure				32
MRC re Capacity Building		728	728	
MRC re Durban Forum Subsidy	50		50	
Total	4,664	728	5,392	8,027

NOTE 3

Investment income	2005 €000	2004 €000
Deposit interest	460	366

NOTE 4

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Programme activities	2005 Total €000	2004 Total €000
Staff costs (see note 8)	1,205	1,333
Depreciation	12	4
Recruitment & pay survey	80	14
Travel & subsistence	179	338
Annual scientific forum	173	144
Advertising in scientific media	21	13
SRC	22	172
Consultancy	72	144
Other	307	338
<i>Total direct costs</i>	<i>2,071</i>	<i>2,500</i>
Support costs (see note 7)	269	140
Total research activities	2,340	2,640

NOTE 5 GRANTS PAYABLE

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

5a EDCTP Grant awarding for 2005 – split by disease

Total grants signed up in 2005

Country	Site	Bio Ethics	HIV	MAL	TB	Grand Total
Belgium	Tropical Medicine Institute			494,234		494,234
Burkina Faso	Muraz Centre			161,508		161,508
France	Epicentre MSF Paris			202,680		202,680
Gabon	Albert Schweitzer Hospital			175,872		175,872
Gambia	MRC Gambia		200,000			200,000
Germany	University of Tuebingen			20,160		20,160
Holland	Nijmegen Medical Centre		120,098			120,098
Ivory Coast	NGO Aconda		200,000			200,000
Kenya	Kenya Medical Research Institute /Welcome Trust Research Programme			200,000		200,000
Malawi	Welcome Trust Global Forum for Bio-ethics in Research	15,000				15,000
Mali	University of Bamako			200,000		200,000
Mozambique	Manhica Research Centre			183,346		183,346
Nigeria	University of Calabar			147,624		147,624
Rwanda	National Malaria Control Programme Rwanda			94,680		94,680
South Africa	MRC SA				773,904	773,904
	University of Cape Town				200,000	200,000
	University of Pretoria				84,128	84,128
	University of Stellenbosh				532,397	532,397
South Africa Total					1,590,429	1,590,429

5a continued

Country	Site	Bio Ethics	HIV	MAL	TB	Grand Total
Spain	Centre International Health Barcelona			7,560		7,560
Sudan	University of Khartoum				200,000	200,000
Tanzania	Kilimanjaro Christian Medical College				605,812	605,812
Uganda	Mulago Hospital			188,400		188,400
UK	London School of Hygiene and Tropical Medicine				356,508	356,508
	LSTM Liverpool			141,502		141,502
	MRC UK		379,093		256,994	636,087
	University College London				786,611	786,611
UK Total			379,093	141,502	1,400,113	1,920,708
Zambia	Tropical Diseases Research Centre in Ndola			182,424		182,424
	University Teaching Hospital Lusaka		600,879		564,553	1,165,432
Zambia Total			600,879	182,424	564,553	1,347,856
Grand Total		15,000	1,500,070	2,399,990	4,360,907	8,275,967

5b EDCTP Grant awarding for 2005 – split by type of grant

Total grants signed up in 2005

Country	Site	Capacity Building	Clinical Trials	Bio Ethics	Grand Total
Belguim	Tropical Medicine Institute	120,000	374,234		494,234
Burkina Faso	Muraz Centre		161,508		161,508
France	Epicentre MSF Paris		202,680		202,680
Gabon	Albert Schweitzer Hospital		175,872		175,872
Gambia	MRC Gambia	200,000			200,000
Germany	University of Tuebingen		20,160		20,160
Holland	Nijmegen Medical Centre	9,000	111,098		120,098
Ivory Coast	NGO Aconda	200,000			200,000
Kenya	Kenya Medical Research Institute/Welcome Trust Research Programme	200,000			200,000
Malawi	Welcome Trust Global Forum for Bio-Ethics in Research			15,000	15,000
Mali	University of Bamako	200,000			200,000
Mozambique	Mahnicá Research Centre		183,346		183,346
Nigeria	University of Calabar		147,624		147,624
Rwanda	National Malaria Control Programme Rwanda		94,680		94,680
South Africa	MRC SA	68,690	705,214		773,904
	University of Cape Town	200,000			200,000
	University of Pretoria		84,128		84,128
	University of Stellenbosh		532,397		532,397
South Africa Total		268,690	1,321,739		1,590,429
Spain	Centre International Health Barcelona		7,560		7,560
Sudan	University of Khartoum	200,000			200,000
Tanzania	Kilimanjaro Christian Medical College	112,472	493,340		605,812
Uganda	Mulago Hospital	13,200	175,200		188,400
UK	London School of Hygiene and Tropical Medicine		356,508		356,508
	LSTM, Liverpool		141,502		141,502
	MRC UK		636,087		636,087
	University College London		786,611		786,611
UK Total			1,920,708		1,920,708
Zambia	Tropical Diseases Research Centre In Ndola		182,424		182,424
	University Teaching Hospital Lusaka	80,850	1,084,582		1,165,432
Zambia Total		80,850	1,267,006		1,347,856
Grand Total		1,604,212	6,656,755	15,000	8,275,967

NOTE 5 (CONTINUED)

Sponsoring EDCTP oriented forums and workshops	2004 Total €000
<i>For the preceding year the total grants awarded were:</i>	
Institut voor tropische geneeskunde, Antwerp, Belgium	46
Total institutional grants	46

