



EDCTP

European and Developing Countries
Clinical Trials Partnership



Annual Report 2009

French and Portuguese summary and Financial Summary included

The calls for proposals to be launched

in 2010 will complement and strengthen

past and current activities

Project at a glance



Custom made treatments for HIV- infected children

Prof. Chifumbe Chintu,
Zambia

Lack of appropriate
antiretroviral formulations
for HIV-infected children
has been one of the major
constraints to scaling up
of treatment in HIV-1

infected children in resource limited countries. Triomune
Baby/Junior is a fixed dose combination of stavudine (d4T),
lamivudine (3TC) and nevirapine (NVP) in a new formulation
specifically developed for children.

Professor Chintu and his team in collaboration with the
Medical Research Council of UK, with a grant of EDCTP
studied the appropriate dosing of, and adherence to Triomune
Baby/Junior. This project, which started in November 2005,
so far has had a major breakthrough.

The outcomes of this trial have resulted in World Health
Organization (WHO) recommendations for the most optimal
ratios of antiretroviral drugs in fixed dose combination solid
formulas, and have been used as input for the definition of an
optimal weight band for these drugs in children.

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Statistics in brief





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Empowerment

The African participation in EDCTP-funded projects by the end of 2009 had a total of 278 mid-career to senior African scientists that were actively involved in EDCTP projects either as project coordinators or collaborators. Additionally, EDCTP has given Awards for Outstanding African Scientist to Dr Alexis Nzila and Dr Dominique Pepper. The award ceremony took place at the Fifth EDCTP Forum in Arusha, Tanzania, on 14 October 2009. These awards are aimed at motivating and empowering African scientists to take scientific leadership and to stimulate building of research capacity in sub-Saharan Africa and will be launched biannually.

2009 in a nutshell – by EDCTP values



Transparency

In July 2009, EDCTP commissioned the Swiss Centre for International Health at the Swiss Tropical Institute to undertake an internal assessment of the EDCTP programme covering the period from its inception in 2003 to 2009. The goal of the assessment was to gauge the progress that EDCTP had made by the end of 2009 and to collect views on the future direction. This report has been published and is available on the EDCTP website (www.edctp.org).

Mutual trust

Various EDCTP-funded consortia have been formed with genuine collaboration between northern and southern partners; notable among these is the Pan African Consortium for the Evaluation of Antituberculosis Antibiotics (PanACEA). This consortium was formed to conduct a series of cooperative trials evaluating three different drugs (Moxifloxacin, Rifampicin and SQ109) in a drug development programme. The consortium brings together many stakeholders besides EDCTP, including researchers and funders from public and private institutions from Africa, Europe and USA.

Partnership and networking

In 2009, contracts for three Regional Networks of Excellence (NoEs) were signed. These networks were constituted based on African regional economic framework and unite institutions that collaborate on the basis of their individual strengths and complementarities. Four regions of sub-Saharan Africa now have functional NoEs: Central Africa has Central African Network on tuberculosis, HIV/AIDS and malaria (CANTAM), Eastern Africa has East Africa Consortium for Clinical Research (EACCR), Southern Africa has Trials of Excellence for Southern Africa (TESA), and Western Africa has capacity building to prepare West African sites for clinical trials on HIV/AIDS, tuberculosis and malaria (WANETAM).

Responsibility

EDCTP encourages African countries to take responsibility and ownership in supporting research as well as devising sustainability strategies for these research and development programmes. In April, the Tanzanian government set an excellent example announcing a rise of public investment. By taking this step, Tanzania is the first African country with a high disease burden to significantly increase its health research budgets following repeated calls for such a move. EDCTP encourages other African leaders to follow suit.



Innovation

In May 2009 EDCTP held a stakeholder meeting on optimisation of HIV treatment and HIV-TB co-infection which was hosted by Portugal at the Centro Científico e Cultural de Macau in Lisbon. Stakeholders meetings based on thematic topics are part of EDCTP innovative approaches aimed at garnering updated information and engaging with various partners prior to launching calls. EDCTP launched a call for proposals on HIV treatment and HIV-TB co-infection in December 2009 with available funds of € 5 M.

Best practices

In September, the World Health Organization (WHO) granted the EDCTP-funded Pan-African Clinical Trials Registry (PACTR) primary registry status. This makes PACTR the first WHO endorsed trials registry in Africa. This registry will feed data into the global WHO International Clinical Trials Registry Platform (ICTRP) search portal facilitating African representation in the global picture of planned, ongoing and completed clinical trials.

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Message from the Executive Director



2009 proved to be yet another successful and rewarding year for EDCTP. In the course of the year the *Partnership* launched seven calls including a new grant scheme of European Member State Initiated (MSI) projects which aims at improving the coordination of their national programmes. The MSI grant scheme encourages Member States to work together and to join hands with their African counterparts to submit joint proposals that are mostly pre-financed by the Member States themselves. The year also saw the launching of three of the four selected EDCTP regional networks of excellence for conducting clinical trials. The regional networks of excellence brought together different centres from eastern, western, southern and central Africa to improve clinical trial capacity and readiness in each of



the regions. The networks are made up of centres with different level of development, but complementing each other's capacities in terms of disease themes, project and data management, laboratory capabilities and other areas. They foster south-south mentorship and proliferation of knowledge and capacities in their respective regions. They are already proving to be a great success.

Another highlight of the year was the Fifth EDCTP Forum. The event – which has become Africa's major platform for bringing together scientists, policy makers, programme managers, funders and other stakeholders working on HIV/AIDS, tuberculosis and malaria – was held in Arusha, Tanzania. The theme '*Fighting HIV/AIDS, tuberculosis and malaria – One World, One Partnership*' was well reflected by the wide participation which included 450 delegates from 49 different

countries. In keeping with the forum slogan of *One World, One Partnership* there were presentations from many EDCTP partners. During the forum, we held four main satellite meetings and workshops including an EDCTP/NACCAP Workshop on Ownership of Research Outcomes in sub-Saharan Africa; Universal Standards for Clinical Trials in Practice; ESSENCE funders meeting to explore synergy; and a Roundtable Meeting of Regional Economic Communities on the African representation at the EDCTP-EEIG General Assembly. At the forum, EDCTP also for the first time in its history gave two awards in honour of the achievements of African scientists working on poverty-related diseases. These awards for senior and junior research scientists were given to Dr Alexis Nzila of Kenya Medical Research Institute, Wellcome Trust Research Centre and Dr Dominique Pepper of the Institute of Infectious Diseases and Molecular Medicine of the University of Cape Town, South Africa, respectively.

To EDCTP, 2009 was a year of both consolidation and reflections. As we consolidated our efforts, and the first phase of the programme was coming towards an end, EDCTP commissioned a self-assessment to gauge the achievements attained to date and explore ways of improvement in the delivery of the programme. The self-assessment that was done using an independent party showed that EDCTP was doing well and was on track in achieving its mission. In addition to the self-assessment, EDCTP also conducted an exhaustive consultative process which ended up with an all-constituency meeting to discuss future plans and strategy of EDCTP. Through this process it was generally agreed to extend the scope of EDCTP to include all phases of clinical trials (I-IV) and to include health research on optimisation of clinical interventions. Regarding governance, it was decided to have with immediate effect four high-level African representatives in the EDCTP-EEIG General Assembly (GA). Additionally, in order to ensure a closer working relationship between European national programmes and the GA and to streamline governance, it was decided to elevate the constituency of the European Network of National Programmes (ENNP) to be part of the General Assembly, replacing European Network Officers (ENOs) with Deputy GA Members.

All this underpins a very satisfying 2009. However, it must be emphasised that none of these achievements would have been possible without the dedication, support and hard work of all our stakeholders and partners. I therefore, wholeheartedly extend my heartfelt thanks to everybody who has made 2009 a very successful year for EDCTP. Special thanks go to ENOs who have over the years contributed tirelessly to the coordination and integration of the national programmes. We look forward to 2010 and the transition into the second phase of EDCTP.

Charles S Mgone
Executive Director

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Constituencies

Joint Report



The EDCTP Partnership Board (PB) is an independent scientific expert committee that develops the strategy of EDCTP and oversees the scientific integrity of the programme. The PB advises the EDCTP General Assembly on technical and scientific matters relating to the programme.

What was the highlight of 2009 for the PB?

One of the main highlights of 2009 for the PB was the drafting of the Joint Programme of Action (JPA) for the second phase of EDCTP. The PB proposed to broaden the



scope of EDCTP to incorporate all phases of clinical trials, phases I to IV. This is important, since unfortunately most clinical trials usually stop after the registration of new products, whilst the implementation, administration and distribution of these medicinal products greatly impacts on the effectiveness of these products vis-à-vis the functioning and efficiency of the existing health systems. Furthermore, the PB provided strategic guidance on the applications received and reviewed by the various independent scientific advisory committees (SRCs) for the calls for proposals that were launched during the year and followed up on the large number of projects that were approved in 2008.

How did the PB contribute to improving strategic needs and priorities of EDCTP this year?

In close collaboration with the EDCTP Secretariat, the PB was involved in the preparation for the HIV treatment stakeholder meeting that took place in Portugal on 19 May 2009. The objective of this meeting was to identify and prioritise potential products in the pipeline, and recommend the funding procedure for launching the call. Following the recommendations from this stakeholder meeting, the PB provided technical input in the preparation of the HIV treatment call that was launched later in the year.

What are other gaps in scientific strategy that can be filled by EDCTP in future?

The first and most important action should be the implementation of a strategy that will create an effective and sustainable health research system, enabling vaccines and drugs to reach the people who actually need them. There will be research components on how to deliver them to patients. Local facilities and communities should be used, and training to local people should be provided. Another important factor is to make the actual administration of the drugs and treatments easier. For a therapy to be successful in the poor areas of Africa, it is necessary to avoid developing products that will require patient going to the hospital frequently, when this is a two-day walk.

On behalf of the PB,
Dr Sodiomon Sirima

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

What was the highlight of 2009 for the DCCC?

In 2009 the DCCC managed to effectively increase its efforts to advocate the goals, objectives and way of working of EDCTP. DCCC members continued to lobby African countries encouraging them to allocate two percent of their national



health budgets into research. The DCCC concentrated on encouraging African contribution to the *Partnership* by actively involving African governments, regional economic and regional health bodies. Furthermore, we have made important steps in identifying the gaps to strengthen weaker institutions in African countries through the regional Networks of Excellence.

How did the DCCC contribute to improving the commitment of African countries and researchers into EDCTP's mission this year?

The DCCC members together with the EDCTP Secretariat and the EDCTP High Representative attended different meetings to foster research partnerships. Site visits were conducted where DCCC members were part of the delegations that strategically met with officials from ministries of health, research, science and technology in several African countries. Overall, we have seen that the EDCTP model is starting to bear fruit. The self esteem of African researchers is rising as a result of the EDCTP way of working, in which the African researchers are equal partners in projects with their European counterparts. The awareness that they can solve their own problems, by conducting high quality research, is a lasting and valuable achievement of the programme.

What are the gaps for empowering Africa that can be filled by EDCTP in future?

The main gaps are human capacity building, regional and institutional networking and the development of a viable ethics capacity strengthening strategy. EDCTP has proven to be able to coordinate different initiatives related to the three main poverty-related diseases, and to bridge the gap between French speaking and English speaking African countries. The colonial barriers have been brought down by the programme, resulting for example in four Networks of Excellence, in which the more established institutions help their weaker counterparts by sharing science and facilities. In some cases, researchers from better endowed institutions train their colleagues from the less endowed institutions and by doing so making them stronger. And this is exactly what the *Partnership* is meant to do.

On behalf of the DCCC,
Prof. Alioune Dieye

The European Network of National Programmes (ENNP) consists of representatives of the European national programmes (European Networking Officers or ENOs). The ENNP coordinates the national programmes of the EDCTP Member States.

What was the highlight of 2009 for the ENNP?

For the ENNP, the EDCTP All-Constituency meeting in February marked an important development for 2009 and onwards. In this meeting on the future of the structure and mandate of EDCTP, it was decided that the role of the ENNP



within the *Partnership* will be changed. From the start of 2010 the European Networking Officers (ENOs) will be acting as Deputy General Assembly (GA) members. For the ENNP, 2009 therefore was dominated by the question on how to fill in the new role of the ENO's, and on establishing what the added value of the newly installed Deputy GA's should be for EDCTP.

How did the ENNP contribute to improving the creation of synergies between European National Programmes?

The most important achievement of the ENNP in the past years has been to create insights into how the different Member States organise their support to the fight on poverty-related diseases. The ENNP has increased the amount and intensity of bi and trilateral contacts between the different Member States participating in EDCTP, and has contributed to the stakeholder meetings. Besides this, the ENNP has put much effort in increasing the amount of cofunding of the Member States. In 2009, the ENO's have been occupied with the question on how to deal with the increasing amount of the launched calls.

What are the gaps for creating a true European Research Area for poverty-related diseases that can be filled by EDCTP in future?

To be able to reach a true European Research Area (ERA), a principal and political decision has to be made by all Member States. At this moment, each European Member State has its own set of rules and regulations to which support to EDCTP goals has to comply. These will be streamlined as it has recently been agreed at the meeting which had involved all EDCTP constituencies.

Dr Dirk Van der Roost

Project at a glance



Predicting the outcome of anti-tuberculosis therapy

Prof. Paul van Helden, South Africa

With support from EDCTP, Prof. Paul van Helden and his research team have demonstrated and achieved proof-of-concept that a number of surrogate or bio-markers can be used to predict outcome in tuberculosis (TB) patients. Patients who subsequently relapse or who remain healthy following drug cure can be readily identified during their first episode of TB, based on their gene expression profile in peripheral blood. Around 2000 genes were found to be consistently differentially expressed between relapse and cured patients. These outcomes might lead to tests which could facilitate clinical trials of new drugs by detecting how well a patient is responding to treatment, and might eventually aid in clinical management.

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Calls and grants



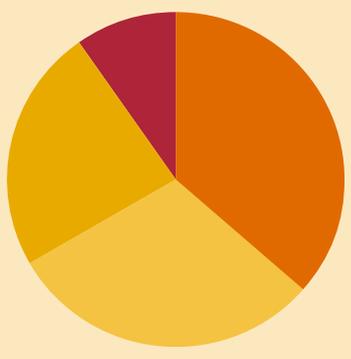


5.1 Grants funding 2003-2009

EDCTP funds phase II and III clinical trials on HIV/AIDS, tuberculosis and malaria in sub-Saharan Africa. Additionally, EDCTP grants are used to strengthen capacity to conduct these trials to the highest standards and to facilitate networking. The graphs below present an overview of how

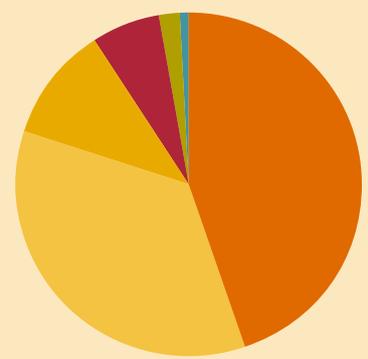
EDCTP-funding has been distributed among the three diseases, and among the various interventions (from drugs and vaccines to non-clinical trial grants used for training and strengthening ethics and regulatory framework in Africa).

EDCTP-funding 2003-2009 by disease (€ 000)



- HIV/AIDS € 54,244
- Tuberculosis € 45,111
- Malaria € 35,061
- Non-disease specific € 14,209

EDCTP-funding 2003-2009 by intervention (€ 000)



- Drugs € 66,757
- Vaccines € 52,385
- Non-clinical trials specific € 16,200
- Microbicides € 9,379
- Networks of Excellence € 2,968
- Surrogate markers € 937

5.2 Calls launched in 2009

In 2009, EDCTP successfully launched seven calls under the various grant schemes including Integrated Projects on Clinical Trials, Senior Fellowships, Ethics Review Strengthening, Joint Programme Activities and Member States Initiated Projects. The latter call is a new grant scheme with the primary objectives of increasing cooperation among Member States.

In order to foster development of scientific leadership from all African regions, a new grant was established under the Senior Fellowship scheme that is linked to EDCTP-funded regional Networks of Excellence. The objective of this call is to develop capacity for research in African institutions targeting all four sub-Saharan African regions that are part of the EDCTP supported networks of excellence. These include West, Central, East and Southern Africa.

EDCTP calls for proposals launched in 2009

Call/Disease Area	Budget (€)	Launch Date	Deadline	No. of Projects Approved
Ethics/Institutional Review Boards	500,000	1 February 2009	1 June 2009	5
Senior Fellowships linked to EDCTP Networks of Excellence	2,400,000	1 February 2009	1 June 2009	8
Joint Programme Activities**	5,000,000	1 February 2009	4 June 2009	2
TB Diagnostics	8,000,000	24 March 2009	24 July 2009	3
Member States Initiated Projects	2,500,000	15 August 2009	15 November 2009	Pending
HIV Treatment	5,000,000	15 August 2009	15 December 2009	Pending
TB Vaccines	3,000,000	15 August 2009	15 December 2009	Pending
Total	26,400,000			18+

* This total is expected to be matched by an equal amount of Member State cofunding

** 'Rolling call' with initial budget of 5 million euro (this call was discontinued in 2009).

5.3 Grant contracts signed in 2009

In 2009, a total of 31 grant contracts were signed. These include 17 grants for Integrated Projects on Clinical Trials, 4 Senior Fellowships, 6 Ethics/IRB support, 2 Joint Programme Activities and 3 Networks of Excellence. Although the contract for the first Network of Excellence, the Central African Network on tuberculosis, HIV/AIDS and malaria (CANTAM) was finalised in 2008, the network became fully functional in 2009.

The integrated projects grant scheme that was introduced in 2007 to accelerate development of interventions against HIV/AIDS, tuberculosis and malaria in a sustainable way by combining clinical trials activities with networking and capacity strengthening activities are now well-established.

Integrated projects

The following section gives a short overview of integrated project grant contracts that were signed in 2009.

1 Novel biomarkers to measure safety of microbicides

Project Coordinator	Dr Kishor Mandaliya
Institution	International Centre for Reproductive Health (ICRH-K), Kenya
Target disease	HIV/AIDS (microbicides)
Partners	Belgium, Kenya, The Netherlands, Rwanda, South Africa, Tanzania, United Kingdom and United States
Budget	€ 3,994,112 (€ 2,688,595 EDCTP)
Duration of project	April 2009-April 2012

Products used in a number of recent microbicide trials have turned up unexpected results in terms of safety. Apparently there is a need for more reliable biomarkers during the phase I and II safety trials. A better understanding and measurement is needed of the effect of substances introduced in the vaginal environment. The project will sample a variety of study populations in four African settings to try and refine both clinical and laboratory methods and findings in search of more reliable safety biomarkers. The consortium offers the combination of multidisciplinary experience and cutting-edge technology to make this possible.

2 Building HIV vaccine trial capacity in Tanzania and Mozambique using a HIV DNA-MVA vaccine concept delivered by novel technologies

Project Coordinator	Prof. Eligius Lyamuya
Institution	Muhimbili University of Health and Allied Sciences, Tanzania
Target disease	HIV/AIDS (vaccines)
Partners	Germany, Mozambique, Sweden, Tanzania and United Kingdom
Budget	€ 6,367,429 (€ 5,521,889 EDCTP)
Duration of project	November 2009-June 2014

The aim of the project is to conduct phase II HIV vaccine trials in Tanzania and Mozambique, strengthen capacity building and promote South-South collaboration for future phase II/III HIV vaccine trials in sub-Saharan Africa. The project will capitalise on and sustain human and infrastructural capacity building and other investments already established at the trial sites through North-South collaboration.

The primary endpoint is safety and immunogenicity as measured by IFN-gamma Elispot on fresh cells at 2 weeks after the last scheduled immunisation. The secondary endpoints include assessment of the breadth of immune response; harmonisation, standardisation and validation of laboratory methodologies and techniques; increased capacity for GCLP certification and development of youth cohorts.

3 International phase III randomised clinical trial to study two once-a-day simplified strategies after an initial antiretroviral therapy among HIV-infected infants in Africa (MONOD)

Project Coordinator	Dr Valérie Leroy
Institution	Inserm U897/Université Bordeaux 2/ ISPED, France
Target disease	HIV/AIDS
Partners	Belgium, Burkina Faso, Cote d'Ivoire, France, Luxembourg and Rwanda
Budget	€ 3,442,969 (€ 1,640,862 EDCTP)
Duration of project	November 2009-March 2013

The MONOD project provides a unique opportunity to study and implement an early and successful antiretroviral treatment strategy in HIV-infected infants in field conditions in three African countries where there is an effective

integration of treatments into the national health systems (Burkina Faso, Côte d'Ivoire and Rwanda). The MONOD trial is a randomised clinical trial aimed to assess the feasibility and the efficacy of simplifying durably a successful 12-month antiretroviral triple therapy (AZT-3TC-LPV/r twice a day) initiated in HIV-infected infants between age 6 and 52 weeks, with a once-a-day suppressive antiretroviral therapy, sparing or not the lopinavir (ABC-3TC-EFV or ABC-3Tc-LPV/r). In the perspective of identifying lifelong antiretroviral strategies, this project is aimed at improving antiretroviral access in African children.

4 Evaluating options for second-line therapy in patients failing a first-line 2NRTI + NNRTI regimen in Africa (EARNEST)

Project Coordinator	Prof. Peter Mugenyi
Institution	Joint Clinical Research Centre, Uganda
Target disease	HIV/AIDS
Partners	Belgium, Ireland, Italy, Malawi, The Netherlands, South Africa, Spain, Switzerland, Uganda, United Kingdom and Zimbabwe
Budget	€ 4,872,368 (€ 4,352,914 EDCTP)
Duration of project	September 2009-September 2013

The EARNEST trial aims to compare boosted protease inhibitor (bPI) containing second-line regimens in patients failing first-line therapy in Africa. The trial will establish whether bPI plus raltegravir results in superior long term clinical and immunological outcomes compared to standard of care bPI plus 2 NRTIs and whether the latter regimen results in equivalent clinical and immunological parameters as bPI monotherapy. Patients will be evaluated after a minimum follow up of 144 weeks for good clinical and immunological outcomes defined as being alive, no new or recurrent WHO stage 4 clinical events since time of switch to second-line and having a CD4 count >250 cells at 144 weeks. This study hopes to provide evidence that will directly influence national treatment guidelines and the worldwide public health approach to ART rollout.

5 Developing research capacity and networking through the evaluation of two second-line antiretroviral HIV treatment strategies in sub-Saharan Africa

Project Coordinator	Prof. Eric Delaporte
Institution	Université de Montpellier et Institut de Recherche pour le Développement (IRD), France
Target disease	HIV/AIDS
Partners	Belgium, France, Germany, Senegal, South Africa, Switzerland and Tanzania
Budget	€ 4,040,244 (€ 2,007,885 EDCTP)
Duration of project	July 2009-July 2013

Currently no second-line strategy has been rigorously evaluated in resource-limited settings. The aim of this project is to conduct a phase III clinical trial to evaluate the two WHO recommended second-line treatments in Senegal, Cameroon, Tanzania and South Africa. During preparation and conduct of this trial the researchers will establish a sustainable African HIV/AIDS network of South-South and North-South partnerships that will develop and expand collaboration with strengthened clinical trial capacity and network in focused skills, tools, infrastructure and technology of four sites in West, East, Central and South Africa. The expected outcome of this project is to provide recommendations on use of the second-line strategy that are recommended by WHO and to develop clinical research expertise capacity.

6 Children with HIV in Africa Pharmacokinetics and Acceptability/Adherence of Simple Antiretroviral Regimens (CHAPAS-3)

Project Coordinator	Dr Veronica Mulenga
Institution	University Teaching Hospital, Lusaka, Zambia
Target disease	HIV/AIDS
Partners	Ireland, Italy, The Netherlands, South Africa, Spain, Uganda, United Kingdom and Zambia
Budget	€ 5,003,849 (€ 4,617,034 EDCTP)
Duration of project	December 2009-July 2013

The CHAPAS-3 project is conducting a paediatric clinical trial comparing 3 different antiretroviral regimens in order to identify optimal first-line regimens for HIV-infected children.

The regimens are being compared in terms of toxicity, pharmacokinetics, adherence/acceptability, cost, cost-effectiveness and viral load suppression. CHAPAS-3 uses 4 new simplified paediatric ARV fixed dose combination (FDC) tablets administered according to WHO dosing tables in addition to 2 FDCs already available. Alongside the trial, over 4 years the project aims to build all aspects of capacity for implementing paediatric clinical trials in Africa.

7 Fostering research capacity, networking and project management through phase I-IIB clinical trials of candidate malaria vaccine GMZ2

Project Coordinator	Dr Ramadhani Noor
Institution	African Malaria Network Trust, Tanzania
Target disease	Malaria (vaccines)
Partners	Burkina Faso, Denmark, Gabon, The Gambia, Kenya, Tanzania, Uganda and United Kingdom
Budget	€ 9,863,901 (€ 5,140,147 EDCTP)
Duration of project	January 2009-January 2014

This project aims to develop a promising candidate malaria vaccine GMZ2. GMZ2 is a hybrid combination of Glutamate Rich Protein (GLURP) and merozoite surface protein (MSP3), which targets the malaria parasite in the blood stage. In doing so the vaccine stimulates immune system to produce antibodies against GLURP and MSP3 targets on the malaria parasite. This project is taking the candidate vaccine through a phase Ib clinical trial in Gabonese children and in a multi-centre phase IIB trials in Burkina Faso, Gabon, The Gambia and Uganda. Through this project, capacity building will be achieved by infrastructural upgrade and short- and long-term training. The consortium will also enhance its networking activities leading to sharing of skills and resources that will ensure less developed institution are developed towards level 4. This project comprises of four work packages that include project management, conducting of the clinical trials, capacity building and networking. The project is run by a consortium of seven partners, namely AMANET (Tanzania), SSI (Denmark), CNRFP (Burkina Faso), UKT (Germany), ASH (Gabon), MUK (Uganda) and MRC (The Gambia).

8 Malaria Vectored Vaccine Consortium (MVVC)

Project Coordinator	Dr Egeruan Babatunde Imoukhuede
Institution	European Vaccine Initiative, Germany
Target disease	Malaria (vaccines)
Partners	Austria, Burkina Faso, The Gambia, Germany, Italy, Kenya, United Kingdom and Senegal
Budget	€ 9,543,310 (€ 7,882,536 EDCTP)
Duration of project	December 2009-December 2013

This project aims to integrate capacity building and networking in the conduct of clinical trials of AdCh63 ME-TRAP and MVA ME-TRAP administered with the prime-boost strategy.

Two phase Ib clinical trials will be conducted in Kenya and The Gambia and a multicentre phase IIB clinical trial will be conducted in 2 or 3 sites from either Burkina Faso, Kenya, The Gambia or Senegal. Capacity building will be achieved through infrastructure upgrading, and short- and long-term training. The MVVC will establish networks within the consortium partners and with already existing networks. This process will ensure that the less developed sites are upgraded. The MVVC partners include CNRFP (Burkina Faso), EVI (Universitäts Klinikum Heidelberg, Germany), KEMRI (Kenya), MRC (The Gambia), Okairois (Italy), UCAD (Senegal), UOXF (UK) and VSCR (Austria).

9 Antimalarial treatment for African pregnant women

Project Coordinator	Prof. Umberto D'Alessandro
Institution	Institute of Tropical Medicine, Belgium
Target disease	Malaria (in pregnancy)
Partners	Austria, Belgium, Burkina Faso, Ghana, Malawi, The Netherlands, Rwanda, United Kingdom, Tanzania and Zambia
Budget	€ 5,993,753 (€ 3,708,775 EDCTP)
Duration of project	February 2009-May 2013

Pregnant women are a high-risk group for malaria infection requiring effective antimalarial treatment when this occurs. There is, however, paucity of information on the safety and efficacy of currently used antimalarials in pregnancy because this category of people is usually systematically excluded from clinical trials. This project aims to investigate the safety and efficacy of 4 ACTs (dihydroartemisinin-piperaquine,

mefloquine-artesunate, amodiaquine-artesunate and artemether-lumefantrine) when administered to pregnant women with *P. falciparum* infection during the second and the third trimester. This head-to-head comparison of the 4 treatments aims at identifying at least 2 valid first-line and one second-line treatments. An additional specific research objective is to collect explanatory variables, i.e. drug pharmacokinetics and *in-vitro* parasite drug sensitivity.

10 West African Network for Clinical Trials of Antimalarial Drugs (WANCAM)

Project Coordinator Dr Abdoulaye Djimde
Institution University of Bamako, Mali
Target disease Malaria
Partners Burkina Faso, France, Germany, Guinea, Mali, The Netherlands, Sweden and United Kingdom
Budget € 5,359,268 (€ 4,699,208 EDCTP)
Duration of project September 2009-March 2013

The overall objective of this project is the development of a sub-region composed of Burkina Faso, Guinea and Mali equipped with state of the art clinical trial sites, laboratories, research teams and well characterised populations ready to undertake all clinical trial phases.

This project includes a phase IIIb randomized, comparative, open, multi-centre, study of the efficacy, safety and impact on malaria incidence of repetitive treatment with four artemisinin-based combination therapies for uncomplicated malaria in children: artesunate-pyronaridine, dihydroartemisinin-piperazine, artesunate-amodiaquine and artemether-lumefantrine.

11 Evaluating pharmacokinetic interactions between ACTs and antiretrovirals and appropriate age based dosing strategies for ACTs

Project Coordinator Dr Victor Mwapasa
Institution Malawi-Liverpool-Wellcome Trust, Malawi
Target disease Malaria
Partners Austria, Belgium, Malawi, Mozambique, Spain, United Kingdom and Zambia
Budget € 5,082,545 (€ 3,863,808 EDCTP)
Duration of project July 2009-July 2014

In drug development doses are usually given according to body weight. Patient groups who may have unusual pharmacokinetic profiles, such as HIV-infected individuals are often excluded leaving important knowledge gaps. Currently, several effective Artemisinin based Combination Therapies (ACTs) are used, including in HIV-positive patients on antiretroviral drugs (ARVs). In addition, current dosage recommendations for most ACTs are based on bodyweight, yet most treatments in resource-poor countries are based on age, increasing the risk of under or overdosing. These studies will assess the pharmacokinetics, safety and efficacy of ACTs when given simultaneously with ARVs or when dosed by age, as done in most resource-poor settings. The findings will inform national malaria control programmes in formulating malaria treatment guidelines.

12 Conduct of ICH-GCP level phase II TB vaccine trials in high risk populations in Africa

Project Coordinator Dr Mark Doherty
Institution Statens Serum Institut, Denmark
Target disease Tuberculosis (vaccines)
Partners Denmark, Ethiopia, Guinea-Bissau and The Netherlands
Budget € 8,411,556 (€ 4,164,136 EDCTP)
Duration of project March 2009-March 2014

In Africa tuberculosis represents a major public health challenge, especially given the interaction with HIV/AIDS. In spite of the application of Directly Observed Therapies (DOTs) chemotherapy, it remains obvious that the ultimate, sustainable solution to TB control will be an effective TB vaccine. STOP TB recently updated its strategy to emphasise research on new drugs and vaccines. Recent progress has led to the development of several promising TB vaccine candidates which entered phase I clinical trials in 2005 in Europe. The most advanced of these have now completed phase I trials in Africa. This project involves a phase II, randomised, double-blind, multicenter trial to evaluate the immunogenicity and safety of 2 doses of an adjuvanted TB subunit vaccine (Ag85B-ESAT-6 plus IC31) using 2 different vaccination schedules in tuberculosis skin test (TST) positive healthy adolescents.

13 A phase IIb efficacy trial to evaluate the protective efficacy of a booster MVA85A vaccination in healthy, HIV-infected adults in South Africa, Senegal and The Gambia

Project Coordinator	Dr Martin Ota
Institution	Medical Research Council, The Gambia
Target disease	Tuberculosis (vaccines)
Partners	Belgium, The Gambia, Senegal, South Africa and United Kingdom
Budget	€ 13,177,720 (€ 9,473,720 EDCTP)
Duration of project	August 2009-August 2014

MVA85A is one of the leading new TB vaccine candidates. In every clinical trial conducted to date, this vaccine is safe and immunogenic. This vaccine induces a broad Th-1 immune response and antigen specific CD4+T-cells. The cells proliferate and are not terminally differentiated. Thus, this vaccine induces the type of immune response considered protective though will not be known for sure until the protective efficacy in a proof-of-concept trial is evaluated. The main objective of this trial is to evaluate the protective efficacy of a booster MVA85A vaccination administered to HIV-infected subjects in South Africa, Senegal and The Gambia by comparing the incidence of TB disease and infection in a vaccinated and control group. 1400 subjects will be enrolled across the three sites with a two year follow up.

14 A new TB vaccine for African infants

Project Coordinator	Prof. Gregory Hussey
Institution	University of Cape Town, South Africa
Target disease	Tuberculosis (vaccines)
Partners	Austria, Belgium, Kenya, Mozambique, The Netherlands, South Africa, Spain, Sweden, Switzerland, Uganda and United States
Budget	€ 7,706,813 (€ 3,411,368 EDCTP)
Duration of project	May 2009-August 2014

There is an urgent need for new and more effective TB vaccines. A number of candidate novel TB vaccines have been developed and will need to be tested in phase I, II and III trials. Conducting efficacy trials at multiple sites involving different populations should lead to more robust and generalisable results. In order to conduct such trials each participating site needs to have the required capacity and infrastructure to do so. This project aims to ensure that four trial sites in sub-Saharan Africa possess the infrastructural capacity to conduct phase IIB and III trials of new TB vaccines in the next 5 years. A clinical trial of a new TB vaccine forms part of the project, which also includes capacity development at the sites and networking between African sites and European and American collaborators.

The Pan African Consortium for Evaluation of Anti-tuberculosis Antibiotics (PanACEA) is a TB consortium that aims to provide synergies and efficiencies in the conduct of the trials and capacity development. The overall objectives for the PanACEA program focus on the effective, efficient conduct of the proposed clinical trials and on establishing an enduring framework to benefit future trials of TB drugs.

The PanACEA consists of three consortia:

1. **REMox**: the Rapid Evaluation of Moxifloxacin in Tuberculosis, sponsored by the University College London. Chief Investigator: Stephen Gillespie
2. **HIGHRIF**: the Rapid Evaluation of High-Dose Rifampicin and Other Rifamycines, sponsored by the Radboud University Nijmegen Medical Centre. Chief Investigator: Martin Boeree
3. **SQ109**: Evaluation of a Novel TB drug (SQ109) to Shorten and Simplify Tuberculosis Treatment, sponsored by the Ludwig University of Munich. Chief Investigator: Michael Hoelscher

15 Rapid Evaluation of Moxifloxacin in Tuberculosis (PanACEA - REMoxTB)

Project Coordinator	Prof. Stephen Gillespie
Institution	University College London, United Kingdom
Target disease	Tuberculosis
Partners	Kenya, South Africa, Tanzania United Kingdom and Zambia
Budget	€ 7,382,511 (€ 5,913,631 EDCTP)
Duration of project	September 2009-February 2014

Tuberculosis still kills millions every year and in order to stop this, there is a need to develop more effective treatments which are easier to use and are shorter than the current treatments available. There have been no major advances in tuberculosis therapy from more than forty years. The REMoxTB study is testing two new treatments in comparison to the standard treatment that are two months shorter. If the trial is successful with consequent registration of the regimen internationally, this would be a very significant addition to the antituberculosis armoury. This project is also developing methods that would benefit future researchers testing new drugs and regimens clinically. Capacity development of African centres to perform high quality clinical research is a major component of this project.

16 Clinical studies with high dose rifampicin & development of clinical research capacity in Africa (PanACEA – HIGHRIF)

Project Coordinator	Dr Martin Boeree
Institution	Radboud University Nijmegen, The Netherlands
Target disease	Tuberculosis
Partners	The Netherlands, South Africa, Switzerland, Tanzania, Uganda and United Kingdom
Budget	€ 4,640,849 (€ 3,122,842 EDCTP)
Duration of project	June 2009-December 2013

This project aims to bring high dose rifampicin beyond phase I and II in clinical development, and ready for phase III. The HIGHRIF project consists of a series of 4 trials being performed to international standards for regulatory authorities. This standard will also be achieved by embedding the HIGHRIF project in the existing trial management structure provided by the REMox TB study and by using the

infrastructure and human resources that are already being developed by the REMox TB project. In addition, the HIGHRIF project is anticipated to contribute considerably to the capacity of African research institutes to perform clinical trials. Together with the other trials within the PanACEA consortium it will ensure a continuous supply of TB trials to maintain the developed capacity.

17 Evaluation of a novel TB drug (SQ109) to shorten and simplify TB treatment (PanACEA - SQ109)

Project Coordinator	Dr Michael Hoelscher
Institution	Department for Infectious Diseases and Tropical Medicine, Klinikum of the University of Munich (LMU), Germany
Target disease	Tuberculosis
Partners	Germany, The Netherlands, South Africa, Tanzania, United Kingdom, United States and Zambia
Budget	€ 6,012,526 (€ 1,136,761 EDCTP)
Duration of project	June 2009-June 2014

The Pan African Consortium for the Evaluation of Anti-tuberculosis Antibiotics (PanACEA) aims to explore new drugs that have the potential to shorten TB treatment. This project is pursuing the phase II clinical development of SQ109, a novel anti-TB drug candidate that has demonstrated antimicrobial activity and synergies with standard anti-TB drugs in *in-vitro* and *in-vivo* studies, and has successfully passed phase I studies in humans. University of Munich is acting as the sponsor for the planned clinical trials to assess safety and efficacy of SQ109 in TB patients. The project is conducted in cooperation with Sequella Inc., the company who developed the molecule, and seven African partner institutions, providing the sites to for the clinical trials.

Senior Fellowships

The purpose of this grant scheme is to develop and retain qualified researchers capable of building and leading research groups at sub-Saharan institutions. In 2009, four Senior Fellowship grant contracts were signed.

1 Evaluating antiretroviral drug resistance in HIV-infected children in Africa

Project Coordinator Dr Cissy Kityo
Target disease HIV/AIDS
Partners Joint Clinical Research Center, Uganda and Medical Research Council, United Kingdom
Budget € 196,900
Duration of project November 2009-November 2011

2 The effect of HIV co-infection on the immune response to *Mycobacterium tuberculosis* in the lung

Project Coordinator Dr Wendy Burgers
Target disease Tuberculosis
Partners University of Cape Town, South Africa, Stellenbosch University, South Africa and Research Center Borstel, Germany
Budget € 199,980
Duration of project October 2009-October 2011

3 Immune reconstitution inflammatory syndrome (IRIS) in schistosomiasis patients undergoing HAART

Project Coordinator Dr Pauline Mwinzi
Target disease Tuberculosis
Partners Kenya Medical Research Institute (KEMRI), Kenya and Prince Leopold Institute of Tropical Medicine, Belgium
Budget € 185,669
Duration of project November 2009-November 2011

4 A randomised controlled trial of oral iron therapy for treatment of post-malaria iron-deficiency anaemia in Malawian children comparing immediate post-discharge versus delayed treatment on iron uptake and haematological response

Project Coordinator Dr Kamija Phiri
Target disease Malaria
Partners Malawi-Liverpool-Wellcome Trust Research Programme, Malawi; University Medical Centre Groningen, The Netherlands and University of Liverpool, United Kingdom
Budget € 199,145
Duration of project September 2009-September 2011

Networks of Excellence

This grant scheme is aimed at funding four regional consortia of research institutions referred to as Regional Networks of Excellence for conducting clinical trials in sub-Saharan Africa. These networks are anticipated to expedite the conduct of high quality clinical trials in the region. The member institutions have complementary expertise in various fields. The established clinical trial institutions with expertise in training, conduct of trials and demonstrable ability to provide laboratory procedures and data management, will support the upcoming sister institutions.

In 2009, three Networks of Excellence grant contracts were signed.

1 East African Network of Excellence in Clinical Research and Practice (EACCR)

Project Coordinator	Dr Pontiano Kaleebu
Institution	Uganda Virus Research Institute (UVRI), Uganda
Partners	Ethiopia, Germany, Kenya, The Netherlands, Norway, Sudan, Sweden, Tanzania, Uganda, United Kingdom and United States
Budget	€ 3,499,200 (€ 2,499,200 EDCTP)
Duration of project	May 2009-May 2012

EACCR was established to enhance existing clinical research expertise of HIV, TB and malaria in the East African region. The network aims to strengthen project management, human resource training, infrastructure, and South-South and North-South collaboration. It offers a robust platform for convergence of research experts, research users and industrialists whilst promoting native leadership and multi-disciplinary interaction. The implementation structure constitutes three disease-specific committees, and a training committee, each coordinated by a leading centre of excellence within the region.

2 Capacity building to prepare West African sites for clinical trials on HIV, TB and malaria

Project Coordinator	Prof. Soleymane Mboup
Institution	Université Cheikh Anta DIOP de Dakar (UCAD), Senegal
Partners	Burkina Faso, France, The Gambia, Ghana, Guinea-Bissau, Mali, Nigeria, Senegal, United Kingdom and United States
Budget	€ 3,499,921 (€ 2,499,921 EDCTP)
Duration of project	July 2009-July 2012

WANETAM is a sub-regional Network of Excellence and currently brings together 14 research institutions from 7 West African countries namely Burkina Faso, The Gambia, Ghana, Guinea Bissau, Mali, Nigeria and Senegal. The objectives of WANETAM include capacity building and technology transfer to prepare West African sites for the successful conduct of clinical trials and creation of a network for sub-regional scientific collaborations.

Within the implementation of this programme the established African institutions from the 14 countries will put their expertise at the service of the African sister institutions in order to prepare them for the conduct of successful clinical trials.

3 Trials of Excellence in Southern Africa (TESA)

Project Coordinator	Dr Alexander Pym
Institution	Medical Research Council South Africa (MRC), South Africa
Partners	Botswana, France, Germany, Malawi, Mozambique, The Netherlands, South Africa, United Kingdom, Zambia and Zimbabwe
Budget	€ 2,640,548 (€ 2,337,304 EDCTP)
Duration of project	November 2009-November 2011

Trials of Excellence in Southern Africa (TESA) is a collaborative effort of ten southern African research institutes and universities involved in clinical trials of HIV/AIDS, tuberculosis and malaria. This project aims to build clinical trials capacity and infrastructure by mentoring and training existing researchers, clinicians and laboratory technicians to conduct trials in line with ethical guidelines and Good Clinical Practices. Over the next three years, this project will focus on building capacity for clinical trials and infrastructure among its partner organisations, in addition to improving the cooperation and networking of the clinical research teams through conducting of baseline studies on infectious diseases of HIV/AIDS, TB and malaria.

Ethics and Regulatory strengthening

The purpose of this grant is to promote the establishment and strengthening of ethics review and regulatory capacity in sub-Saharan Africa. In 2009, seven Ethics contracts were signed.

1 Strengthening African research ethics committees' capacity for ethical review of HIV prevention research

Project Coordinator University of KwaZulu-Natal
(Prof. Douglas Wassenaar)
Country South Africa
Budget € 49,935
Duration of project November 2009-November 2012

2 The Mzadi project strengthening research ethics capacity in the Republic of Congo and the Democratic Republic of Congo

Project Coordinator Centre Interdisciplinaire de
Bioéthique pour L'Afrique
Francophone (CIBAF)
(Dr Bavon Mupenda)
Country Democratic Republic of Congo
Budget € 40,800
Duration of project December 2009-December 2010

3 Establishment of national research ethics committee and strengthening of newly established IRBs/RECs in Ghana

Project Coordinator University of Ghana
(Dr Okyere Boateng)
Country Ghana
Budget € 49,808
Duration of project December 2009-December 2011

4 Strengthening capacity for ethics review and monitoring of approved projects at the Kenya Medical Research Institute

Project Coordinator Kenya Medical Research Institute
(KEMRI) (Dr Christine Wasunna)
Country Kenya
Budget € 49,500
Duration of project December 2009-December 2011

5 Programme for strengthening National Research Ethic Committee of Senegal (CNRS) and promoting ethics awareness in Senegal and in West Africa

Project Coordinator Conseil National pour la Recherche
en Sante (CNRS) (Dr Samba Cor Sarr)
Country Senegal
Budget € 50,000
Duration of project December 2009-December 2011

Joint Programme Activities

This grant scheme aims to enhance the activities of researchers investigating the same topic or disease, reduce duplication of effort and improve collaborations within or between African institutions and research centres. In 2009, two grant contracts in the area of Joint Programme Activities were signed.

1 Systematic investigation of clinical *Plasmodium falciparum* isolates

Project Coordinator	Dr Benjamin Mordmüller
Institution	Eberhard Karls Universität Tübingen, Germany
Target disease	Malaria
Partners	Gabon, Germany and The Netherlands
Budget	€ 299,918
Duration of project	March 2009-March 2012

The project is a joint programme activity between Gabon, The Netherlands and Germany to implement and standardise *in-vitro* culture of clinical *Plasmodium falciparum* isolates at two research centres in Gabon. Motivation for this project was based on the fact that almost all malaria related cell biological work has been done using lab-isolates of *P. falciparum* that have been adapted for *in-vitro* growth for decades, which have therefore altered virulence and resistance characteristic and the technically demanding continuous cell culture of clinical *P. falciparum* isolates that has never been standardised to date in Africa. This joint activity is aimed at overcoming current barriers, building capacity development and advancing knowledge on malaria parasites in this area.

2 Strengthening clinical trial management support in Malawi

Project Coordinator	Prof. Exnevia Gomo
Institution	University of Malawi College of Medicine, Malawi
Target disease	HIV/AIDS research training
Partners	Austria, Malawi, The Netherlands and United Kingdom
Budget	€ 299,241
Duration of project	April 2009-April 2012

This project aims to develop clinical trial monitoring, administrative trial coordination and data management. This will be part of the recognised role of clinical trial management that will require appropriate training, professional development programme and defined career structure in Malawi.

The project focuses on local training of Malawian clinical trial monitors to monitor trials on behalf of academic clinical trial sponsors; clinical trial coordinators to support principal investigators in the conduct of clinical trials; and data managers to set up, maintain and operate clinical trial databases.

5.4 Progress on previous calls and preview of 2010 calls

Following the launch in 2007 of a series of calls for Integrated Projects on Clinical Trials (a grant scheme extending large grants to multicentre clinical trials), more than 21 grant contracts have been signed and all these projects are underway. Details of these projects are included in Appendix 9.2.