NOTE 6

Governance costs	2005 Total Unrestricted €000	2004 Total Unrestricted €000
Assembly	61	36
Partnership Board	356	438
D.C. collaborating committee	113	96
ENNP	43	
Audit fees	16	21
Total governance costs	589	591

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NOTE 7

Support costs (from 3rd parties)	NWO €000	MRC SA €000	2005 Total €000	2004 Total €000
Telephones	21	3	24	21
Catering	15		15	11
IT maintenance	37	1	38	32
Rent	93		93	43
Office Cleaning	9	0	9	10
Postage	5		5	
Photocopies	8		8	
Legal/personnel & financial services	76	1	77	23
Total	264	5	269	140

NOTE 8

Staff costs and numbers	2005 €000	2004 €000
Total staff costs comprised:		
Wages and salaries	1,120	1,222
Social security costs	12	54
Pension costs	73	57
Total	1,205	1,333

The number of full time equivalent employees (including casual and part time staff) as at the 31 December 2005 was:

	2005	2004
Secretariat (EDCTP international contract)	6	8
Secretariat (Seconded from NWO)	8	9
Total	14	17

NOTE 9

Tangible fixed assets	As at 31/12/05 Computing Equipment €000
<i>Cost</i>	
At 31 December 2004	21
Additions	10
At 31 December 2005	31
<i>Depreciation</i>	
At 31 December 2004	(4)
Charge for the year	(12)
At 31 December 2005	(16)
<i>Net Book Value</i>	
At 31 December 2004	17
At 31 December 2005	15

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NOTE 10

Debtors	2005 €000	2004 €000
Other debtors	205	8,219
Prepayments	30	15
	235	8,234

NOTE 11

Cash at bank and in hand	2005 €000	2004 €000
Bank balances	26,267	16,844
Cash in hand	21	25
	26,288	16,869

NOTE 12

Creditors: amounts falling due within one year	2005 €000	2004 €000
Other creditors	4	71
Grant creditors	4,353	6
Accruals	337	246
	4,694	323

NOTE 13

Creditors: amounts falling due in over one year	2005 €000	2004 €000
Grant creditors	2,400	0
	2,400	0

NOTE 14

Unrestricted funds of the EEIG General Fund	€000
Balance at 31 December 2004	0
Movement in funds for the year	0
Balance at 31 December 2005	0

NOTE 15

Earmarked funds	€000
Balance at 31 December 2004	24,797
EC Grant funds received	4,614
Released to statement of financial activities	(10,703)
Balance at 31 December 2005	18,708

In accordance with guideline 640 (non-profit organisations) of the Dutch Raad voor de Jaarverslaggeving (RJ, Accounting Standard Setting Body) the unrestricted part of earmarked grants and contributions are presented as earmarked funds as part of the appropriation of funds.

NOTE 16

Restricted funds	At 31/12/04 €000	Incoming resources €000	Outgoing resources €000	At 31/12/05 €000
MRC UK Capacity Development	0	728	0	728
Investment income	0	8	0	8
Total	0	736	0	736

The funding received from the MRC UK is to be used in respect of capacity building and training for staff and infrastructure at the MRC Uganda and MRC Gambia sites.

NOTE 17

NOTES TO CASH FLOW STATEMENT

(a) Reconciliation of income to net cash inflow from operating activities	2005 €000	2004 €000
Net movement in funds for the year	(5,353)	32
Investment income	(460)	(366)
Decrease in debtors	7,999	(8,209)
Increase in creditors	6,771	(22)
Increase in earmarked income		5084
Depreciation	12	4
Net cash inflow from operating activities	8,969	(3,477)

(b) Analysis of net cash resources	31 Dec 05	Cash flow	31 Dec 04
Deposits with no notice & cash	26,288	9,419	16,869

NOTE 18

RELATED PARTIES

The EEIG has signed a hosting arrangement contract with NWO which includes secondment of personnel, rent of office space. Transactions under the hosting agreement, including the cost of seconded staff wages, amounted to €578,163 in 2005, €414,505 (2004). The hosting agreement was extended in 2005 until 15/09/2008.

EDCTP has an outstanding balance with related parties NWO at 31 December 2005 of €30,218.43 in relation to pre agreement expenditure; this will be repaid to NWO when all the member states have paid their portion of the debt.

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.

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 five 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) 32,609 as at 31/12/05 resulting in a contingent asset of (€000) 167,391 which has not been recognised in the accounts.

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NOTE 21

SUPPLEMENTARY DATA

It is proposed to add the net income for the year to the earmarked funds (18,708) and general funds (0). This proposal has been incorporated in the financial statements.

NOTE 22

REMUNERATION OF GOVERNING BODIES

The Assembly were not paid any honorariums in respect of attending meetings in 2005, instead they were paid only per diems set at the Dutch civil service rates to cover hotel and daily subsistence costs.

The Partnership Board members are paid an annual honorarium of €10,000 per member with €20,000 to the Chair for attending four 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 2005 the total payments to the Partnership Board in respect of honorariums amounted to €209,900 (2004 €222,824).

The Developing Countries Co-ordinating Committee members are paid no annual honorarium, but they are entitled to a daily honorarium of €200 which was introduced in 2005 for each meeting (up to a maximum of four meetings per year) attended. In 2005 the total payments to the DCCC in respect of honorariums amounted to €36,800.

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