Under the Networks of Excellence, the last of the three projects from Eastern, Western and Southern Africa had contracts signed in May, July and November 2009 respectively. By December 2009, all four EDCTP-funded regional Networks of Excellence were operational.

In recognition of the fact that prevention and treatment of poverty-related diseases begins with proper diagnosis, EDCTP launched a call on TB diagnostics in March 2009 and consequently three projects were approved for funding. The contracts for these projects are expected to be signed in the first quarter of 2010.

In 2010, EDCTP will launch the last round of calls under the current funding programme. The calls will mostly be for short-duration projects lasting 1 to 3 years such as Senior Fellowships and Ethics Capacity Building. Additionally, calls on Member States Initiated projects, whereby the majority of funding will come from the Member States themselves, will continue to be launched. All projects emanating from these new calls including clinical trials will be expected to end before December 2013 and this is planned to minimise overlapping activity with the second phase of the EDCTP programme.

5.5 EDCTP involvement in the broader international research and development agenda

EDCTP maintains its focus on clinical trials as the core activity and creating an enabling environment for conducting these trials through an integrated approach strategy for capacity development and networking. In order to keep up to date with new developments of products and the changing landscape in poverty-related diseases, EDCTP involves a broad range of scientific advisors and continuously interacts with scientists, developers and the broader scientific community through stakeholder meetings to formulate strategic plans around

promising candidates. EDCTP also actively interacts with like-minded organisations to explore synergy and complementarities. Among these include the Aeras Global TB Vaccine Foundation, the Africa AIDS Vaccine Programme (AAVP), Africa Malaria Network Trust (AMANET), the African Network for Drugs and Diagnostics Innovation (ANDI), AIDS Vaccine Advocacy Coalition (AVAC), Bayer AG, Bill & Melinda Gates Foundation (BMGF), Drugs for Neglected Diseases Initiative (DNDi), Eurovacc Foundation, the French National Agency for Research on AIDS and Viral Hepatitis (ANRS), Gates Malaria Partnership, the Global HIV Vaccine Enterprise, INDEPTH Network, the International AIDS Vaccine Initiative (IAVI), International Partnership for Microbicides (IPM), the National Institute of Health (NIH), Malaria Clinical Trials Alliance (MTCa), Malaria Vaccine Initiative (EVI), Medicines for Malaria Venture (MMV), the PATH Malaria Vaccine Initiative (MVI), Sanofi Pasteur, TB Global Alliance, the United Nations Joint Programme on HIV/AIDS (UNAIDS), the Wellcome Trust, WHO/TDR and various pharmaceutical partners among others.

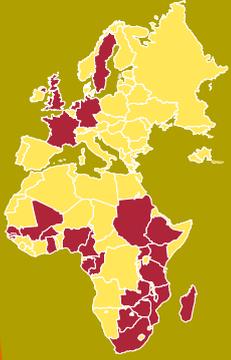
Additionally, EDCTP works with other funding organisations at different forums for exchange of information of mutual benefit such as the Malaria Vaccines Funders Forum and ESSENCE (Enhancing Support for Strengthening the Effectiveness of National Capacity Effort on Health Research).

In the improvement and enhancement of the enabling environment for best practices for conducting clinical trials, EDCTP is collaborating with the World Health Organisation in strengthening the regulatory framework in Africa and with Council on Health Research for Development (COHRED) in mapping of ethics review and trial regulatory capacity in sub-Saharan Africa. EDCTP also works in line with the African science and technology strategies of bodies, the New Economic Partnership for African Development (NEPAD) and the African Union (AU).

6

Partnership
and
networking

Project at a glance

Networks of
Excellence

EDCTP has funded four regional Networks of Excellence (NoEs). Each region of sub-Saharan Africa now has its own network: Western Africa

has WANETAM, Eastern Africa has EACCR, Central Africa has CANTAM, and Southern Africa has TESA. The regional Networks unite institutions that collaborate on the basis of their complementary individual strengths such as in good practises for conduct of clinical trials (GCP and GCLP), data management and laboratory capacity. The networks have infrastructural development as well as human capacity development components. Through facilitation of collaborative research activities, training and mentorship schemes, these networks are anticipated to raise the quality of clinical research and practice in sub-Saharan Africa.

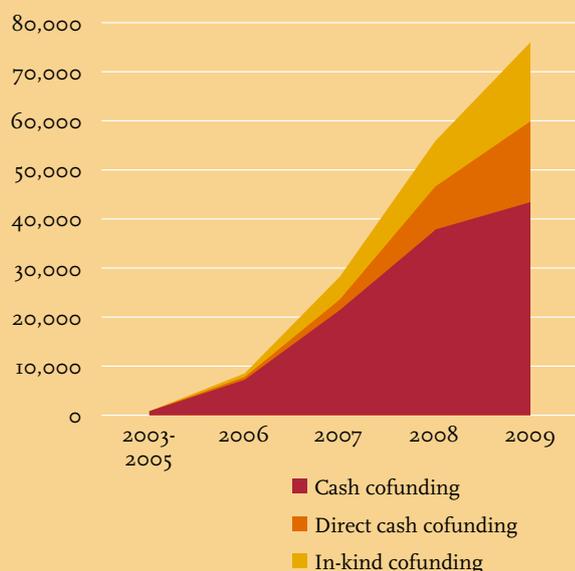


6.1 Member State cofunding

In 2009, the EDCTP-EEIG Member States contributed € 20.2 M to EDCTP-funded projects and activities. These contributions are divided into cash contributions to EDCTP (€ 5.6 M), direct cash cofunding to projects (€ 7.7 M) and in-kind contribution towards EDCTP projects (€ 6.7 M).

Since the start of the EDCTP programme in 2003 up until 31 December 2009, Member States have contributed a total of € 76 M to EDCTP signed projects. Additionally, the Member States have committed another € 28 M in direct and in-kind cofunding towards ongoing projects which will be come into effect after 2009. There is also approximately € 2.5 M in cash cofunding to projects which has been earmarked for projects approved in 2009 and currently still under budget negotiation. EDCTP accounting policy is to recognise the cofunding in the statutory accounts once the contract has been signed so this figure will rise again in 2010 as the last grants in the first phase of EDCTP have been negotiated and agreed.

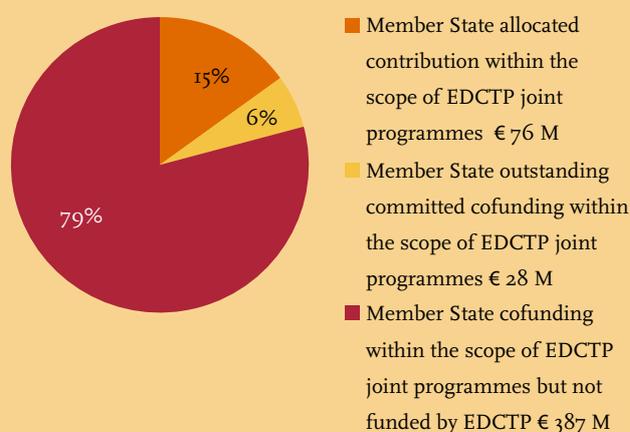
Total Member State eligible cofunding within the scope of the EDCTP joint programme for projects funded by EDCTP according to the type of contribution (2003-2009) (€ 000)



Eligible cofunding within the scope of the EDCTP joint programme for projects not funded by EDCTP

In addition, in 2009 Member States also provided eligible cofunding for national programme activities within the scope of EDCTP, but not funded by EDCTP, to the tune of € 52.9 M as was accredited by the annual Member States certificate. Overall the eligible cofunding provided by the Member States has reached € 463 M as at the end of 2009, well in excess of the required € 200 M for the programme.

Total Member State eligible cofunding within the scope of the EDCTP joint programme (€ 000)



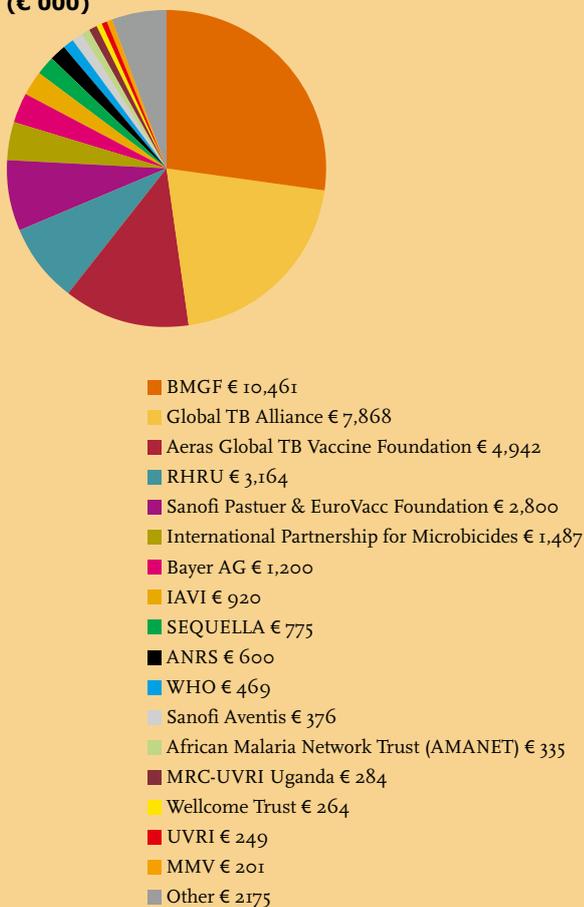
Composition of total Member State eligible cofunding within the scope of the EDCTP joint programme per country (€ 000)



6.2 Third-party cofunding

Between the start of the EDCTP programme in 2003 and 31 December 2009 an estimate of approximately € 38 M was received and an additional € 21 M was committed by third-parties to EDCTP-funded projects. The largest third-party funders are the Bill & Melinda Gates Foundation (BMGF) who have contributed over € 10.4 M in cash to EDCTP projects involving research and capacity building in HIV vaccines, tuberculosis treatment and vaccines in sub-Saharan Africa.

Third-party funding to EDCTP activities 2003-2009 (€ 000)



6.3 Coordination and integration of Member State activities and Euro-African partnership

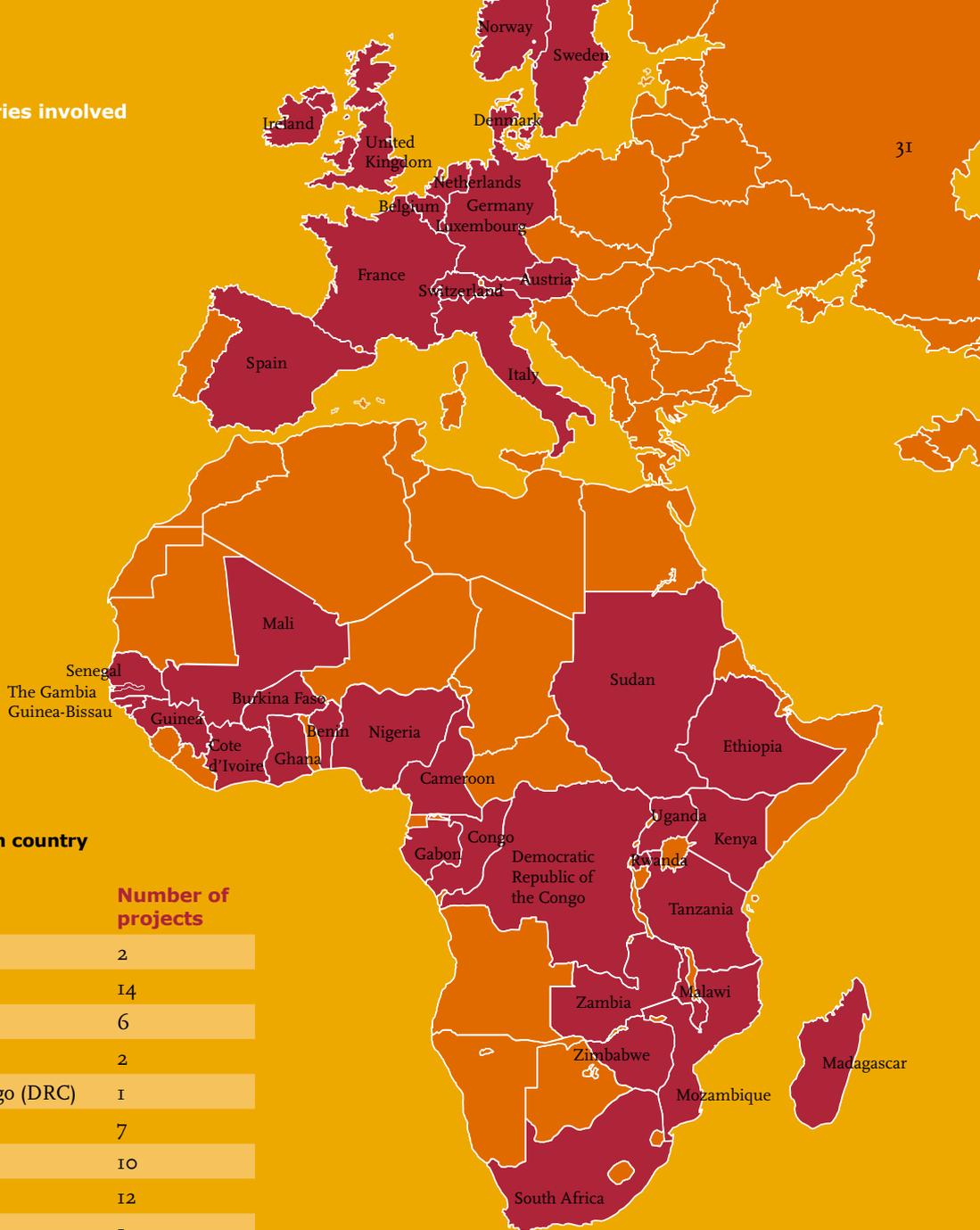
The EDCTP principle that requires at least two European Member States and two African countries to collaborate in projects and the encouragement of third-party participation has been very much instrumental in the formation of many international consortia. This mechanism has played a key part in EDCTP's role in facilitating integration of activities between different European national programmes on the three diseases. The formation or support of these research consortia is very cost-effective and fosters strong synergies. Despite the planned decrease in calls for proposals launched in 2009 it was a year in which again EDCTP-EEIG Member States actively participated in EDCTP initiatives. A total of seven EDCTP European Member States and eleven African countries were involved in successful proposals submitted in 2009 to the calls for proposals on TB diagnostics and the Joint Programme Activity.

In 2009, the average number of countries collaborating in EDCTP integrated projects was three for European and seven for sub-Saharan African countries. Furthermore, a significant proportion of clinical trials had a greater involvement of European Member States with 35% of all EDCTP-funded clinical trials having four or more European Member States collaborating in a project. This represents a very good level of integration.

6.4 North-South partnerships

EDCTP has been very intentional in encouraging partnerships and strengthening collaborative research. EDCTP requires the participation of a minimum of two European and two African countries working together in each project. The programme fosters nurturing of partnerships between established research institutions with newly developing ones and seeks to develop sustainable regional cooperation. This also calls for the European partners to seek cofunds from a minimum of two European Member States, which can be either in cash or in-kind. Besides the cofunding from European Member States, EDCTP encourages working together with third-parties including like-minded organisations and private sector who are also encouraged to contribute funds to the projects.

European and African countries involved in EDCTP-funded projects



Number of projects per African country

Country	Number of projects
Benin	2
Burkina Faso	14
Cameroon	6
Cote d'Ivoire	2
Democratic Republic of the Congo (DRC)	1
Ethiopia	7
Gabon	10
Ghana	12
Guinea	1
Guinea-Bissau	2
Kenya	17
Madagascar	1
Malawi	15
Mali	7
Mozambique	13
Nigeria	8
Republic of the Congo (Brazzaville)	2
Rwanda	6
Senegal	9
South Africa	40
Sudan	1
Tanzania	30
The Gambia	14
Uganda	23
Zambia	18
Zimbabwe	7

Number of projects per European country

Country	Number of projects
Austria	12
Belgium	24
Denmark	5
France	21
Germany	21
Ireland	4
Italy	10
Luxembourg	1
The Netherlands	30
Norway	6
Spain	14
Sweden	14
Switzerland	19
United Kingdom	56

6.5 North-North and South-South networking

Visits to EDCTP Member States and potential new Member States

The North-North Networking team continued to maintain regular contact with the Member States (MS) in order to collect information on the National Programmes, to identify MS priorities and discuss how to overcome impediments to the funding mechanism (in relation to MS involvement with EDCTP). Visits by the Executive Director, the General Assembly Chairperson and the Joint Programme Manager to the MS are very beneficial in establishing a closer relationship with the MS. The aim of these visits is to meet with constituency members, funding agencies/ministries representatives, scientists with interest in EDCTP activities and major national stakeholders. In 2009 the Secretariat made visits to Belgium, Portugal, Italy and Denmark, in order to update officials on the activities and progress of EDCTP, discuss further integration of national research programmes and explore opportunities for funding and other means of supporting EDCTP. Visits to EDCTP Member States will continue in 2010. In addition, in preparation for the possibility of a new co-decision on EDCTP, the Secretariat has also been conducting a programme of visits to European Union (EU) Member States that joined the EU after the start of EDCTP in 2003. The purpose of these visits is to meet with both Ministry officials and scientists to raise awareness of EDCTP, gauge the interest of their scientists in being involved in EDCTP activities and explore the possibility of these countries becoming EDCTP members after 2010. During the course of 2009, visits were made to Finland, Poland, Estonia and Czech Republic. This programme of visits to the newer European Union Member States will be completed in 2010.

Joint Programme Activities call

The Joint Programme Activities (JPA) call was first launched in April 2008 as a 'rolling call' with an evaluation of proposals every six months. This call aimed to identify and strengthen ongoing research activities, reducing duplication of effort and contribute towards integration of the National Programmes of the EDCTP Member States (MSs) and improve collaboration within or between African institutions and research centres.

This call was ended in June 2009. In 2009, two JPA grants from the first evaluation were signed, two from the second evaluation were under negotiation and the final two proposals from the June 2009 deadline were approved in November 2009 and are expected to be signed by the end of March 2010.

Member States Initiated Proposals call

In August 2009 a call for Member States Initiated (MSI) proposals was launched. This is a new instrument with the primary objectives to stimulate National Programme integration and to increase the level of cofunding of EDCTP Member States. As such, EDCTP will contribute up to a maximum of 25% of the grant while the EDCTP-EEIG Member States and third-parties will contribute at least 75% of the grant. EDCTP contribution to any single project will have a fixed limit, but there will not be any limit to the total project budget as contributed by all other funding parties. Projects that are already partially or fully funded by EDCTP are not eligible. The main objective of EDCTP is to support the development of new clinical interventions to fight HIV/AIDS, malaria and tuberculosis. This new call will serve as yet another platform for strengthening of north-south partnership, coordinating and networking of African researchers and establishing sustainable capacity building in Africa. In order to fulfil the requirements for this call, participants in a proposal must be from at least two publicly funded institutions from the EDCTP-EEIG Member States and at least one publicly funded institution from participating African countries. Five proposals were received in response to the first MSI proposals call.

All-Constituency meeting

On 16 and 17 February 2009 the full governance and advisory structure of EDCTP (General Assembly, Partnership Board, Developing Countries Coordinating Committee and European Network of National Programmes together with the EDCTP Secretariat) met to discuss and develop recommendations to the European Commission in respect of a new EDCTP programme to succeed the current EDCTP programme, which ends on 15 September 2010. Discussions covered the areas of governance, scientific strategy, and on the improvement of joint programme activities and cofunding strategies. Discussions took full account of the recommendations of the 2007 Independent Review of EDCTP. Key recommendations included:

- Strengthening the Governance of EDCTP and inclusion of African representation
- Extension of EDCTP remit to include phases I and IV clinical trial and some research on health systems
- Simplification of cofunding strategy.

Copies of these recommendations from the EDCTP General Assembly were sent to the individual Member States and the European Commission.

Fifth EDCTP Forum

The Fifth EDCTP Forum was held in Arusha, Tanzania on 12 to 14 October 2009. It brought together around 450 participants from 49 different countries including 26 from Africa, 15 from Europe and others from Australia, Cambodia, China, Cuba, Indonesia, Nepal, Peru and the United States of America. The theme of the fifth forum was *Fighting HIV/AIDS, tuberculosis and malaria: One World, One Partnership*. This theme is in line with the global call for all partners and stakeholders to work in unison and synergy to contain and possibly rid the world the scourge of these diseases of poverty.

The forum involved plenary and parallel sessions during which 58 oral presentations, 81 concise electronic presentations and 69 posters were presented. The presentations covered a wide range of topics that included clinical trials, capacity development, networking and other issues regarding HIV/AIDS, tuberculosis and malaria. This also included keynote addresses on state-of-the-art on the three poverty-related diseases (PRDs).

Several of EDCTP partners were involved and made presentations including the African AIDS Vaccine Programme (AAVP), the African Malaria Network Trust (AMANET), AERAS Global TB Vaccine Foundation, the Bill & Melinda Gates Foundation (BMGF), the European Vaccines Initiative (EVI), the Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts (ESSENCE), the International Partnership for Microbicides (IPM), the Medicines for Malaria Venture (MMV) and the Wellcome Trust. There were also four satellite meetings and workshops on Ownership of Research Outcomes in sub-Saharan Africa; Universal Standards for Clinical Trials in Practice; ESSENCE funders meeting to explore synergy; and a Roundtable Meeting of African Regional Economic Communities on the African representation to EDCTP-EEIG General Assembly.

At the forum, EDCTP also launched awards for Senior and Junior scientists in honour of the achievements of African scientists working on PRDs. The award for the senior scientist went to Dr Alexis Nzila of Kenya Medical Research Institute, Wellcome Trust Research Centre and of junior scientist to Dr Dominique Pepper from the Institute of Infectious Diseases and Molecular Medicine, University of Cape Town, South Africa.

African participation in EDCTP initiatives

By the end of 2009, 278 mid-career to senior African scientists were participating in EDCTP projects either as project coordinators or collaborators. These include 249 in clinical trials and regional Networks of Excellence projects; 5 Career Development (Postdoctoral) Fellows; 22 Senior Fellows and 2 in the Pan African Clinical Trials Registry (PACTR). Among these 57 are female.

In July 2009, Dr Michael Makanga was appointed Director of South-South Cooperation and Head of Africa Office, filling a vacancy that was vacant since 2007 and Dr Thomas Nyirenda appointed to be the South-South Networking and Capacity Development Manager. Additionally, the EDCTP collaboration with WHO-AFRO was also further strengthened by the appointment of Dr Issa Sanou who is now an observer on the Developing Countries Coordinating Committee of EDCTP. In 2009, EDCTP continued to proactively engage with the different stakeholders in Africa promoting African commitment, leadership and co-ownership of the Partnership. In order to further strengthen the African involvement and commitment in EDCTP, it was recommended in the EDCTP all-constituency meeting (EDCTP family meeting) and approved by the EDCTP General Assembly (GA) to have African representation at the GA. The proposed African representation will comprise of four high-level African representatives in the EDCTP-EEIG General Assembly (GA). These representatives are to be selected from African Regional Ministries for Health, Regional Economic Communities, Commission for Social Affairs of the African Union and African Regional Ministries of Finance or Science and Research.

EDCTP through the Africa Office and the activities of the High Representative maintained close collaboration with African governments, the African Union, NEPAD, WHO/AFRO, African Regional Economic Communities and their health organisations and like-minded partners.

Site visits

According to strategic importance and number of EDCTP supported projects in the country, two countries were visited in 2009. Benin was visited on 25 to 29 May 2009 and Congo Brazzaville from 17 to 21 August 2009. These visits involve three main objectives: advocacy, data collection and technical assessment on finance and capacity building aspects for health research.

Project at a glance



**The 4abc trial:
Artemisinin-based
combination
therapies (ACTs)
for treating
uncomplicated
malaria in African
children**

Prof. Umberto D'Alessandro
Belgium

This EDCTP funded study made a head-to-head comparison between 4 artemisinin-based combination treatments. This project features a commendable display of north-south collaborative research. The study is carried out in 10 sites distributed in 7 African countries (Burkina Faso, Gabon, Mozambique, Nigeria, Rwanda, Uganda and Zambia) with the involvement of local and European institutions (Belgium, United Kingdom, Germany, France and Spain). More than 4,000 children aged 6-59 months with clinical malaria were randomised to either amodiaquine plus artesunate, dihydroartemisinin plus piperazine, artemether plus lumefantrine or chlorproguanil-dapsone plus artesunate (CDA), the first three co-formulated combinations and the last one co-administered and CDA stopped prematurely for safety reasons. Children were followed up actively for 28 days and thereafter passively for 6 months; repeat clinical episodes were treated with the same drug used for first one and coupled with had a repeat 28-day active follow up. Data analysis for this study is underway.

We anticipate the results of this study to contribute significantly to the malaria research community and to inform policy in all malaria endemic countries involved.

Financial summary



Composition of income - EDCTP 2008/2009

	2009	2008
	€ 000	€ 000
Incoming resources		
EC income cash	0	29,514
Third-party and Member State income - cash	4,418	17,839
Third-party and Member State income - in-kind and direct	20,459	33,016
Total donor income	24,877	80,369
Finance income (interest)	2,903	3,160
Total income	27,780	83,529

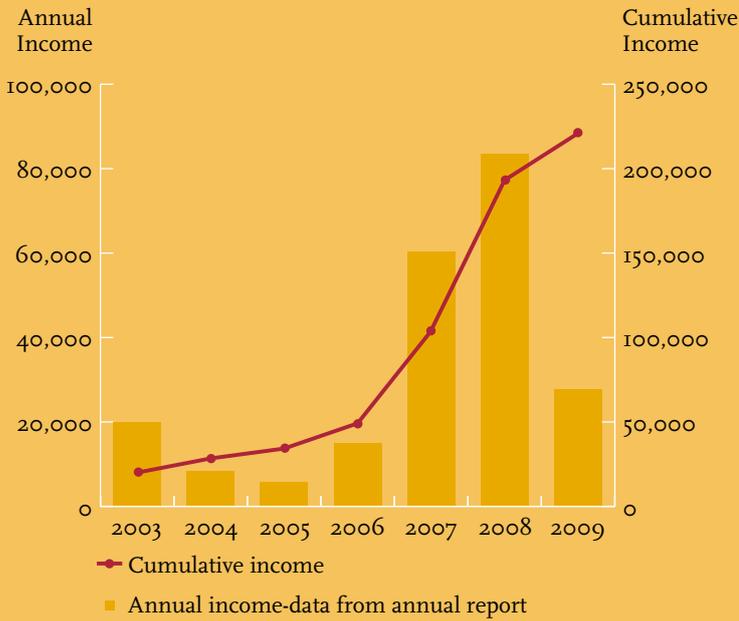
All of the amounts quoted in the financial summary and in the accompanying accounts are specifically in relation to EDCTP-funded projects only.

The strong growth in income which had been achieved over the years from 2005 to 2008 was not maintained in 2009 as receipts dropped to € 27.8 M compared to the previous year level of € 83.5 M. A major contributing factor to this decline was the fact that the European Commission (EC) did not make any disbursements to the Programme in the year, due to the high level of unused funds held in EDCTP bank accounts from the previous payments. Disbursements are set to recommence in 2010 as EDCTP had used up the majority of the surplus by the end of 2009.

New cash generated from donations received from Member States and third-parties saw a sharp reduction to € 4.4 M from € 17.8 M in the previous year, whilst in-kind and direct income also dropped to € 20.5 M. Of the two components it is the lower cash receipts which is the more concerning as the in-kind and direct income is affected significantly on an annual basis by timing issues but will continue to increase over the remaining life of the Programme. Attracting new cash funding from the Member States and third-parties is likely to be challenging as this is normally received in relation to the launching of new calls, and for the first Programme of EDCTP these are currently projected to end in 2010.

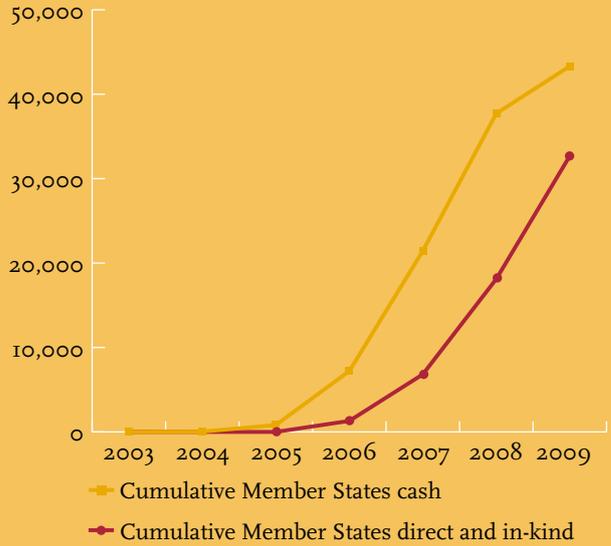
The total income for the Programme since 2003 has now reached € 221 M of which € 115 M (52%) has been provided by the Member States and third-parties in the amounts of € 76 M and € 39 M respectively.

**EDCTP total annual income levels 2003 to 2009
(€ 000)**

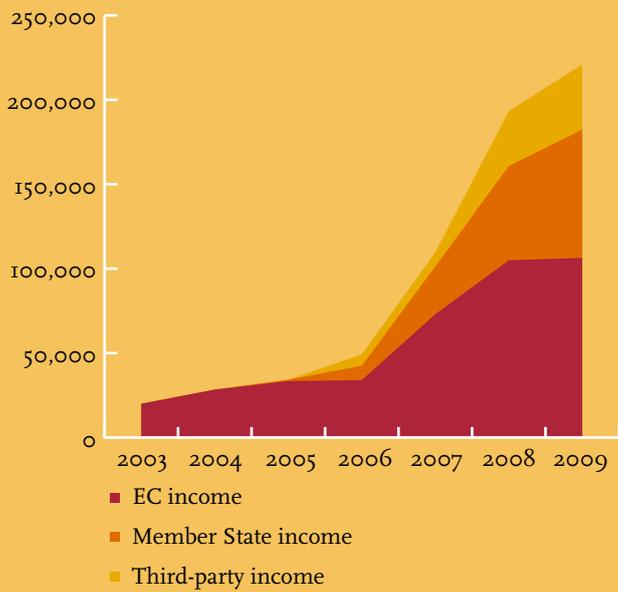


The graphs below illustrate the relative proportions of cofunding split between cash and in-kind/direct for Member States and third-parties since the start of the project.

Member States income by category (€ 000)

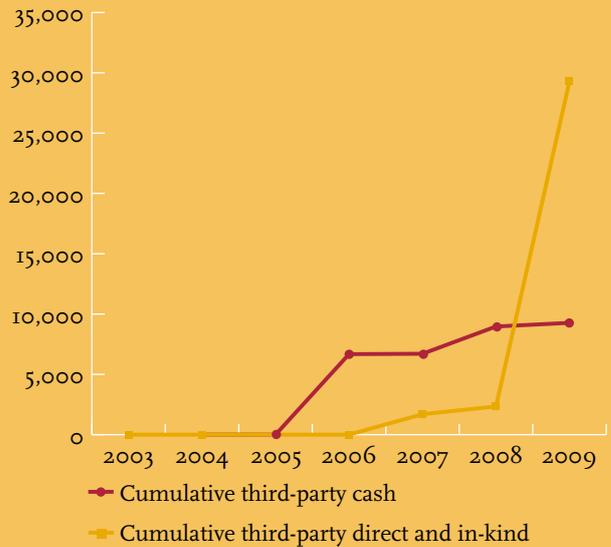


€ 000's

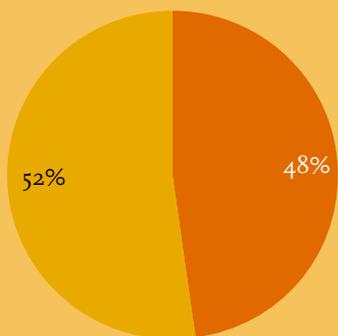


Member State income since 2003 continues to exhibit strong rising trend with cash exceeding direct and in-kind contributions. Third-party income has also risen but in this case of value of in-kind and direct cash contributions significantly exceeds the amount of cash provided to EDCTP.

Third-party income by category (€ 000)



Cumulative income (2003-2009)



- European Commission income € 106 M
- Member State and third-party donor income € 115 M

Resources expended - EDCTP 2008/2009

	2009	2008
	€ 000	€ 000
Resources expended		
Programme activities	4,351	3,277
Grants payable	100,309	56,010
Governance costs	653	640
Total resources expended	105,313	59,927

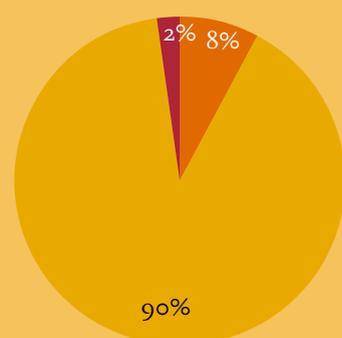
Total expenditure increased by 76% since 2008 with the vast majority of the rise being accounted for by the € 44 M surge in grant disbursements.

Programme activity costs rose over € 1 M over the year due mostly to costs associated with the biennial EDCTP Forum and Investigators meeting in Arusha plus various other smaller costs not incurred in 2008, whilst governance costs were broadly unchanged from last year, and are expected to remain at these levels for the foreseeable future. Of the total costs incurred to date grants expenditure now accounts for 90% of the amount as can be seen from the graph below.

Support costs incurred at the Hosting Institutions in The Netherlands and South Africa, which includes the cost of seconded staff and shared positions, came in at € 0.5 M in the year. The figure was boosted by the resumption of office rental charges for the Secretariat at NWO following a two year rent holiday.

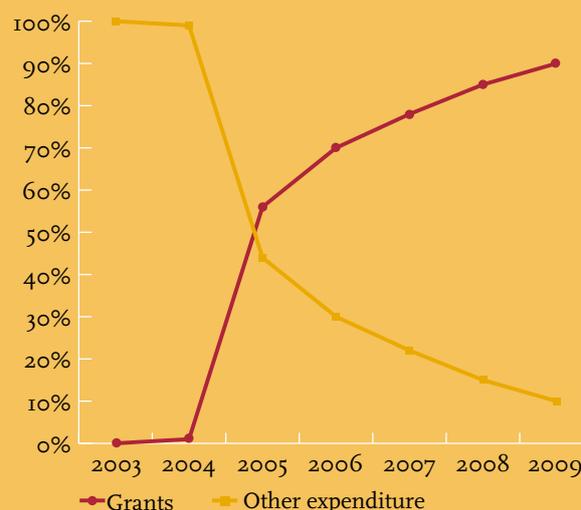
Staff salary costs for the year were marginally higher at € 2.6 M compared to € 2.5 M in the previous year. During the year one new Director position was created and filled as the Director of South-South Networking and Head of Africa Office. The effect on the salary cost was limited as this post was taken over by the previous Capacity Building Manager, whose previous job was then amalgamated with that of the South-South Manager.

Cumulative expenditure (2003-2009)



- Activities in furtherance of EDCTP objectives € 20 M
- Grants payable € 209 M
- Governance costs € 4 M

Grants vs other expenditure since 2003



Principal funding sources and cash-flow position

The key facts relating to income received during 2009 by EDCTP and how these funds were composed may be summarised as follows:

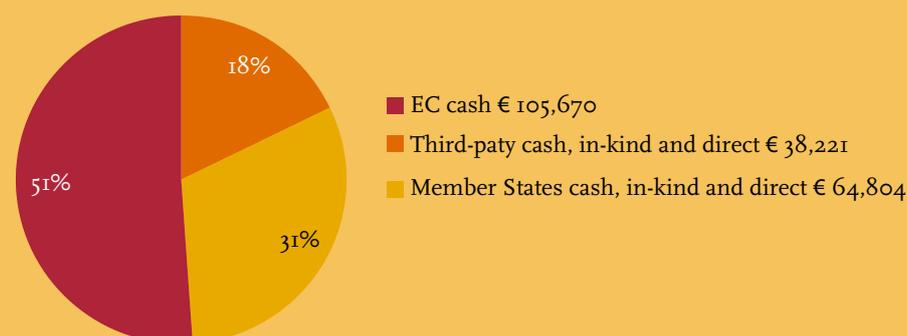
- The EC funding for the year was nil versus € 29.5 M in 2008
- Overall, the value of income excluding finance income received decreased to € 24.9 M from € 80.4 M in 2008, caused by a drop in Member State and third-party income of € 26 M
- Of the € 24.9 M contributed by Member States and third-parties, € 20.5 M is in-kind and direct cofunding to grantees whilst € 4.4 M is paid into EDCTP bank deposits
- Unallocated donor funds held in cash by the EDCTP and available as cofunding for future EDCTP grants, as at 31 December 2009 stood at € 8.1 M; a decrease of € 20.8 M from 2008 as the cash funding was used to finance a steep increase in the numbers of grants signed in 2008
- EC funding as per the balance sheet is technically in deficit to the tune of € 19.4 M as at 31 December 2009, but this is only because the remaining undisbursed funds of € 94 M from the EC are not recognised as an asset in the balance sheet. The net liability position of EDCTP is therefore a consequence of choice of accounting treatment rather than an operational position. The next disbursement of funds from the EC is expected in 2010 and will return the position to one of net assets on the balance sheet once the cash has been received into the EDCTP bank account
- EDCTP ended 2009 with € 64.6 M in cash and bank balances compared to € 99.3 M in 2008. The EDCTP has a very strong cash position at the year end and able to comfortably disburse large amounts to grants during the course of 2010 and beyond
- EDCTP has received significant cash donations on behalf of 7 out of 16 Member State donors and two third-parties (BMGF and TRAC Rwanda)
- New cash funding greater than € 0.1M and excluding interest receipts, from Member States and third-parties during 2009 included the following:
 - € 3.0 M grant for future calls for MRC UK
 - € 1 M from SIDA for future EDCTP calls
 - € 0.2 M from TRAC Rwanda (the first African credited cash contribution to EDCTP) for the MONOD HIV treatment clinical trial in Rwanda
 - € 0.1 M from the Luxembourg Development for the same clinical trial in Rwanda as TRAC above.

Despite having very high bank balances throughout the year finance income dropped in response to lower interest rates in the Eurozone and were marginally lower in 2009 at € 2.9 M versus € 3.2 M the year before.

Funding source for EDCTP grants signed 2003-2009 (€ 000)

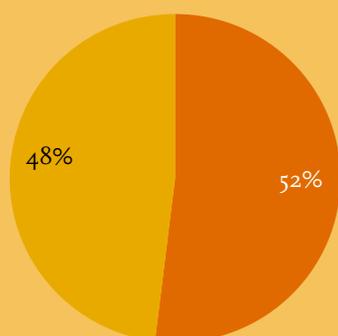
EDCTP aims to split the cost of grant expenditure overall, equally between the donors and the EC, and as at the end of 2009, this has very nearly been achieved.

Grants signed



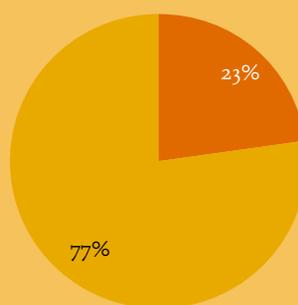
From the amounts provided by the donors shown in the graph above the relative amounts of funding divided between cash and in-kind can be seen below. The Member States have achieved a good balance of cash to in-kind/direct whilst the third-parties have provided the majority of their contribution in the form of in-kind funding which is usually the cost of drugs and associated costs for the development of clinical trial interventions provided by pharmaceutical organisations.

Allocation of Member States contributions for grants expenditure (2003-2009) (€ 000)



- Cash funding for grant expenditure € 33,996
- In-kind and direct for grant expenditure € 30,808

Allocation of third-party cofunding contributions for grants expenditure (2003-2009) (€ 000)



- Cash funding for grant expenditure € 8,961
- In-kind and direct for grant expenditure € 29,260

Statement of financial activity 2009 (SOFA)

Incoming resources		2009	2008
	Notes	€ 000	€ 000
Incoming resources from generated funds:			
Voluntary and donor income	2	24,877	80,369
Finance income	3	2,903	3,160
Total incoming resources	2	27,780	83,529
Resources expended			
Activities in furtherance of EDCTP objects	5	(4,351)	(3,277)
Grants payable	6	(100,309)	(56,010)
Governance costs	7	(653)	(640)
Total resources expended	4	(105,313)	(59,927)
Net income (expenditure) for the year		(77,533)	23,602
Allocations			
Allocated to earmarked funds		(56,730)	16,018
Allocated to general funds		0	0
Allocated to restricted funds		(20,803)	7,584
		(77,533)	23,602

Statement of changes in reserves 2009

	Notes	Unrestricted € 000	Earmarked € 000	Restricted € 000	Total € 000
Balance as at 1 January 2008		0	21,283	21,364	42,647
Allocation of result for the year		0	16,018	7,584	23,602
Balance as at 31 December 2008		0	37,301	28,948	66,249
Allocation of result of the year		0	(56,730)	(20,803)	(77,533)
Balance as at 31 December 2009	15,16,17	0	(19,429)	8,145	(11,284)

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

Statement of financial position as at 31 December 2009

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	Notes	2009 € 000	2008 € 000
Assets			
<i>Non-current assets</i>			
Tangible assets	10	0	0
Total non-current assets		0	0
<i>Current assets</i>			
Debtors	11	4,072	6,870
Cash and cash equivalents	12	64,614	99,250
Total current assets		68,686	106,120
Total assets		68,686	106,120
Liabilities and reserves			
<i>Liabilities</i>			
<i>Current liabilities</i>			
Creditors: amounts falling due within one year	13	36,600	23,702
<i>Non-current liabilities</i>			
Creditors: amounts falling due over one year	14	43,370	16,169
Total liabilities		79,970	39,871
<i>Reserves</i>			
<i>Unrestricted reserves</i>			
General funds	15	0	0
Earmarked funds	16	(19,429)	37,301
Total unrestricted reserves		(19,429)	37,301
<i>Restricted reserves</i>			
Restricted funds	17	8,145	28,948
Total reserves		(11,284)	66,249
Total liabilities and reserves		68,686	106,120

Approved by the EDCTP Secretariat on behalf of EEIG General Assembly



Prof. Charles Mgone

Dated 11 May 2010

Statement of cash flow for the year ended 31 December 2009

	Notes	2009 € 000	2008 € 000
Cash flows from operating activities			
Net income for the period		(77,533)	23,602
Adjustments for:			
Depreciation		0	0
Net finance income	3	(2,903)	(3,160)
Change in receivables	11	2,798	1,276
Change in payables	13, 14	40,099	10,526
Net cash from operating activities		(37,539)	32,244
Cash flows from investing activities			
Interest received	3	2,937	3,274
Net cash from investing activities		2,937	3,274
Net increase in cash and cash equivalents			
Cash and cash equivalents at 1 January		99,250	63,846
Effect of exchange rate fluctuations	3	(34)	(114)
Effect of prior year adjustment		0	0
Cash and cash equivalents at 31 December	12	64,614	99,250

Notes forming part of the financial statements for the year ended 31 December 2009

Statement of compliance

The accounts for 2009 have been prepared under international financial reporting standards and are fully compliant with requirements. The financial statements were authorized for issue by the EEIG General Assembly on 11 May 2010.

Note 1 Significant accounting policies

(a) 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.

(b) 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 2c below).

(c) Grants payable

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 6 below.

(d) Investment income and interest receivable

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

(e) 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.

(f) Support costs

In undertaking activities EDCTP incurs support costs under the hosting agreements signed with NWO and MRC; these are detailed in note 8 below. Support costs are those costs incurred directly in support of expenditure on the objects of the EDCTP.

(g) 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 5 below).

(h) Costs of governance

These represent the costs attributable to the strategic planning bodies of the EDCTP; the General Assembly (GA), 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.

(i) Capitalisation and depreciation of tangible fixed assets

Individual fixed assets costing 5,000 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

(j) 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 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.

(k) Functional and presentation currencies

EDCTP conducts its operations in Euro which is also the currency in which the financial statements are presented. EDCTP does not hold any non Euro bank accounts. All grants are signed in Euro and the vast majority of all operating costs are in Euro.

(l) Currency translation

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 was one foreign currency asset as at 31 December 2009 which was the grant receivable in US dollars from BMGF.

Under the terms of the contract with BMGF contribution their contribution (€ 6.7 M) for the first grant re HIV vaccines is fixed in Euro so there is no exchange risk involved, on the second grant from BMGF this is a \$ 3 M grant of which \$ 2 M is still outstanding as at 31 December 2009, this contribution is not fixed against the Euro and so will fluctuate in value when translated into Euro over the years in which it is receivable. Grant expenditure for these will be managed so that the grants awarded from this contribution will, so far as is possible, not exceed the Euro value of the foreign currency donations.

The rates used for translating other currencies into Euro at 31 December 2009 and 2008 are reported in note 26.

All non Euro currency receipts are translated into Euro as soon as they are received on the EDCTP bank account. Any exchange differences are recognized 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 staffs 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.

(n) Critical accounting judgments and key sources of estimation uncertainty

In the preparation of financial statements in conformity with IFRS, management makes certain estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses as well as the disclosure of contingent liabilities. Actual results could differ from such estimates. Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. The most significant judgments and estimates are summarised below:

i) Significant Judgments

EDCTP accounting policies require that cofunding from Member States and third-parties is recognised and identified in the financial statements. Such cofunding can be designated into three different accounting categories. Such decisions require significant judgment and relate to the following circumstances:

- Cash cofunding to EDCTP – the donor has deposited funds directly with EDCTP for the purpose of providing grants. This is specified and quantified in note 17 below
- Direct cofunding – cash funds paid over to the grantee institution in connection with an EDCTP grant by the donor directly and not through EDCTP, see note 2 below
- In-kind cofunding – funding provided to the grantee by the donor, in the form of services or materials provided to conduct the grant free of charge to EDCTP, see note 2 below.

The in-kind and direct categories of cofunding are shown as received and spent in the same year for which they are in respect of, and at the same amounts, so there are no asset or liability values in respect of them included in the balance sheet. Held-to-Maturity - The Bank follows the guidance of IAS 39 on classifying non-derivative financial assets with fixed or determinable payments and fixed maturity as held-to-maturity. In making this judgment, the Bank evaluates its intention and ability to hold such investments to maturity.

ii) Significant estimates

For in-kind cofunding being provided for a grant, the value of the cofunding and items of expenditure are identified in a budget sheet sent to EDCTP by the donor for the grant concerned and corroborated in writing. These values are estimated by the donor organisation concerned and accepted by EDCTP at these estimations.

For cash sent directly to the grantee without first passing through EDCTP the donor again provides EDCTP with a signed corroborating letter verifying the amount of the funding

provided to the grantee institution. Where either in-kind or direct cofunding is provided by a Member State then this is further supported by being included in the signed annual Member State certificate provided to the EDCTP at the end of each year and forwarded to the EC as evidence of that state's financial contribution to EDCTP for the year in question.

(o) Basis of measurement

The financial statements have been prepared on the historical cost basis except for financial instruments which are measured at fair value.

(p) Financial instruments

i) Non-derivative financial assets

Sums receivable and deposits are recognised on the date that they are originated. Such assets are recognised at fair value.

Cash and cash equivalents comprise cash balances and call deposits with original maturities of three months or less.

ii) Non-derivative financial liabilities

EDCTP initially recognises liabilities on the date that they are originated. Financial liabilities are recognised at fair value.

iii) Other (non)-derivative financial assets and liabilities

EDCTP has no financial assets at fair value through profit or loss, held-to-maturity financial assets, other loans and receivables and available-for-sale financial.

Note 2 (a) Voluntary and donor income by type of fund

	Earmarked		Restricted	
	2009	2008	2009	2008
	€ 000	€ 000	€ 000	€ 000
Voluntary and donor income	0	29,514	24,877	50,855
Finance income	1,426	2,457	1,477	703
Total incoming resources	1,426	31,971	26,354	51,558

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

	Earmarked	Restricted	2009 Total	2008 Total
	€ 000	€ 000	€ 000	€ 000
Cash cofunding to EDCTP				
EC for period 4 of the grant agreement	0		0	29,513
Member State and third-party cofunding re grant contributions (2c)		4,150	4,150	17,811
Member State and third-party cofunding re programme activities (2c)		240	240	12
Member State and third-party cofunding re governance (2c)		6	6	7
Member State EC ineligible cost reimbursement				9
Registration fees for annual forum		22	22	1
Total cash cofunding	0	4,418	4,418	47,353
In-kind, direct cofunding to EDCTP and grantees				
Member State and third-party cofunding grant contributions (2d)		19,998	19,998	32,618
Member State and third-party cofunding re programme activities (2d)		230	230	89
Member State and third-party cofunding re support activities (2d)		0	0	99
Member State and third-party cofunding re governance (2d)		231	231	210
Total cash, in-kind and direct cofunding	0	20,459	20,459	33,016
Total cofunding	0	24,877	24,877	80,369

**Note 2 (c) Incoming resources from Member State and third-party cofunding
(cash cofunding only)**

	Programme				2009	2008
	Grants	activities	Support	Governance	Total	Total
	€ 000	€ 000	€ 000	€ 000	€ 000	€ 000
BMGF					0	2,198
Belgium		24			24	0
France		4			4	0
Luxembourg	100	4			104	0
Netherlands		16			16	3,358
Norway					0	4
Spain					0	999
Sweden	945	20		6	971	7
Switzerland	37	5			42	606
United Kingdom	2883	147			3,030	10,658
United States		20			20	0
Rwanda	185	0			185	0
Others		22			22	0
Total	4,150	262	0	6	4,418	17,830

**Note 2 (d) Incoming resources from Member State and third-party cofunding
(in-kind and direct cofunding to grantees only)**

	Programme				2009	2008
	Grants	activities	Support	Governance	Total	Total
	€ 000	€ 000	€ 000	€ 000	€ 000	€ 000
Third-party	5,860	30			5,890	21,715
Austria	120			29	149	28
Belgium	1,878	2		24	1,904	1,096
Denmark	1,891			62	1,953	341
France	1,721				1,721	2,251
Germany	912	8		16	936	395
Greece					0	0
Ireland					0	0
Italy	87				87	195
Luxembourg	202				202	0
Netherlands	1,783	135			1,918	767
Norway	276			6	282	1,361
Portugal		6		3	9	3
Spain	-224	7		10	-207	1,098
Sweden	3,427	3			3,430	600
Switzerland	318	-27			291	2
United Kingdom	1,747	66		81	1,894	3,164
Total	19,998	230	0	231	20,459	33,016

Note 3 Financial income and expenses

	2009 € 000	2008 € 000
Net foreign exchange loss	(34)	(114)
Interest income	2,937	3,274
Total financial income	2,903	3,160

Note 4 Resources expended by type of fund

	Earmarked		Restricted	
	2009 € 000	2008 € 000	2009 € 000	2008 € 000
Activities in furtherance of EDCTP objects	3,853	2,948	498	329
Grants payable	53,888	12,579	46,421	43,431
Governance costs	415	426	238	214
Total resources expended	58,156	15,953	47,157	43,974

Note 5 Activities in furtherance of EDCTP objects

	2009 Total € 000	2008 Total € 000
Staff costs (see note 9)	2,593	2,448
Temporary staff costs	20	74
Depreciation	0	0
Recruitment	13	22
Travel and subsistence	260	255
Biennial scientific forum and bursaries	329	14
Advertising in scientific and other media	20	8
Scientific Review Committee meetings	109	117
Principal Investigators and Stakeholders meeting	41	20
Ineligible EC costs	0	9
NACCAP cofunded Secretariat costs	104	46
Office running cost, courier and consumables	23	45
Production of EDCTP reports	65	81
Mobile telecommunications	24	23
Annual staff retreat	10	14
Project database and data management system	10	32
Computing equipment and supplies	30	58
Office furniture	19	7
Professional services	17	81
Training	21	0

Note 5 Activities in furtherance of EDCTP objects (continuation)

	2009 Total € 000	2008 Total € 000
African Outstanding Scientist Awards	30	0
Independent EDCTP review by STI	26	0
SIDA/Makarere Capacity Development Joint Initiative	70	0
Access accounting system	0	32
Other	1	14
Total direct costs	3,835	3,400
Support costs (see note 8)	516	-123
Total research activities	4,351	3,277

Note 6 Grants payable

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

	Earmarked € 000	Restricted € 000	2009 € 000	2008 € 000
Grants payable				
EDCTP	53,888		53,888	12,579
Member States		24,038	24,038	5,346
Third-parties		2,385	2,385	5,467
Sub total	53,888	26,423	80,311	23,392
In-kind and direct payable				
Member States		14,138	14,138	10,903
Third-parties		5,860	5,860	21,715
Sub total	0	19,998	19,998	32,618
Total Member States/third-party/EDCTP grants	53,888	46,421	100,309	56,010

Note 7 Governance costs

	Total 2009 Earmarked and Restricted € 000	Total 2008 Earmarked and Restricted € 000
Assembly	206	156
Partnership Board	150	129
ENNP	61	75
Developing Countries Collaborating Committee	219	248
Audit fees	17	32
Total governance costs	653	640

Note 8 Support costs from third-parties

	NWO € 000	MRC SA € 000	Total 2009 € 000	Total 2008 € 000
Telephones	37	10	47	31
Catering	10	0	10	12
IT maintenance	25	3	28	(24)
Rent/service charge/parking	133	26	159	139
Office cleaning	12	0	12	12
Postage	1	0	1	0
Photocopies	21	0	21	14
Travel	12	0	12	(13)
Recruitment	0	0	0	0
Sundry	1	0	1	0
Legal/personnel professional and financial services	225	0	225	(294)
Total support costs	477	39	516	(123)

Note 9 Staff costs and numbers

Total staff costs comprised:

	2009 € 000	2008 € 000
Wages and salaries	2,362	2,308
Social security costs	104	43
Pension costs	127	97
Total staff costs	2,593	2,448

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

	2009	2008
Secretariat (EDCTP contract)	17.50	10.75
Secretariat (Seconded from NWO/MRC and Department of Health)	5	11.75
Total staff numbers	22.5	22.5

Note 10 Tangible fixed assets

		As at 31 December 2009
		Computing Equipment
		€ 000
Cost		
At 31 December 2008		31
Additions		0
At 31 December 2009		31
Depreciation		
At 31 December 2008		(31)
Charge for the year		(0)
At 31 December 2009		(31)
Net book value		
At 31 December 2008		0
At 31 December 2009		0

Note 11 Debtors

	2009	2008
	€ 000	€ 000
Donor owed funds	3,144	6,788
Other debtors	918	76
Prepayments	10	6
Total debtors	4,072	6,870

Donor owed funds include € 2.26 M from BMGF and € 0.88 M from NACCAP. Other debtors included € 0.78 M regarding the interest for 2009 paid in January 2010.

Note 12 Cash and cash equivalents

	2009	2008
	€ 000	€ 000
Bank balances	64,590	99,240
Cash in hand	24	10
Total cash and cash equivalents	64,614	99,250

Note 13 Creditors: amounts falling due within one year

	2009 € 000	2008 € 000
Other creditors	0	0
Grant creditors	36,474	23,596
Accruals	126	106
Total creditors falling due within one year	36,600	23,702

Note 14 Creditors: amounts falling due over one year

	2009 € 000	2008 € 000
Grant creditors	43,370	16,169
	43,370	16,169

Note 15 Unrestricted funds of the EEIG general fund

	€ 000
Balance at 31 December 2008	0
Movement in funds for the year	0
Balance at 31 December 2009	0

Note 16 Earmarked funds

	€ 000
Balance at 31 December 2008	37,301
EC Grant funds received	0
Released to statement of financial activities	(56,730)
Balance at 31 December 2009	(19,429)

The deficit on earmarked funds arises because EDCTP accounts for liabilities (full value of grant contracts signed) as at the day of signing the contract whilst the outstanding funds yet to be paid by the EC are shown as a contingent asset (note 20) rather than a normal debtor. The contingent asset as at 31 December 2009 is € 93.6 M which provides a cover of 4.8 times the size of the deficit on earmarked funds.

Note 17 Restricted funds

	At 31/12/08	Incoming resources	Outgoing resources	At 31/12/09
	€ 000	€ 000	€ 000	€ 000
MRC UK Capacity Development Training awards	180	0	0	180
DFID/MRC UK contribution to EDCTP calls	9,428	0	(9,097)	331
Medical Research Council (MRC) UK HIV trials contribution to joint call with BMGF	28	0	0	28
Medical Research Council (MRC) UK contribution to bursary costs 2009 biennial forum	0	40	(40)	0
Medical Research Council (MRC) UK contribution to EDCTP calls and management costs	7,833	2,989	(8,606)	2,216
Investment income	913	907	0	1,820
Bill and Melinda Gates Foundation (BMGF) HIV Vaccines	91	0	0	91
Bill and Melinda Gates Foundation (BMGF) TB Treatment	2,198	0	(2,200)	(2)
Investment income	95	98	0	193
Foreign exchange adjustment	0	0	(30)	(30)
Swedish International Development Cooperation Agency (SIDA) contribution to EDCTP calls	2,774	945	(2,150)	1,569
Swedish International Development Cooperation Agency (SIDA) contribution to bursary costs 2009 biennial forum, constituency meeting costs and audit costs	0	26	(26)	0
Investment income	157	221	0	378
Foreign exchange adjustment	(191)	0	0	(191)
Spanish Ministry of Health and Consumer Affairs (ISC) contribution to EDCTP calls	1,581	0	(804)	777
Spanish Ministry of Health and Consumer Affairs (ISC) contribution to bursary costs 2009 biennial forum and GA meeting costs	0	0	(16)	(16)
Investment income	196	123	0	319
Irish Aid contribution to EDCTP calls	165	0	(165)	0
Investment income	36	46	0	82
Center for treatment and research on AIDS, malaria and tuberculosis and other Epidemics Rwanda contribution to EDCTP calls	0	185	(185)	0
Investment Income	0	4	0	4
Luxembourg Development Co operation contribution to EDCTP calls	0	100	(100)	0
Investment income	0	2	0	2
NACCAP contribution to EDCTP calls	3,000	0	(3,000)	0
NACCAP contribution to bursary costs 2009 biennial forum	0	16	(16)	0
Investment Income	57	89	0	146
Swiss National Science Foundation (SNSF) contribution to EDCTP calls	0	38	(38)	0
Swiss Agency for Development and Cooperation (SDC)/Swiss State Secretariat for Education and Research (SER) contribution to EDCTP calls	401	0	(164)	237

Note 17 Restricted funds (continued)

	At 31/12/08	Incoming resources	Outgoing resources	At 31/12/09
	€ 000	€ 000	€ 000	€ 000
Swiss Agency for Development and Cooperation (SDC)/Swiss State Secretariat for Education and Research (SER) contribution to bursary costs 2009 biennial forum	0	0	(8)	(8)
Foreign exchange adjustment	0	0	(4)	(4)
Investment income	2	21	0	23
Norwegian Directorate of Health (NODH) contribution to EDCTP bursaries 2009 forum	4	0	(4)	0
Other donor contribution to EDCTP bursaries 2009 forum	0	79	(79)	0
Total	28,948	5,929	(26,732)	8,145

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

The SIDA, TRAC Rwanda, Luxembourg Development Cooperation and SNSF grants are for clinical trials and capacity building grants awarded within the EDCTP programme.

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 December 2006. The BMGF grant is to be used for TB treatment, namely the PANACEA consortium, an EDCTP integrated projects of clinical trials, capacity building and networking in sub-Saharan Africa.

Note 18 Related parties

The EEIG has signed a hosting arrangement contract with NWO and MRC SA which includes the costs providing personnel, legal, IT and communications services plus the rent and associated costs of Secretariat office space. Transactions under the hosting agreement, amounted to € 476,513 in 2009 for NWO and € 38,932 in 2009 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 was made for exemption from income taxes on EDCTP in 2008 in South Africa which is still pending, 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) 106,402 as at 31 December 2009 resulting in a contingent asset of (€ 000) 93,598 which has not been recognised in the accounts.

Note 21 Supplementary data

It is proposed to add the net costs for the year to the earmarked funds (€ 000's) (56,730) 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 2009. Member States are encouraged to pay for their own travel costs and only reimbursed where this is not possible.

The Partnership Board members are no longer paid an annual honorarium except for the € 10,000 to the Chair, 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 four meetings per year) attended pro rated down if less than the full session is attended. In 2009 the total payments to the Partnership Board in respect of honorariums amounted to € 48,601 (2008 € 44,508).

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 2009 the total payments to the DCCC in respect of honorariums amounted to € 40,642 (2008 € 50,620)

Note 23 Subsequent events

There are no subsequent financial events which have arisen by the date of formal approval of the 2009 statutory accounts which are material to these financial statements or would lead to a restatement in any of the values included in the accounting statements above.

Note 24 Segment reporting

EDCTP operates through two Secretariat offices based in The Netherlands and South Africa which support each other. The operations and activities of the two offices are the same; to provide grants advertised by open call to foster capacity building and new clinical interventions into the three main poverty-related diseases afflicting sub-Saharan Africa. The two Secretariats operate in a combined and uniform manner. In the opinion of management, the organisation operates in a single operating segment.

Note 25 Exchange rates

EDCTP has adopted risk management policies in 2008 to manage and mitigate the operational, reputational and financial risks which it faces in executing its mandate. Oversight of the risk management policies is the responsibility of the Secretariat management team. The four major types of financial risk are liquidity, credit, currency and interest rate.

Credit risk

Credit risk is the potential financial loss due to default of one or more debtors/obligors either to EDCTP itself or to a grantee whom EDCTP has entered into a contract with. There are two principal sources of credit risk: (i) sovereign credit risk (ii) non-sovereign credit risk. EDCTP makes no provisions for non payment of debts, owed by either type of donor, which have been pledged or contracted to the organisation and against which EDCTP is making grants. This is due to the financial standing of the debtor organisations concerned which are all Member State government organisations plus one NGO, the BMGF. All pledged amounts of cash cofunding to EDCTP are confirmed in writing, by letter or contract, and the management judges that there is no risk of non payment.

As at 31 December 2009 the donor debt profile was as shown below:

	€ 000
Public sector debt	882
Private sector debt	2,262
Total donor debt	3,144

In relation to grants made by EDCTP the grantee is required to submit annual financial reports and if the final financial report shows costs to have been less than the total value of the grant EDCTP contracted for, then the excess will be deducted from the 10% which EDCTP retains until the grant has ended, in this way reducing any amounts it would have to reclaim from the grantee themselves. As at 31 December 2009 no grantee owed the EDCTP any returnable funds.

EDCTP held all of its EC funds with Fortis bank as the end of the 2009 financial year, new accounts were also opened with different banks in 2009 following the financial crisis as part of risk management policy, these accounts are used for the donor funds. EDCTP does not invest in any other type of financial instruments or derivatives.

Liquidity risk

Liquidity risk is the potential for loss resulting from insufficient liquidity to meet cash flow needs in a timely manner. In order to minimize this risk, EDCTP maintains instantly accessible bank deposits based on the projected net cash requirement for a rolling one-year period. EDCTP currently invests funds only in bank deposits of up to 1 year maturity, this will be reviewed when the grant portfolio and hence the cashflow is more predictable.

Currency risk

Currency risk is the potential loss due to adverse movements in market foreign exchange rates. To minimize this risk EDCTP signs all grants in Euro and receives the vast majority of its income also in Euro. Where income is received from donors in other currencies where possible EDCTP contracts a fixed exchange rate with the donor against the Euro. If this is not possible, then any grants made against it either be made after it has been received and converted into Euro or will assume a very conservative future exchange rate to minimise any potential liability to EDCTP arising when it is received and converted into Euro. All foreign currency receipts are transferred into Euro as soon as they are received. The situation is monitored regularly to check that such a shortfall does not arise. EDCTP does not hedge any foreign exchange risk as it is deemed unnecessary. The vast majority of the EDCTP operating costs are also in Euro which reduces any risk to minimal in that area. Any foreign exchange losses incurred by grantees with whom EDCTP have signed a contract, are ineligible for charging back to EDCTP and must be covered by their own financial resources.

Interest rate risk

Interest rate risk is the risk that EDCTP receives less interest income than it expected due to falls in deposit rates. As EDCTP does not forecast or rely upon interest income, other than where by fixed rate deposit, this risk does not affect the organisation. Under the terms of the grant agreement with the EC, EDCTP is not allowed to borrow any funding and hence interest rate risk is of no concern, neither does EDCTP charge interest on any of its grants.

Operational Risk

Operational risks includes all aspects of risk-related exposure other than those falling within the scope of credit, market and liquidity risks including specifically the risk of loss resulting from inadequate or failed internal processes, people and systems or from external events and reputational risk.

EDCTP relies largely on internal controls and standard operating procedures for operational risk management. In 2008 the management team identified and categorised the major risks which impinge on EDCTP, management attestation on the adequacy of internal controls was published in the annual reports for the first time in 2008. In 2009 the risk controls continued to be monitored regularly and adjusted as necessary.

Note 26 Financial instruments

Credit risk

The carrying amount of financial assets represents the maximum credit exposure. The maximum exposure to credit risk at the reporting date is stated in Note 11.

Liquidity risk

The following are the contractual maturities of financial liabilities, including estimated interest payments in thousands of Euro:

	Carrying amount € 000	Contractual cash-flows € 000	6 months or less € 000	6-12 months € 000	1-2 years € 000	2-5 years € 000	more than 5 years € 000
Non-derivative financial assets							
Debtors	4,072	4,072	741	0	3,331	0	0
Cash and cash equivalents	64,614	64,614	64,614	0	0	0	0
	68,686	68,686	65,355	0	3,331	0	0

Currency risk

EDCTP's exposure to foreign currency risk was as follows based on notional amounts

	31 December 2009			31 December 2008		
	EUR € 000	USD € 000	CHF € 000	EUR € 000	USD € 000	CHF € 000
Debtors	1,810	2,262	0	1,364	5,105	401
Current liabilities	(36,600)			(23,701)		
Non-current liabilities	(43,370)			(16,169)		
Net exposure	(78,160)	2,262		(38,506)	5,105	401

The following significant exchange rates applied during the year:

	Average rate		Reporting date spot Rate	
	2009	2008	2009	2008
1 Euro				
USD	1.38	1.48	1.440	1.409
ZAR	11.8	12	10.66	13.06
CHF	1.52	1.56	1.484	1.497
SEK	10.7	10.2	10.25	10.87

Interest rate risk

At the reporting date the interest rate profile of EDCTP's interest-bearing financial instruments was:

	2009 € 000	2008 € 000
Fixed rate instruments		
Financial assets	34,200	0
Financial liabilities	0	0
Variable rate instruments		
Financial assets	30,414	99,250
Financial liabilities	0	0
	64,614	99,250

Auditor's report



We have audited the accompanying financial statements 2009 of EDCTP-EEIG, The Hague, which comprise statement of financial position as at 31 December 2009, the statement of financial activity and cash flows for the year then ended and the notes, comprising 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.

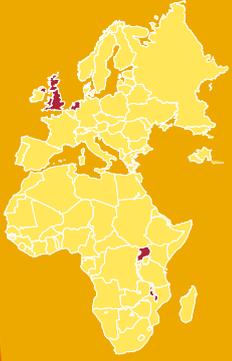
Opinion

In our opinion, the financial statements give a true and fair view of the financial position of EDCTP-EEIG as at 31 December 2009, 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, 17 May 2010
KPMG Accountants N.V.

W.A. Touw RA

Project at a glance



Fisher folk study on HIV/AIDS in Uganda and Malawi

Dr Pontiano Kaleebu,
Uganda

More than 95% of the new infections with HIV/AIDS occur in developing countries. Finding and involving those that are most affected is a major challenge. Dr

Pontiano Kaleebu is currently coordinating an EDCTP-funded Fisher folk study project involving about 2000 fishermen in Uganda and Malawi, until now considered a 'hard to reach' research population.

Fishermen are a mobile community, often spending extended periods on the water and away from home. They have no or limited access to health services, rendering them largely excluded from AIDS programmes and research. As a result, these communities suffer from high rates of HIV infection, putting the local fisheries industry under serious threat.

The Fisher folk study is already generating very significant findings that will soon be published and also shared with policy makers and affected populations.

Additionally, this work has greatly enhanced capacity of Dr Kaleebu's research team in HIV genetic characterisation.

At the end of 2009, laboratories at Uganda Virus Research Institute (UVRI) were accredited to become the regional reference laboratory for HIV drug resistance testing.

Moreover, the collaborative efforts in this study are contributing greatly to building AIDS research capacity in Malawi.

Appendices



9.1 Governance

General Assembly

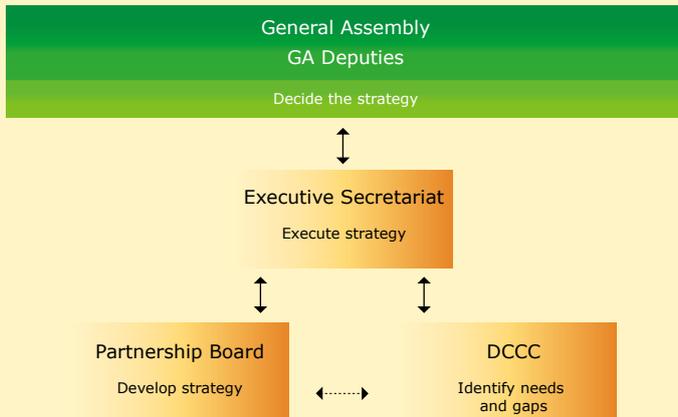
Christiane Druml	Austria
Bruno Gryseels	Belgium
Søren Jepsen (Vice-Chair)	Denmark
Patrice Debre (Vice-Chair)	France
Gabriele Hausdorf	Germany
Antonis Antoniadis	Greece
Teresa Maguire	Ireland
Stefano Vella	Italy
Carlo Duprel	Luxembourg
Marja Esveld	Netherlands (appointed May 2009)
Arne-Petter Sanne	Norway (appointed January 2009)
Ana Maria Faisca	Portugal
Rafael de Andres Medina	Spain (appointed May 2009)
Hannah Akuffo	Sweden
Isabella Beretta	Switzerland
Diana Dunstan (Chair)	United Kingdom
Kevin Moreton	United Kingdom

Partnership Board

Rosemary Musonda	Botswana
Sodiomon Sirima (Chair)	Burkina Faso
Peter Kreamsner	Germany
Martin Grobusch	South Africa
Eric Sandström (Vice-Chair)	Sweden
Christian Burri	Switzerland
Richard Adegbola (Vice-Chair)	The Gambia
Shabbar Jaffar	United Kingdom
Carolyn Petersen	USA

Developing Countries Coordinating Committee

Herman Awono Ambene	Cameroon
Veronique Nintchom Penlap (Vice-Chair)	Cameroon (elected October 2009)
Issa Sanou	Congo
Angelique Ndjovi Mbiguino	Gabon
Saadou Issifou	Gabon
David Ofori-Adjei	Kenya
Omu Anzala	Kenya
Abraham Alabi	Nigeria
Alioune Dieye (Chair)	Senegal (elected October 2009)
Hulda Swai	South Africa
Mecky Isaac Mateo	Tanzania
Martin Antonio	The Gambia
Jasper Ogwal-Okeng	Uganda
Modest Mulenga	Zambia
Nkandu Luo (Vice-Chair)	Zambia (elected October 2009)



European Network of National Programmes*

Brigitte Bloechl-Daum
 Dirk van der Roost (Chair)
 Klaus Winkel
 Bernadette Murgue
 Claudia A. Herok
 Suzanne Kolyva
 Teresa Maguire
 Giovanni Guidotti
 Carlo Duprel
 Judith de Kroon
 Kårstein Måseide
 Catarina Resende
 Rafael de Andres Medina (Vice- Chair)
 Olle Stendahl
 Isabella Beretta (Vice-Chair)
 Claire Newland

Austria
 Belgium (elected June 2009)
 Denmark
 France
 Germany
 Greece
 Ireland
 Italy
 Luxembourg
 Netherlands
 Norway
 Catarina Resende
 Spain (elected June 2009)
 Sweden
 Switzerland (elected June 2009)
 United Kingdom

* This Constituency was dissolved by end of 2009.



EDCTP Secretariat Staff

Charles Mgone
 Pascoal Mocumbi
 Simon Belcher
 Michael Makanga
 David Coles
 Waley Salami
 Thomas Nyirenda
 Anabela Atanásio
 Danielle Roordink
 Montserrat Blázquez Domingo
 Lara Pandya
 Christian Geib
 Marjolein Robijn
 Pete Murphy
 Lidwien van der Valk
 Joan Ruberg
 Ilona van den Brink
 Chris Bruinings
 Mary Jane Coloma-Egelink
 Emma Qi
 Raquel Rovira Blanco
 Kevin Burke
 Suzanne Hoogervorst
 Sanne Zoun
 Caroline Bijkerk
 Martijn Ek
 Daniela Pereira-Lengkeek
 Gail Smith
 Patricia Sáez
 Sabina Stanescu

Executive Director
 High Representative
 Director of Finance and Administration
 Director South-South Cooperation and Head of Africa Office
 Joint Programme Manager
 Operations Manager
 South-South Networking and Capacity Development Manager
 Senior Networking Officer
 Networking Officer
 Project Officer
 Project Officer
 Project Officer
 Project Officer*
 Project Officer
 Legal Advisor
 Human Resources Advisor
 Communications Officer
 Senior Bookkeeper
 Grants Financial Assistant
 Grants Financial Assistant
 Grants Financial Assistant
 Financial Assistant
 Travel and Events co-ordinator
 Travel and Events co-ordinator
 Travel and Events co-ordinator*
 Travel and Events co-ordinator*
 Senior Administration Officer (Communications)
 Senior Administration Officer
 Administration Officer
 Administration Officer

* These staff members left EDCTP during the course of 2009.



Clinical trials and integrated projects

<p>Grantee Prof. Chifumbe Chintu</p> <p>Title CHAPAS trial: Children with HIV in Africa - Pharmacokinetics and Adherence of Simple Antiretroviral Regimens</p> <p>Target disease HIV/AIDS (treatment)</p> <p>Partners Italy, The Netherlands, United Kingdom and Zambia</p> <p>Budget € 1,100,070</p> <p>Status Completed</p>	<p>Grantee Dr Muhammad Bakari</p> <p>Title HIV vaccine trial capacity building in Tanzania and Mozambique by continued exploration of optimal DNA priming and MVA boosting strategies (TaMoVac)</p> <p>Target disease HIV/AIDS (vaccines)</p> <p>Partners Denmark, Germany, Mozambique, The Netherlands, Sweden, Tanzania and United Kingdom</p> <p>Budget € 6,806,671 (€ 3,283,886 EDCTP)</p> <p>Status Ongoing</p>
<p>Grantee Dr Pontiano Kaleebu</p> <p>Title Strengthening of long term clinical and laboratory research capacity, cohort development, and collection of epidemiological and social science baseline data in Uganda and Malawi to prepare for future HIV vaccine trials</p> <p>Target disease HIV/AIDS (vaccines)</p> <p>Partners Malawi, The Netherlands, Uganda and United Kingdom</p> <p>Budget € 5,006,698 (€ 3,035,532 EDCTP)</p> <p>Status Ongoing</p>	<p>Grantee Prof. Linda-Gail Bekker</p> <p>Title Preparing for adolescent HIV vaccine trials in South Africa (CATSA)</p> <p>Target disease HIV/AIDS (vaccines)</p> <p>Partners France, Ireland, The Netherlands, South Africa, Sweden, Switzerland and United Kingdom</p> <p>Budget € 3,332,750 (€ 2,999,836 EDCTP)</p> <p>Status Ongoing</p>
<p>Grantee Prof. Jonathan Weber</p> <p>Title Africa-European HIV Vaccine Development Network (AfrEVacc)</p> <p>Target disease HIV/AIDS (vaccines)</p> <p>Partners Denmark, France, Germany, Mozambique, The Netherlands, South Africa, Spain, Switzerland, Tanzania and United Kingdom</p> <p>Budget € 6,959,444 (€ 3,309,861 EDCTP)</p> <p>Status Ongoing</p>	<p>Grantee Dr Teresa Katzenstein</p> <p>Title Back-up with Combivir (AZT/3TC) or single dose Truvada (FTC/TDF) in order to avoid Non Nucleoside Reverse Transcriptase Inhibitor (NNRTI) resistance after single dose Nevirapine for the prevention of mother-to-child transmission (MTCT)</p> <p>Target disease HIV/AIDS (PMTCT)</p> <p>Partners Denmark, Tanzania and Sweden</p> <p>Budget € 1,319,234 (€ 418,648 EDCTP)</p> <p>Status Ongoing</p>
<p>Grantee Dr Saidi Kapiga</p> <p>Title Capacity development and strengthening in preparation for HIV vaccine trials in Tanzania and Burkina Faso (HIVTAB)</p> <p>Target disease HIV/AIDS (vaccines)</p> <p>Partners Burkina Faso, France, Ireland, Italy, Tanzania and United Kingdom</p> <p>Budget € 3,348,434 (€ 2,205,798 EDCTP)</p> <p>Status Ongoing</p>	<p>Grantee Dr Elton Kisanga</p> <p>Title Improving the balance between efficacy and development of resistance in women receiving single dose nevirapine (Viramune[®], NVP) for the prevention of mother-to-child transmission in Tanzania and Zambia (VITA studies)</p> <p>Target disease HIV/AIDS (PMTCT)</p> <p>Partners The Netherlands, Tanzania, United Kingdom and Zambia</p> <p>Budget € 1,708,335 (€ 1,508,335 EDCTP)</p> <p>Status Ongoing</p>

Grantee Prof. Marie Louise Newell
Title Impact of HAART during pregnancy and breastfeeding on MTCT and mother's health The Kesho Bora Study
Target disease HIV/AIDS (PMTCT)
Partners France, Kenya, South Africa, Sweden and United Kingdom
Budget € 2,714,440 (€ 1,303,062 EDCTP)
Status Ongoing

Grantee Dr Tomás Hanke
Title Development of an infant vaccine against mother-to-child transmission of HIV-1 through breast milk (PedVacc)
Target disease HIV/AIDS (PMTCT)
Partners The Gambia, Kenya, Spain, Sweden, United Kingdom and United States
Budget € 3,266,045 (€ 3,030,725 EDCTP)
Status Ongoing

Grantee Prof. Philippe van de Perre
Title Efficacy and safety of infant periexposure prophylaxis with lamivudine to prevent HIV-1 transmission by breastfeeding (PROMISE-PEP)
Target disease HIV/AIDS (PMTCT)
Partners Burkina Faso, France, Norway, South Africa, Sweden, Uganda and Zambia
Budget € 12,199,421 (€ 2,800,000 EDCTP)
Status Ongoing

Grantee Dr Janneke van de Wijgert
Title Preparing for phase III vaginal microbicide trials in Rwanda and Kenya - Preparedness studies, capacity building, and strengthening of medical referral systems
Target disease HIV/AIDS (microbicides)
Partners Belgium, Italy, Kenya, Rwanda and The Netherlands
Budget € 5,690,926 (€ 2,000,000 EDCTP)
Status Ongoing

Grantee Prof. Richard Hayes
Title Site preparation and capacity strengthening for trials of vaginal microbicides in Tanzania and Uganda
Target disease HIV/AIDS (microbicides)
Partners The Netherlands, Tanzania, Uganda and United Kingdom
Budget € 6,263,866 (€ 2,435,071 EDCTP)
Status Ongoing

Grantee Dr Sheena McCormack
Title Establishing HIV microbicide clinical trial capacity in Mozambique and expanding and existing site in South Africa
Target disease HIV/AIDS (microbicides)
Partners Mozambique, South Africa, Spain and United Kingdom
Budget € 6,535,570 (€ 2,255,382 EDCTP)
Status Ongoing

Grantee Prof. Leif Bertilsson
Title Optimisation of tuberculosis and HIV co-treatment in Africa: Pharmacokinetic and pharmacogenetic aspects on drug-drug interactions between rifampicin and efavirenz
Target disease Tuberculosis
Partners Ethiopia, Germany, Sweden, Tanzania and Zimbabwe
Budget € 2,086,052 (€ 907,052 EDCTP)
Status Ongoing

Grantee Dr Anja van 't Hoog
Title Prospective epidemiological studies of TB in neonates and adolescents in Karemo Division, Siaya district, Western Kenya, in preparation for future clinical trials
Target disease Tuberculosis
Partners Austria, Kenya and The Netherlands
Budget € 5,327,369 (€ 2,678,216 EDCTP)
Status Ongoing

<p>Grantee Dr Philippa Musoke</p> <p>Title Towards conducting phase III trials of novel TB vaccines in Ugandan infants and adolescents</p> <p>Target disease Tuberculosis</p> <p>Partners Belgium, The Netherlands, South Africa, Sweden and Uganda</p> <p>Budget € 5,604,429 (€ 2,916,192 EDCTP)</p> <p>Status Ongoing</p>	<p>Grantee Dr Concepta Merry</p> <p>Title Determining the optimal doses of antiretroviral and antituberculous medications when used in combination for the treatment of HIV/TB in co-infected patients</p> <p>Target disease Tuberculosis</p> <p>Partners Ireland, South Africa, Uganda and United Kingdom</p> <p>Budget € 1,026,952 EDCTP</p> <p>Status Ongoing</p>
<p>Grantee Prof. Paul van Helden</p> <p>Title Surrogate markers to predict the outcome of antituberculosis therapy</p> <p>Target disease Tuberculosis</p> <p>Partners South Africa and United Kingdom</p> <p>Budget € 937,437</p> <p>Status Completed</p>	<p>Grantee Prof. Umberto D'Alessandro</p> <p>Title Evaluation of 4 artemisinin-based combinations for treating uncomplicated malaria in African children</p> <p>Target disease Malaria</p> <p>Partners Belgium, Burkina Faso, Denmark, France, The Gambia, Mozambique, Nigeria, Rwanda, Spain, Uganda, United Kingdom and Zambia</p> <p>Budget € 5,950,827 (€ 2,396,717 EDCTP)</p> <p>Status Ongoing</p>
<p>Grantee Dr Abraham Aseffa</p> <p>Title Capacity building for the conduct of ICH-GCP level TB vaccine trials in high risk populations in Ethiopia and East Africa</p> <p>Target disease Tuberculosis</p> <p>Partners Belgium, Denmark, Ethiopia, Madagascar, The Netherlands and Zambia</p> <p>Budget € 2,796,283 (€ 795,458 EDCTP)</p> <p>Status Ongoing</p>	<p>Grantee Prof. Peter Kremsner</p> <p>Title Artesunate for severe malaria in African children</p> <p>Target disease Malaria</p> <p>Partners Austria, Gabon, The Gambia, , Germany, Ghana Kenya, Malawi and United Kingdom</p> <p>Budget € 7,189,448 (€ 5,365,420 EDCTP)</p> <p>Status Ongoing</p>
<p>Grantee Prof. Stephen Gillespie</p> <p>Title Rapid Evaluation of Moxifloxacin in Tuberculosis - REMox TB</p> <p>Target disease Tuberculosis</p> <p>Partners South Africa, Tanzania, United Kingdom and Zambia</p> <p>Budget € 12,736,532 (€ 3,157,240 EDCTP)</p> <p>Status Ongoing</p>	<p>Grantee Prof. Clara Menéndez</p> <p>Title Malaria in Pregnancy Preventive Alternative Drugs (MiPPAD)</p> <p>Target disease Malaria (in pregnancy)</p> <p>Partners Austria, Benin, France, Gabon, Germany, Kenya, Mozambique, Spain and Tanzania</p> <p>Budget € 8,579,434 (€ 3,649,943 EDCTP)</p> <p>Status Ongoing</p>
<p>Grantee Dr Amina Jindani</p> <p>Title A controlled clinical trial to evaluate high dose rifapentine and a quinoline in the treatment of pulmonary tuberculosis</p> <p>Target disease Tuberculosis</p> <p>Partners Mozambique, South Africa, United Kingdom, Zambia and Zimbabwe</p> <p>Budget € 4,773,485 (€ 4,251,991 EDCTP)</p> <p>Status Ongoing</p>	<p>Grantee Dr Feiko ter Kuile</p> <p>Title Intermittent preventive therapy with SP for the prevention of malaria in pregnancy Regimen optimisation studies in Africa</p> <p>Target disease Malaria</p> <p>Partners Austria, Burkina Faso, Denmark, The Gambia, Ghana, Malawi, Mali, Mozambique and United Kingdom</p> <p>Budget € 6,243,458 (€ 3,648,811 EDCTP)</p> <p>Status Ongoing</p>

Networking Grants

Grantee Prof. Bruno Gryseels, Institute for Tropical Medicine, Belgium
Title European science and training for the promotion of health in developing countries “Networking the Networks”
Budget € 45,965
Location Belgium
Status Completed

Grantee Dr Christoph Male, Vienna School of Clinical Research, Austria
Title Establishment and implementation of a joint international MSc in Clinical Research with a focus on Clinical Trial Methodology
Budget € 10,000
Location Austria
Status Completed

Grantee Dr Robert Colebunders, Institute of Tropical Medicine, Antwerp, Belgium
Title Workshop on Tuberculosis Immune Reactivation Inflammatory Syndrome (TB IRIS)
Budget € 31,397
Location Uganda
Status Completed

Grantee Prof. Jenny Hill, Liverpool School of Tropical Medicine, Liverpool, United Kingdom
Title A north-south working group to support the design integrated research proposals for malaria in pregnancy
Budget € 40,996
Location United Kingdom
Status Completed

Grantee Prof. Marleen Temmerman, University of Ghent, Belgium
Title 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
Budget € 357,168
Location Kenya and Burkina Faso
Status Completed

Grantee Dr Enric Jane, Fundació Clínica per a la Recerca Biomèdica, Spain
Title Ifakara-Lambarene-Manhiça Partnership
Budget € 166,605
Location Tanzania, Mozambique and Gabon
Status Completed

Grantee Dr Amina Jindani, St George’s Medical College, London, United Kingdom
Title 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
Budget € 29,931
Location South Africa
Status Completed

Grantee Dr Sheena McCormack, Medical Research Council, United Kingdom
Title 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
Budget € 15,125
Location United Kingdom
Status Completed

Grantee Dr Daniel Kyabayinze, Regional Center for Quality of Health Care (RCQHC), Kampala, Uganda
Title KIDS-ART-LINC Network of clinical centres treating HIV-infected children with antiretroviral therapy in Africa to inform public health care and treatment programs
Budget € 30,000
Location South Africa
Status Completed

Grantee Dr Concepta Merry, Trinity College, Dublin, Ireland
Title Networking of European and sub-Saharan African research and capacity building in pharmacology
Budget € 27,524
Location Uganda
Status Completed

Grantee Dr Abraham Aseffa, Armauer Hansen
Research Institute (AHRI), Addis Ababa,
Ethiopia

Title Strengthening the National Tuberculosis
Research Network in Ethiopia

Budget € 22,227

Location Ethiopia

Status Completed

Grantee Prof. Andrew Hall, London School of Hygiene
and Tropical Medicine

Title Masters courses in clinical trials for
sub-Saharan Africa

Budget € 379,000

Location United Kingdom, Burkina Faso and Ghana

Status Ongoing

Grantee Prof. Diana Elbourne, London School of
Hygiene and Tropical Medicine (LSHTM)

Title EDCTP Grant to support at least 21
Studentships for distance learning Master-
course in clinical trials offered by LSHTM

Budget € 315,000

Location Coordination done in the United Kingdom

Status Ongoing (21 African candidates enrolled)

Grantee Prof. Francine Ntoumi

Title Establishment of the Central Africa Network
on Tuberculosis, HIV/AIDS and Malaria for
the conduct of clinical trials (CANTAM)

Partners Cameroon, France, Gabon, Germany and
Republic of the Congo

Budget € 2,997,644 (€ 2,967,644 EDCTP)

Status Ongoing

Ethics and regulatory strengthening

Grantee Wellcome Trust (Dr Anthony Woods)

Title Global Forum on Bioethics

Budget € 15,000

Location Malawi

Status Completed

Grantee World Health Organization

Title Programme to strengthen regulatory systems in African countries (Phase 1 and 2)

Location Burkina Faso, Cameroon, Cote d'Ivoire, Ethiopia, Gabon, Gambia, Ghana, Kenya, Madagascar, Malawi, Mali, Mozambique, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda, Zambia and Zimbabwe

Budget € 1,269,918 (€ 801,285 EDCTP)

Status Completed

Grantee Africa Malaria Network Trust-AMANET (Dr Roma Chilengi)

Title Continuation and expansion of the web-based learning platform for research training courses in biomedical research ethics for Africans

Location Tanzania

Budget € 106,914 (€ 100,000 EDCTP)

Status Completed

Grantee University of Stellenbosch (Prof. Keymanthri Moodley)

Title Enhancing research ethics capacity and compliance in Africa

Budget € 66,257

Location South Africa

Status Completed

Grantee Africa Malaria Network Trust (AMANET) (Prof. Wen Kilama)

Title Creating web-based research training courses in biomedical research ethics for Africans

Budget € 73,028

Location Tanzania

Status First phase completed

Grantee Cardiff University (Prof. Søren Holm)

Title Developing a distance learning research ethics course for East Africa

Budget € 77,013

Location United Kingdom

Status Ongoing

Grantee Institut de Droit de la Santé (Prof. Dominique Sprumont)

Title Training and resources in research ethics evaluation for Africa (TRREE for Africa)

Budget € 362,016 (€ 98,700 EDCTP)

Location France

Status Ongoing

Grantee Vienna School of Clinical Research VSCR (Dr Christa Janko)

Title Training on ethical aspects of clinical research for members of African national ethics committees and for African physicians/ investigators

Budget € 114,780 (€ 69,880 EDCTP)

Location Austria

Status Ongoing

Grantee University of Malawi (Prof. Joseph Mfutso-Bengo)

Title Proposal for building and strengthening national capacities in ethical review and clinical trial monitoring

Budget € 98,123

Location Malawi

Status Ongoing

Grantee Medical Research Council, Zimbabwe MRCZb&c (Mrs. Shungu Munyati)

Title Proposal for building national capacities in health research ethics, ethical review and clinical trial monitoring in Zimbabwe

Budget € 147,100

Location Zimbabwe

Status Ongoing

Grantee Nigerian Institute for Medical Research NIMR (Dr Ogenna Manafa)

Title Capacity strengthening of Nigerian researchers and ethics committee members on ethics

Budget € 77,662

Location Nigeria

Status Completed

Grantee	University of Ibadan (Prof. Adeyinka Falusi)	Grantee	University of Ibadan, West African
Title	Strengthening the capacity of research ethics committees in Africa	Title	Bioethics Training (WABT) (Prof. Clement Adebamowo)
Budget	€ 50,881 (€ 49,957 EDCTP)	Title	Strengthening the National Health Research Ethics Committee of Nigeria (NHREC)
Location	Nigeria	Location	Nigeria
Status	Completed	Budget	€ 45,000
Grantee	Rwanda National Ethics Committee (RNEC) (Dr Justin Wane/Dr Kayitesi Kayitenkore)	Status	Ongoing
Title	Strengthening the Rwanda National Ethics Committee	Grantee	Biomedical Research and Training Institute (BRTI) (Prof. Peter Mason)
Location	Rwanda	Title	Establishing an ethics research unit
Budget	€ 47,516	Location	Zimbabwe
Status	Ongoing	Budget	€ 49,273
Grantee	Tanzania National Health Research Forum (TANHER) (Dr Yohana Mashalla)	Status	Ongoing
Title	Strengthening ethical standards and practices in the protection of participants in health research in Tanzania	Grantee	Ministry of Health Benin (Dr Roch Hounghinin)
Location	Tanzania	Title	Establishment and strengthening of the Benin National Ethics Committee
Budget	€ 47,202	Location	Benin
Status	Ongoing	Budget	€ 47,940
Grantee	Uganda National Council for Science and Technology (UNCST) (Dr Maxwell Onapa)	Status	Ongoing
Title	Strengthening the national scientific and ethical review system and process in Uganda	Grantee	University of Malawi (Prof. Joseph Mfutso-Bengo)
Location	Uganda	Title	Proposal to strengthen the National Health Science Committee and College of Medicine Ethics Committee
Budget	€ 49,140	Budget	€ 44,768
Status	Ongoing	Location	Malawi
Grantee	National Institute for Medical Research (NIMR) (Dr John Changalucha)	Status	Ongoing
Title	Establishment of a local Institutional Review Board (IRB) in Mwanza, Tanzania and strengthening collaboration between the local and national IRBs	Grantee	Ministry of Public Health, Gabon (Dr Pierre-Blaise Matsiegui)
Location	Tanzania	Title	Establishment and support of a National Ethics Committee in Gabon
Budget	€ 49,966	Budget	€ 49,960
Status	Ongoing	Location	Gabon
Grantee	Ethiopian Bioethics Initiative (ETBIN) (Prof. Beyenne Petros)	Status	Ongoing
Title	Strengthening the ethics of health research in Ethiopia	Grantee	Navrongo Health Research Centre (Dr Abraham Hodgson)
Location	Ethiopia	Title	A proposal for strengthening capacity of six research ethics committees in Ghana
Budget	€ 50,000	Budget	€ 33,178
Status	Ongoing	Location	Ghana
		Status	Completed

Knowledge Management

Grantee Makerere University
(Prof. Nelson Sewankambo)

Title Supporting research through enhancement of the IRB processes at Makerere Medical School

Budget € 50,048

Location Uganda

Status Ongoing

Grantee Pan African Bio-Ethics Initiative PABIN
(Dr Abraham Aseffa)

Title Establishment of a regional ethics coordinating office

Budget € 60,659

Location Ethiopia

Status Completed

Grantee Council on Health Research for Development (COHRED) (Prof. Carel Ijsselmuiden)

Title Mapping of ethics review and trial regulatory capacity in sub-Saharan Africa

Budget € 345,000

Location Coordination done in Switzerland but activity applies to all EDCTP African Member States

Status Ongoing

Grantee Cochrane Centre, Medical Research Council
(Dr Nandi Siegfried/Prof. Jimmy Volmink)

Title The Pan African Clinical Trials Registry (PACTR)

Budget € 320,000

Location Coordination done in South Africa but activity applies to all EDCTP African Member States

Status Ongoing

Senior fellowships

Grantee	Dr Harr Freeya Njai	Grantee	Dr Christian Happi
Title	Identifying and assessing the prevalence and potency of broadly neutralising antibodies in a cohort of non-B HIV chronically infected individuals in rural Uganda	Title	Validation of new biomarkers for monitoring <i>Plasmodium falciparum</i> reduced susceptibility/tolerance or resistance to artemisinin derivatives and partner drugs in Nigeria
Target disease	HIV/AIDS	Target disease	Malaria
Location	Uganda	Location	Nigeria
Budget	€ 302,388 (€ 199,998 EDCTP)	Budget	€ 198,330
Status	Ongoing	Status	Ongoing
Grantee	Dr Nicaise Ndembi	Grantee	Dr Issa Nebie
Title	Frequency and determinants of dual infection with different strains of HIV-1 in low and high-risk populations in Uganda	Title	Understanding the mechanisms underlying the difference in susceptibility to malaria in an area of hyperendemic malaria in Burkina Faso: The potential role of regulatory T-cells
Target disease	HIV/AIDS	Target disease	Malaria
Location	Uganda	Budget	€ 199,013
Budget	€ 194,269	Location	Burkina Faso
Status	Ongoing	Status	Completed
Grantee	Dr Keertan Dheda	Grantee	Dr Davis Nwakanma
Title	Human lung innate immune pathways regulating the stasis and killing of <i>M. tuberculosis</i> in a high burden setting	Title	Evaluation and implementation of high throughput PCR-based method for diagnosis and measurement of <i>Plasmodium falciparum</i> parasitaemia in clinical trials.
Target disease	Tuberculosis	Target disease	Malaria
Location	South Africa	Budget	€ 180,862
Budget	€ 199,870	Location	The Gambia
Status	Ongoing	Status	Completed
Grantee	Dr Mark Nicol	Grantee	Dr Ambrose Talisuna
Title	The impact of rapid genotypic detection of multi-drug resistant tuberculosis on treatment outcome in a semi-rural region of South Africa	Title	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
Target disease	Tuberculosis	Target disease	Malaria
Location	South Africa	Budget	€ 199,440
Budget	€ 200,000	Location	Uganda
Status	Ongoing	Status	Ongoing
Grantee	Dr Daniel Dodoo		
Title	Assessment of functionality of antibodies that associate with protection from clinical malaria using the <i>in-vitro Plasmodium falciparum</i> growth inhibition assay		
Target disease	Malaria		
Location	Ghana		
Budget	€ 242,500 (€ 192,500 EDCTP)		
Status	Ongoing		

Grantee Dr Badara Cisse
 Title Implementation of seasonal intermittent preventive treatment with community participation in Senegal
 Target disease Malaria
 Budget € 198,159
 Location Senegal
 Status Ongoing

Grantee Dr Abraham Alabi
 Title 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
 Target disease HIV/AIDS
 Budget € 291,218
 Location The Gambia
 Status Completed

Grantee Dr Didier Koumavi Ekouevi
 Title Preventing peri-partum transmission of HIV-1 in Africa. Truvada[®]-based alternatives to Single-Dose Nevirapine in the light of future treatment options.
 Target disease HIV/AIDS
 Budget € 194,622
 Location Ivory Coast
 Status Completed

Grantee Dr Abdoulaye Djimde
 Title Assessment of the Public Health Benefit of artemisinin based combination therapies for uncomplicated malaria treatment in Mali
 Target disease Malaria
 Budget € 374,200 (€ 299,200 EDCTP)
 Location Mali
 Status Completed

Grantee Dr Alexis Nzila
 Title Understanding the mechanism of piperaquine resistance
 Target disease Malaria
 Budget € 299,498
 Location Kenya
 Status Completed

Grantee Prof. Maowia Mukthar
 Title The burden of tuberculosis in eastern Sudan
 Epidemiology and drug resistance patterns of *Mycobacterium tuberculosis* isolates
 Target disease Tuberculosis
 Budget € 197,505
 Location Sudan
 Status Completed

Grantee Prof. Willem Hanekom
 Title BCG-induced immune correlates of protection against tuberculosis
 Target disease Tuberculosis
 Budget € 291,632
 Location South Africa
 Status Completed

Career Development Fellowships

Grantee Dr Jennifer Serwanga
Title Patterns of HIV₁ specific CD8⁺ T-cell epitope recognition determining plasma viral load trajectory and set point following HIV-1 infection
Target disease HIV/AIDS
Budget € 99,095
Location Uganda
Status Ongoing

Grantee Dr Carole Eboumbou Moukoko
Title Identification of *Plasmodium falciparum* parasite virulence markers for the evaluation of the impact of malaria control intervention according to the local parasite populations
Target disease Malaria
Budget € 96,047
Location Cameroon
Status Completed

Grantee Dr Esperanca Sevene
Title Intensive safety monitoring of antimalarial and antiretroviral drugs in pregnancy
Target disease Malaria
Budget € 97,524
Location Mozambique
Status Ongoing

Grantee Dr Molebogeng Rangaka
Title Immunological investigation of the HIV-tuberculosis associated immune reconstitution
Target disease Tuberculosis
Budget € 87,960
Location South Africa
Status Completed

Grantee Dr Idefayo Adetifa
Title A double blind, placebo controlled randomised trial of vitamin A supplementation for modulation of *Mycobacterium tuberculosis* immune responses in children aged 5-14 years with latent tuberculosis reconstitution
Target disease Tuberculosis
Budget € 96,624
Location The Gambia
Status Ongoing

PhD Scholarships

Grantee Louis Marie Yindom
Title 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
Target disease HIV/AIDS
Budget € 75,000
Location Gambia
Status Ongoing

Grantee Bornwell Sikateyo
Title An assessment of the understanding of the informed consent process by participants in microbicide intervention trials in Zambia
Target disease HIV/AIDS
Budget € 99,000
Location Zambia
Status Ongoing

Grantee Thuli Mithiyane
Title Reconstitution of TB antigen specific IFN- γ responses in TB-HIV co-infected participants
Target disease Tuberculosis
Budget € 32,640
Location South Africa
Status Ongoing

Grantee Getnet Yimer Ali
Title Anti tuberculosis-anti retroviral drugs induced Hepatotoxicity and interaction of these drugs at the level of CYP 450 metabolism
Target disease Tuberculosis
Budget € 75,000
Location Ethiopia
Status Ongoing

Grantee Charles Arama
Title Host immunogenetic factors involved in the susceptibility to malaria in sympatric ethnic groups (Dogon and Fulani) in Mali
Target disease Malaria
Budget € 75,000
Location Mali
Status Ongoing

Grantee Leah Mwai
 Title Understanding the mechanism of resistance to lumefantrine by *Plasmodium falciparum*
 Target disease Malaria
 Budget € 75,000
 Location Kenya
 Status Ongoing

Grantee Janha Ramatoulie
 Title Investigating the effects of inactive CYP2C19 alleles on chlorproguanil pharmacokinetics in adults and in children with mild malaria following Lapdap[®] treatment
 Target disease Malaria
 Budget € 75,000
 Location The Gambia
 Status Ongoing

MSc studentships

Grantee Mr Alasan Jobe
 Title Masters in Reproductive and Sexual Health Research
 Budget € 21,000
 Location The Gambia
 Status Completed

Grantee Sunny Oyakhirome
 Title MSc in public Health
 Budget € 21,000
 Location Gabon
 Status Completed

Since 2007, training awards grant schemes such as MSc studentships, PhD scholarships and Career Development (now renamed as Postdoctoral fellowships) are no longer supported as stand-alone grants but are incorporated in the capacity development work package of the integrated projects.

French

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Rapport Annual 2009



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Autonomisation

La participation africaine aux projets financés par l'EDCTP fin 2009 concernait un total de 278 scientifiques à mi-carrière ou seniors activement impliqués dans des projets de l'EDCTP soit en tant que coordinateurs, soit en tant que collaborateurs. En outre, l'EDCTP a décerné ses prix destinés à récompenser des scientifiques africains remarquables au Dr Alexis Nzila et au Dr Dominique Pepper. La cérémonie de remise des prix a eu lieu lors du Cinquième Forum de l'EDCTP à Arusha en Tanzanie le 14 octobre 2009. Ces prix ont pour but d'encourager les scientifiques africains à diriger des recherches scientifiques en leur donnant les moyens de le faire, et de stimuler le développement des capacités de recherche en Afrique subsaharienne.

2009 en bref - selon les valeurs de l'EDCTP



Transparence

En juillet 2009, l'EDCTP a demandé au Centre helvétique de Santé internationale de l'Institut suisse des Tropiques d'entreprendre une évaluation interne du programme de l'EDCTP portant sur la période depuis sa création en 2003 jusqu'en 2009. Le but de cette évaluation était de mesurer les progrès faits par l'EDCTP à la fin de 2009 et de rassembler les opinions concernant la direction future à adopter. Ce rapport a été publié et est disponible sur le site de l'EDCTP (www.edctp.org).

Confiance mutuelle

Divers consortiums financés par l'EDCTP ont été constitués, reposant sur une véritable collaboration entre partenaires du Nord et du Sud ; à noter parmi eux le Consortium panafricain pour l'évaluation des antibiotiques antituberculeux (PanACEA). Ce consortium a été constitué pour mener une série d'essais en coopération afin d'évaluer trois médicaments distincts (Moxifloxacine, Rifampicine et SQ109) dans le cadre d'un programme de développement de médicaments. Outre l'EDCTP, le consortium rassemble de nombreuses parties prenantes, y compris des chercheurs et des investisseurs provenant d'organismes publics et privés d'Afrique, d'Europe et des États-Unis.

Partenariat et constitution de réseaux

En 2009, l'EDCTP a signé des contrats pour trois Réseaux d'excellence régionaux (RER). Ces réseaux ont été constitués en se basant sur la structure économique régionale africaine et réunissent des organismes qui collaborent en tenant compte de leurs forces individuelles et de leurs complémentarités. Quatre régions d'Afrique subsaharienne ont maintenant des RER fonctionnels : l'Afrique centrale avec CANTAM, l'Afrique de l'Est avec EACCR, l'Afrique australe avec TESA et l'Afrique de l'Ouest avec WANETAM.

Responsabilité

L'EDCTP encourage les pays africains à prendre la responsabilité et la prise en main en soutenant la recherche et en créant des stratégies durables pour mettre en place ces programmes de recherche et de développement. Le gouvernement tanzanien a donné un excellent exemple en annonçant en avril une augmentation des investissements publics. En prenant cette mesure, la Tanzanie est le premier pays africain fortement touché par les maladies à augmenter de façon conséquente ses budgets consacrés aux recherches de santé suite à des appels répétés en faveur d'une telle mesure. L'EDCTP encourage les autres leaders africains à suivre cet exemple.



Innovation

En mai 2009, l'EDCTP a réuni les parties prenantes autour des thèmes de l'optimisation du traitement contre le VIH et de la co-infection VIH/tuberculose. Cette réunion a été accueillie par le Centro Científico e Cultural de Macau à Lisbonne, Portugal. Réunir les parties prenantes sur des sujets thématiques fait partie de l'approche innovante de l'EDCTP, qui vise à recueillir des informations actualisées et à entrer en contact avec divers partenaires avant de lancer des appels d'offres. L'EDCTP a lancé un appel d'offres sur le traitement du VIH et sur la co-infection VIH/tuberculose en décembre 2009, en mettant 5 000 000 d'€ de fonds à disposition.

Pratiques d'excellence

En septembre, l'Organisation mondiale de la Santé (OMS) a reconnu le Registre panafricain des essais cliniques (PACTR) financé par l'EDCTP comme registre primordial d'essais cliniques. Cela fait du PACTR le premier registre d'essais cliniques en Afrique reconnu par l'OMS. Ce registre va alimenter en données le portail de recherche de la Plateforme internationale des registres d'essais cliniques de l'OMS (ICTRP), pour pouvoir avoir une idée globale de la représentation de l'Afrique dans les essais cliniques à venir, en cours et terminés.

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Message du Directeur exécutif



Une fois encore, 2009 a été une année gratifiante et couronnée de succès pour l'EDCTP. Dans le courant de l'année, le *Partenariat* a lancé 7 appels d'offres y compris un nouveau programme de bourses pour des projets initiés par les États membres européens (IEM). Le programme de bourse IEM encourage les états membres à collaborer et à joindre leurs efforts avec leurs homologues africains afin de soumettre des propositions conjointes principalement préfinancées par les États membres eux-mêmes. Cette année a aussi vu le lancement de trois des quatre réseaux d'excellence régionaux sélectionnés par l'EDCTP pour mener des essais cliniques. Les réseaux régionaux d'excellence ont rassemblé différents centres d'Afrique de l'Est, d'Afrique de l'Ouest, d'Afrique australe et d'Afrique centrale afin d'améliorer la capacité d'essais cliniques et l'efficacité opérationnelle dans chacune des régions. Les réseaux sont constitués de centres ayant des niveaux différents



de développement, mais dont les capacités mutuelles se complètent en matière de thèmes de maladie, de gestion des projets et des données, de capacités de laboratoire et dans d'autres domaines. Ils se révèlent être déjà un grand succès.

Le Cinquième Forum de l'EDCTP a été un autre temps fort de l'année. Cet événement s'est tenu à Arusha en Tanzanie. Le thème '*Combattre le VIH/SIDA, la tuberculose et le paludisme – Un Monde, un Partenariat*' a été bien illustré par la vaste participation comprenant 450 délégués venus de 49 pays différents. Au cours du forum, nous avons saisi l'occasion d'organiser 4 réunions satellites importantes et des ateliers, notamment l'atelier EDCTP/NACCAP sur la propriété des résultats des recherches en Afrique subsaharienne, une réunion sur les normes universelles pour les essais cliniques dans la pratique, une réunion des investisseurs d'ESSENCE afin d'explorer la synergie et une table ronde des communautés

économiques régionales sur la représentation africaine à l'Assemblée générale de l'EDCTP-EEIG. Lors du Forum, pour la première fois dans son histoire, l'EDCTP a aussi remis deux prix récompensant les performances de scientifiques africains travaillant sur les maladies liées à la pauvreté. Ces prix destinés à récompenser des scientifiques seniors et juniors ont été décernés respectivement au Dr Alexis Nzila de l'Institut de recherche médicale du Kenya au Centre de recherche du Trust Wellcome et au Dr Dominique Pepper, de l'Institut sur les maladies infectieuses et la médecine moléculaire de l'Université du Cap en Afrique du Sud.

Alors que nous consolidions nos efforts et que la première phase du programme parvenait à sa fin, l'EDCTP a commandé une évaluation interne afin de mesurer les résultats obtenus jusqu'à présent et d'explorer de nouvelles possibilités d'améliorer la façon dont le programme est proposé. Cette autoévaluation menée par un organisme indépendant a montré que l'EDCTP fonctionnait bien et était sur la bonne voie pour réaliser sa mission. En plus de cette autoévaluation, l'EDCTP a aussi mené une procédure consultative exhaustive qui s'est conclue par une réunion de tous les membres afin de discuter des plans et de la stratégie futurs de l'EDCTP. Dans le cadre de cette procédure, un accord général a été passé pour étendre la portée de l'EDCTP afin d'inclure toutes les phases des essais cliniques (I-IV) et les recherches de santé sur l'optimisation des interventions cliniques. En ce qui concerne la gouvernance, il a été décidé d'admettre immédiatement quatre représentants africains de haut niveau à l'Assemblée générale (AG) de l'EDCTP-EEIG. Ces représentants doivent être choisis dans les Ministères régionaux africains de la Santé, les communautés économiques régionales, la Commission des Affaires sociales de l'Union africaine et les Ministères africains régionaux des Finances ou de la Science et de la Recherche. Il a aussi été décidé que les représentants du Réseau européen des programmes nationaux (REPN) feraient partie de l'Assemblée générale, remplaçant ainsi les agents nationaux de réseaux européens (ENO) par des membres délégués de l'AG. Cela a été fait afin d'assurer une relation de travail plus étroite entre les programmes nationaux européens et l'Assemblée générale et pour rationaliser la gouvernance.

Tout ceci confirme que 2009 a été une année particulièrement satisfaisante. Il faut cependant insister sur le fait qu'aucune de ces réalisations n'aurait pu être possible sans le dévouement, le soutien et le travail intensif de toutes les parties prenantes et de tous nos partenaires. J'étends par conséquent mes sincères remerciements à tous ceux qui ont fait de 2009 une année particulièrement réussie pour l'EDCTP. Je remercie tout particulièrement les ENO qui, au cours des années, ont contribué inlassablement à la coordination et à l'intégration des programmes nationaux. Nous envisageons avec plaisir l'année 2010 et le passage à la seconde phase de l'EDCTP.

Charles S Mgone
Directeur exécutif

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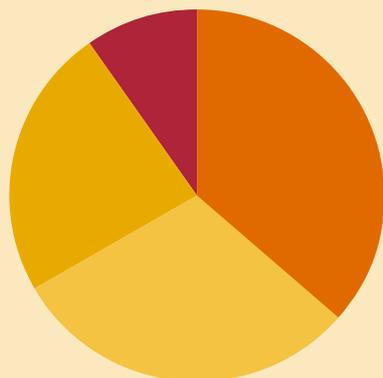
Financement des bourses entre 2003 et 2009



L'EDCTP finance des essais cliniques de phase II et III sur le VIH/SIDA, la tuberculose et le paludisme en Afrique subsaharienne. En outre, les bourses accordées par l'EDCTP sont utilisées pour développer les capacités afin de conduire ces essais cliniques dans les normes les meilleures et favoriser la constitution de réseaux. Les graphiques ci-dessous

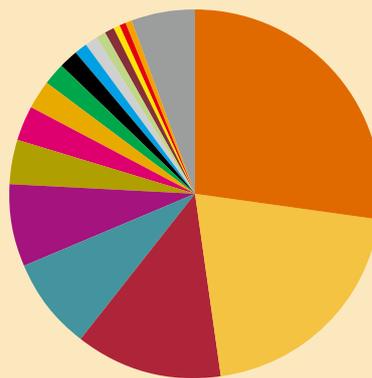
présentent une vue d'ensemble de la répartition du financement de l'EDCTP entre les trois maladies et entre les différentes interventions (des médicaments et vaccins aux bourses d'essais non-cliniques utilisées pour la formation et le renforcement du cadre éthique et réglementaire en Afrique).

Financement de l'EDCTP par maladie de 2003 à 2009 (€ 000)



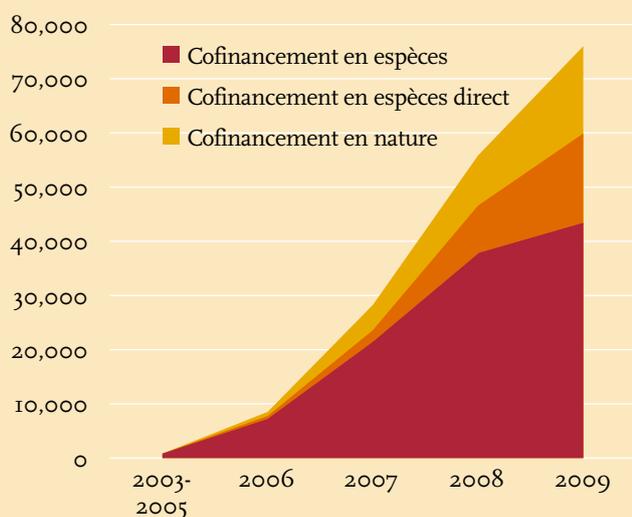
- VIH/SIDA € 54,244
- Tuberculose € 45,111
- Paludisme € 35,061
- Non lié à une maladie spécifique € 14,209

Financement provenant de tiers pour des activités de l'EDCTP entre 2003 et 2009



- BMGF € 10,461
- Alliance mondiale contre la tuberculose € 7,868
- Fondation Aeras pour le développement mondial de vaccins contre la tuberculose € 4,942
- RHRU € 3,164
- Sanofi Pasteur et Fondation EuroVacc € 2,800
- Partenariat international pour des Microbicides € 1,487
- Bayer AG € 1,200
- IAVI € 920
- SEQUELLA € 775
- ANRS € 600
- WHO € 469
- Sanofi Aventis € 376
- African Malaria Network Trust (AMANET) € 335
- MRC-UVRI UGANDA € 284
- Wellcome Trust € 264
- UVRI € 249
- MMV € 201
- Other € 2175

Total du cofinancement éligible des Etats Membres dans le cadre du programme commun de l'EDCTP pour des projets financés par l'EDCTP en fonction du type de contribution (2003-2009) (€ 000)



Projets intégrés

1 Nouveaux biomarqueurs pour évaluer la sécurité des microbicides

Coordinateur du projet Dr. Kishor Mandaliya
Institution Centre international de la Santé de la Reproduction (ICRH-K), Kenya
Maladie visée VIH/SIDA (microbicides)
Partenaires Belgique, Kenya, Pays-Bas, Rwanda, Afrique du Sud, Tanzanie, Royaume-Uni et États-Unis
Budget € 3 994 112
 (€ 2 688 595 de l'EDCTP)
Durée du projet avril 2009-avril 2012

2 Développement de la capacité d'essai pour réaliser un vaccin contre le VIH en Tanzanie et au Mozambique en utilisant un concept de vaccin vectorisé ADN-MVA grâce à l'apport de technologies novatrices

Coordinateur du projet Professeur Eligius Lyamuya
Institution Université de la Santé et des Sciences connexes de Muhimbili, Tanzanie
Maladie visée Vaccins contre le VIH/SIDA
Partenaires Allemagne, Mozambique, Suède, Tanzanie et Royaume-Uni
Budget € 6 367 429
 (€ 5 521 889 de l'EDCTP)
Durée du projet novembre 2009-juin 2014

3 Essai clinique international aléatoire de phase III destiné à étudier deux stratégies simplifiées d'entretien une fois par jour après une thérapie antirétrovirale initiale sur des bébés contaminés par le VIH en Afrique (MONOD)

Coordinateur du projet Dr Valérie Leroy
Institution Inserm U897/Université de Bordeaux 2/ISPED, France
Maladie visée VIH/SIDA
Partenaires Belgique, Burkina Faso, Côte d'Ivoire, France, Luxembourg et Rwanda
Budget € 3 442 969
 (€ 1 640 862 de l'EDCTP)
Durée du projet décembre 2009-août 2013

4 Options d'évaluation pour la thérapie en seconde ligne sur des patients où a échoué la thérapie en première ligne avec le régime 2NRTI + NNRTI en Afrique (EARNEST)

Coordinateur du projet Professeur Peter Mugenyi
Institution Centre conjoint de Recherche clinique, Ouganda
Maladie visée VIH/SIDA
Partenaires Belgique, Irlande, Italie, Malawi, Espagne, Ouganda, Pays-Bas, Royaume-Uni et Zimbabwe
Durée du projet € 4 872 368
 (€ 4 352 914 de l'EDCTP)
 septembre 2009-septembre 2013

5 Développement de la capacité de recherche et constitution de réseaux à travers l'évaluation de deux stratégies de traitement antirétroviral du VIH en seconde ligne en Afrique subsaharienne

Coordinateur du projet Professeur Eric Delaporte
Institution Université de Montpellier et Institut de Recherche pour le Développement (IRD), France
Maladie visée VIH/SIDA
Partenaires Belgique, France, Allemagne, Sénégal, Afrique du Sud, Suisse et Tanzanie
Budget € 4 040 244
 (€ 2 007 885 de l'EDCTP)
Durée du projet septembre 2009-juillet 2013

6 Enfants séropositifs en Afrique, Pharmacocinétiques et Acceptabilité/Adhésion des régimes antirétroviraux simples (CHAPAS-3)

Coordinateur du projet Dr Veronica Mulenga
Institution Hôpital universitaire de formation de Lukasa, Zambie
Target disease VIH/SIDA
Partenaires Irlande, Italie, Pays-Bas, Afrique du Sud, Espagne, Ouganda, Royaume-Uni et Zambie
Budget € 5 003 849
 (€ 4 617 034 de l'EDCTP)
Durée du projet novembre 2009-juillet 2013

7 Favoriser la capacité de recherche, la création de réseaux et la gestion de projet à travers des essais cliniques de phase I-IIB du vaccin candidat GMZ2 contre le paludisme.

Coordinateur du projet Dr Ramadhani Noor

Institution Africa Malaria Network Trust (AMANET), Tanzanie

Target disease Paludisme (vaccins)

Partenaires Burkina Faso, Danemark, Gabon, Gambie, Kenya, Tanzanie, Ouganda et Royaume-Uni

Budget € 9 863 901 (€ 5 140 147 de l'EDCTP)

Durée du projet janvier 2009-janvier 2014

8 Consortium pour des Vaccins vectorisés contre le paludisme (MVVC)

Coordinateur du projet Dr Egeruan Babatunde Imoukhuede

Institution Initiative européenne pour un vaccin contre le paludisme, Allemagne

Target disease Paludisme (vaccins)

Partenaires Autriche, Burkina Faso, Gambie, Italie, Kenya, Royaume-Uni et Sénégal

Budget € 9 543 310 (€ 7 882 536 de l'EDCTP)

Durée du projet décembre 2009-décembre 2013

9 Traitement contre le paludisme pour les femmes enceintes africaines

Coordinateur du projet Professeur Umberto D'Alessandro

Institution Institut de médecine tropicale, Belgique

Target disease Le paludisme et la grossesse

Partenaires Autriche, Burkina Faso, Ghana, Malawi, Pays-Bas, Rwanda, Royaume-Uni, Tanzanie et Zambie

Budget € 5 993 753 (€ 3 708 775 de l'EDCTP)

Durée du projet février 2009-mai 2013

10 Réseau d'Afrique de l'Ouest pour des essais cliniques de médicaments contre le paludisme (WANCAM)

Coordinateur du projet Dr Abdoulaye Djimde

Institution Université de Bamako, Mali

Target disease Paludisme

Partenaires Burkina Faso, France, Allemagne, Guinée, Mali, Pays-Bas, Suède et Royaume-Uni

Budget € 5 359 268 (€ 4 699 208 de l'EDCTP)

Durée du projet septembre 2009-mars 2013

11 Evaluation des interactions pharmacocinétiques entre les ACT et les antirétroviraux et les dosages en fonction de l'âge appropriés pour les ACT

Coordinateur du projet Dr Victor Mwapasa

Institution Trust Malawi Liverpool Wellcome, Malawi

Target disease Paludisme

Partenaires Autriche, Belgique, Malawi, Mozambique, Espagne, Royaume-Uni et Zambie

Budget € 5 082 545 (€ 3 863 808 de l'EDCTP)

Durée du projet juillet 2009-juillet 2014

12 Réalisation d'essais de phase II de vaccins contre la tuberculose de niveau ICH-GCP chez les populations à haut risque en Afrique

Coordinateur du projet Dr Mark Doherty

Institution Statens Serum Institut, Danemark

Target disease Vaccins contre la tuberculose

Partenaires Danemark, Ethiopie, Guinée-Bissau et Pays-Bas

Budget € 8 411 556 (€ 4 164 136 de l'EDCTP)

Durée du projet mars 2009-mars 2014

13 Un essai d'efficacité de phase IIb pour évaluer l'efficacité protectrice d'une vaccination booster MVA85A administrée à des adultes séropositifs en bonne santé en Afrique du Sud, au Sénégal et en Gambie

Coordinateur du projet Dr Martin Ota
Institution Conseil de la Recherche Médicale, Gambie
Target disease Vaccins contre la tuberculose
Partenaires Belgique, Sénégal, Afrique du Sud et Royaume-Uni
Budget € 13 177 720 (€ 9 473 720 de l'EDCTP)
Durée du projet août 2009-août 2014

14 Un nouveau vaccin contre la tuberculose pour les bébés en Afrique

Coordinateur du projet Professeur Gregory Hussey
Institution Université du Cap, Afrique du Sud
Target disease Vaccins contre la tuberculose
Partenaires Autriche, Kenya, Pays-Bas, Espagne, Suisse, Mozambique, Afrique du Sud, Suède, Ouganda et Etats-Unis
Budget € 7 706 813 (€ 3 411 368 de l'EDCTP)
Durée du projet mai 2009-août 2014

15 Evaluation rapide de la Moxifloxacin dans la tuberculose (PanACEA – REMoxTB)

Coordinateur du projet Professeur Stephen Gillespie
Institution University College London, Royaume-Uni
Target disease Tuberculose
Partenaires Kenya, Afrique du Sud, Tanzanie, Royaume-Uni et Zambie
Budget € 7 382 511 (€ 5 913 631 de l'EDCTP)
Durée du projet septembre 2009-février 2014

16 Etudes cliniques réalisées avec une dose élevée de rifampicine et développement des capacités de la recherche clinique en Afrique (PanACEA – HIGHRIF)

Coordinateur du projet Dr Martin Boeree
Institution Radboud University Nijmegen, Pays-Bas
Target disease Tuberculose
Partenaires Pays-Bas, Afrique du Sud, Suisse, Tanzanie, Ouganda et Royaume-Uni
Budget € 4 640 849 (€ 3 122 842 de l'EDCTP)
Durée du projet juin 2009-décembre 2013

17 Evaluation d'un nouveau médicament contre la tuberculose (SQ109) permettant de raccourcir la durée du traitement et de le simplifier (PanACEA – SQ109)

Coordinateur du projet Dr Michael Hoelscher
Institution Département des Maladies infectieuses et de la Médecine tropicale, Clinique de l'Université de Munich (LMU), Allemagne
Maladie visée Tuberculose
Partenaires Tuberculose
Budget Allemagne, Afrique du Sud, Tanzanie, Pays-Bas, Royaume-Uni, Etats-Unis et Zambie
Durée du projet € 6 012 526 (€ 1 136 761 de l'EDCTP)
 juin 2009-juin 2014

Bourses Seniors

1 Evaluation de la résistance aux antirétroviraux des enfants contaminés par le VIH en Afrique

Coordinateur du projet Dr Cissy Kityo
Maladie visée VIH/SIDA
Partenaires Centre conjoint de Recherche clinique, Ouganda et Conseil de la Recherche médicale, Royaume-Uni
Budget € 196 900
Durée du projet novembre 2009-novembre 2011

2 L'effet de la coinfection au VIH sur la réponse immunitaire à *Mycobacterium tuberculosis* dans le poumon

Coordinateur du projet Dr Wendy Burgers
Maladie visée Tuberculose
Partenaires Université du Cap, Afrique du Sud, Stellenbosch University, Afrique du Sud et Centre de Recherche de Borstel, Allemagne
Budget € 199 980
Durée du projet octobre 2009-octobre 2011

3 Syndrome inflammatoire de restauration immunitaire (IRIS) chez des patients souffrant de schistosomiasis et recevant une thérapie antirétrovirale hautement active (HAART)

Coordinateur du projet Dr Pauline Mwinzi
Maladie visée Tuberculose
Partenaires Institut kenyan de la Recherche médicale (KEMRI), Kenya et Institut de Médecine tropicale Prince Leopold, Belgique
Budget € 185 669
Durée du projet novembre 2009-novembre 2011

4 Un essai contrôlé aléatoire de thérapie par apport de fer par voie orale dans le traitement de l'anémie par carence en fer due au paludisme sur les enfants du Malawi comparant le traitement immédiat et le traitement retardé de l'apport de fer et la réponse hématologique

Coordinateur du projet Dr Kamija Phiri
Maladie visée Paludisme
Partenaires Programme de recherche Malawi-Liverpool-Wellcome Trust, Malawi ; Centre médical universitaire de Groningue, Pays-Bas et Université de Liverpool, Royaume-Uni
Budget € 199 145
Durée du projet septembre 2009-septembre 2011

Réseaux d'excellence

1 Consortium d'Afrique de l'Est pour la Recherche clinique (EACCR)

Coordinateur du projet Dr Pontiano Kaleebu

Maladie visée L'institut ougandais de recherche sur les virus (UVRI), Ouganda

Partenaires Ethiopie, Allemagne, Kenya, Pays-Bas, Norvège, Soudan, Suède, Tanzanie, Ouganda, Royaume-Uni et Etats-Unis

Budget € 3 499 200
(€ 2 499 200 de l'EDCTP)

Durée du projet mai 2009-mai 2012

2 Élaboration d'une capacité à préparer des sites en Afrique occidentale pour des essais cliniques sur le VIH, la tuberculose et le paludisme.

Coordinateur du projet Professeur Soleymane Mboup

Maladie visée Université Cheikh Anta DIOP de Dakar (UCAD), Sénégal

Partenaires Burkina Faso, Gambie, Ghana, Guinée-Bissau, Mali, Nigeria, Sénégal, France, Royaume-Uni et Etats-Unis

Budget € 3 499 921
(€ 2 499 921 de l'EDCTP)

Durée du projet juillet 2009-mai 2012

3 Essais d'excellence en Afrique australe (TESA)

Coordinateur du projet Dr Alexander Pym

Maladie visée Conseil de la recherche médicale de l'Afrique du Sud (MRC), Afrique du Sud

Partenaires Botswana, France, Allemagne, Malawi, Mozambique, Pays-Bas, Afrique du Sud, Royaume-Uni, Zambie et Zimbabwe

Budget € 2 640 548
(€ 2 337 304 de l'EDCTP)

Durée du projet novembre 2009-novembre 2011

Renforcement des comités d'éthique et des réglementations

1 Renforcement des capacités des Comités d'éthique de la recherche africains pour l'étude éthique liée à la recherche sur la prévention du sida

Coordinateur du projet Université de KwaZulu-Natal (Professeur Douglas Wassenaar)

Pays Afrique du Sud

Budget € 49 935

Durée du projet novembre 2009-novembre 2012

2 Le projet Mzadi : renforcement de la capacité de recherche éthique en République du Congo et en République démocratique du Congo

Coordinateur du projet Centre interdisciplinaire de Bio-éthique pour L'Afrique francophone (CIBAF) (Dr Bavon Mupenda)

Pays République démocratique du Congo

Budget € 40 800

Durée du projet décembre 2009-décembre 2012

3 Création d'un Comité national d'éthique de la recherche et renforcement des CNE/CEI créés au Ghana

Coordinateur du projet Université du Ghana (Dr Okyere Boateng)

Pays Ghana

Budget € 49 808

Durée du projet décembre 2009-décembre 2012

4 Renforcement de la capacité de contrôle éthique et suivi de projets approuvés à l'Institut de recherche médicale du Kenya

Coordinateur du projet Institut de recherche médicale du Kenya (KEMRI) (Dr Christine Wasunna)
Pays Kenya
Budget € 49 500
Durée du projet décembre 2009-décembre 2012

5 Programme de renforcement du Comité national d'éthique pour la recherche sur la santé du Sénégal (CNRS) et sensibilisation aux questions d'éthique au Sénégal et en Afrique de l'Ouest

Coordinateur du projet Conseil national pour la Recherche en Santé (CNRS) (Dr Samba Cor Sarr)
Pays Sénégal
Budget € 50 000
Durée du projet décembre 2009-décembre 2012

Activités du programme commun

1 Recherche systématique de *Plasmodium falciparum* isolés

Coordinateur du projet Dr Benjamin Mordmüller
Institution Eberhard Karls Universität Tübingen, Allemagne
Maladie visée Paludisme
Partenaires Gabon, Allemagne et Pays-Bas
Budget € 299 918
Durée du projet mars 2009-mars 2012

2 Renforcement du soutien à la gestion des essais cliniques au Malawi

Coordinateur du projet Professeur Exnevia Gomo
Institution Faculté de Médecine de l'Université du Malawi, Malawi
Maladie visée VIH/SIDA (formation à la recherche)
Partenaires Autriche, Pays-Bas et Royaume-Uni
Budget € 299 241
Durée du projet avril 2009-avril 2012

Portuguese

Relatório Annual de
2009



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Emancipação

A participação africana em projectos financiados pela EDCTP no final de 2009 traduzia-se em 278 cientistas africanos, desde cientistas a meio da carreira até cientistas sénior, activamente envolvidos em projectos da EDCTP, quer como coordenadores de projecto quer como colaboradores. Além disso, a EDCTP atribuiu o Prémio de Cientista Africano Excepcional ao Dr. Alexis Nzila e ao Dr. Dominique Pepper. A cerimónia de atribuição dos prémios decorreu durante o Quinto Fórum EDCTP em Arusha, na Tanzânia, a 14 de Outubro de 2009. Estes prémios têm como objectivo motivar e capacitar os cientistas africanos para assumir a liderança científica e para estimular o desenvolvimento da capacidade de investigação na África subsariana.

2009 em resumo – por valores da EDCTP



Transparência

Em Julho de 2009, a EDCTP encarregou o Centro Suíço para a Saúde Internacional do Instituto Tropical da Suíça de levar a cabo uma avaliação interna do programa da EDCTP, desde a sua criação até 2009. O objectivo da avaliação era medir o progresso da EDCTP até ao final de 2009 e reunir opiniões sobre a direcção futura. Este relatório foi publicado e está disponível no site da EDCTP (www.edctp.org).

Confiança mútua

Vários consórcios financiados pela EDCTP foram formados através de uma colaboração genuína entre parceiros do Norte e do Sul, sendo de destacar o Consórcio Pan-Africano para a Avaliação de Antibióticos contra a Tuberculose (PanACEA). Este consórcio foi formado com o objectivo de realizar uma série de ensaios conjuntos para avaliar três medicamentos diferentes (Moxifloxacina, Rifampicina e SQ109) num programa de desenvolvimento de medicamentos. O consórcio reúne vários intervenientes para além da EDCTP, incluindo investigadores e financiadores de instituições públicas e privadas de África, Europa e EUA.

Parceria e trabalho em rede

Em 2009, a EDCTP assinou contratos para três Redes de Excelência Regionais (NoEs). Estas redes foram criadas com base no enquadramento económico regional africano e em instituições unidas que colaboram com base nas suas forças e aspectos complementares individuais. Quatro regiões da África subsariana dispõem agora de NoEs operacionais: A África Central tem CANTAM, a África Oriental tem EACCR, a África Austral tem TESA, e a África Ocidental tem WANETAM.

Responsabilidade

EDCTP incita os países africanos a assumir a responsabilidade e a posse no apoio à investigação, bem como a planear estratégias de sustentabilidade para estes programas de desenvolvimento e de investigação. Em Abril, o governo da Tanzânia dá um excelente exemplo neste sentido, ao anunciar um aumento do investimento público. Com esta medida, a Tanzânia torna-se o primeiro país africano com um elevado ónus da doença a aumentar significativamente os seus orçamentos para a investigação na saúde, após vários pedidos para tal acção. A EDCTP encoraja outros líderes africanos a seguir este exemplo.



Inovação

A 19 de Maio de 2009, a EDCTP organizou uma reunião de intervenientes sobre a optimização do tratamento contra o VIH e contra a co-infecção VIH/TB, que teve lugar no Centro Científico e Cultural de Macau, em Lisboa, Portugal. As reuniões de intervenientes com base em tópicos temáticos fazem parte das abordagens inovadoras da EDCTP, com vista a recolher informação actualizada e a reunir os demais parceiros antes lançar os convites à apresentação de propostas. A EDCTP lançou um pedido de apresentação de propostas para o tratamento do VIH e da co-infecção por VIH/TB em Dezembro de 2009, com € 5.000.000,00 de fundos disponíveis.

Melhores Práticas

Em Setembro, a Organização Mundial de Saúde (OMS) atribuiu ao Registo Pan-Africano de Ensaios Clínicos (PACTR), financiado pela EDCTP, o estatuto de registo principal. Isto faz do PACTR o primeiro registo de ensaios clínicos em África reconhecido pela OMS. Este registo fornecerá dados ao portal de pesquisa da Plataforma de Registo Internacional de Ensaios Clínicos da OMS (ICTRP), possibilitando a representação africana no quadro global dos ensaios clínicos previstos, em curso e já concluídos.

2

Mensagem do Director Executivo



2009 demonstrou ser mais um ano bem-sucedido e gratificante para a EDCTP. Ao longo do ano, a *Parceria* lançou 7 convites à apresentação de propostas, incluindo um novo tipo de bolsa para projectos Iniciados por Estados-membros europeus (MSI). A bolsa MSI encoraja os estados-membros a colaborar e a unir esforços com os seus homólogos africanos, de modo a submeterem propostas conjuntas, na sua maioria pré-financiadas pelos próprios estados-membros. 2009 assistiu igualmente ao lançamento de três das quatro redes de excelência regionais seleccionadas pela EDCTP para a realização de ensaios clínicos. As redes de excelência regionais uniram diferentes centros da África oriental, ocidental, austral e central para melhorar a capacidade e prontidão de ensaios clínicos em cada uma das regiões. As redes são constituídas por centros com diferentes níveis de desenvolvimento, mas que se complementam em termos de temas de doença, gestão



de projecto e dados, capacidades laboratoriais e outras áreas. Estas já demonstram ser um grande sucesso.

Outro destaque do ano foi o Quinto Fórum da EDCTP. Este evento, que se tornou a maior plataforma africana para a reunião de cientistas, decisores políticos, gestores de programa, financiadores e outros intervenientes a desenvolver trabalho no VIH/SIDA, tuberculose e malária, teve lugar em Arusha, na Tanzânia. O tema “*Combater o VIH/SIDA, a Tuberculose e a Malária – Um Mundo, Uma Parceria*” reflectiu-se claramente na forte participação que contou com 450 delegados de 49 países diferentes. Durante o fórum, tivemos a oportunidade de realizar 4 reuniões satélite e workshops principais, incluindo um workshop EDCTP/NACCAP sobre Propriedade de

Resultados de Investigação na África subsariana; Padrões Universais para os Ensaios Clínicos na Prática; reunião de financiadores da ESSENCE para explorar a sinergia; e uma Mesa Redonda das Comunidades Económicas Regionais sobre a representação Africana na Assembleia-geral da EDCTP-AEIE. No fórum, e pela primeira vez na sua história, a EDCTP atribuiu dois prémios em honra dos feitos de cientistas africanos a desenvolver trabalho nas doenças relacionadas com a pobreza. Estes prémios a cientistas de investigação sénior e júnior foram atribuídos ao Dr. Alexis Nzila, do Instituto de Investigação Médica do Quênia, Wellcome Trust Research Centre, e ao Dr. Dominique Pepper, do Instituto de Doenças Infecciosas e Medicina Molecular da Universidade da Cidade do Cabo, África do Sul, respectivamente.

Após a consolidação dos nossos esforços e pela primeira fase do programa estar a chegar ao fim, a EDCTP solicitou uma auto-avaliação para medir os feitos alcançados até à data e explorar formas de melhorar a realização do programa. A auto-avaliação, realizada por uma entidade independente, demonstrou que a EDCTP estava no bom caminho para concretizar a sua missão. Para além da auto-avaliação, a EDCTP levou também a cabo um processo consultivo exaustivo que terminou com uma reunião com todos os constituintes para discutir os planos e estratégia futura da EDCTP. Através deste processo, foi acordado alargar o campo de acção da EDCTP, de modo a incluir todas as fases dos ensaios clínicos (I-IV) e a investigação em saúde com o objectivo de otimizar as intervenções clínicas. No que diz respeito à governação, foi decidido ter quatro representantes africanos de alto nível na Assembleia-geral da EDCTP-AEIE, com efeitos imediatos. Estes representantes serão seleccionados a partir dos Ministérios Regionais africanos da Saúde, Comunidades Económicas Regionais, Comissão dos Assuntos Sociais da União Africana e os Ministérios Regionais africanos das Finanças ou da Ciência e Investigação. Foi também decidido que os constituintes da Rede Europeia de Programas Nacionais (REPN) passariam a fazer parte da Assembleia-geral, substituindo assim os Responsáveis de Rede Europeus (RRE) por Membros Suplentes da AG. Esta acção tem como objectivo garantir a aproximação das relações profissionais entre os programas nacionais europeus e a Assembleia-geral e dinamizar a governação.

Tudo isto contribuiu para um ano de 2009 satisfatório. Contudo, deve ser realçado que nenhum destes feitos seria possível sem a dedicação e o trabalho de todos os nossos intervenientes e parceiros. Assim sendo, apresento o meu sincero obrigado a todos aqueles que fizeram de 2009 um ano muito positivo para a EDCTP. Um agradecimento especial a todos os RRE que têm contribuído incansavelmente ao longo dos anos para a coordenação e integração dos programas nacionais. Aguardamos com expectativa 2010 e a transição para a segunda fase da EDCTP.

Charles S Mgone
Director Executivo

3

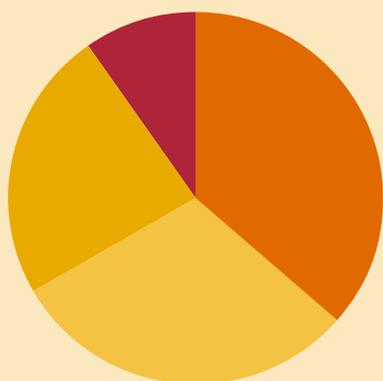
Financiamiento de Bolsas 2003-2009



A EDCTP financia a fase II e III de ensaios clínicos do VIH/SIDA, tuberculose e malária na África subsariana. As bolsas da EDCTP são usadas igualmente para reforçar a capacidade de realizar estes ensaios de acordo com os mais altos padrões e para facilitar o trabalho em rede. Os gráficos abaixo

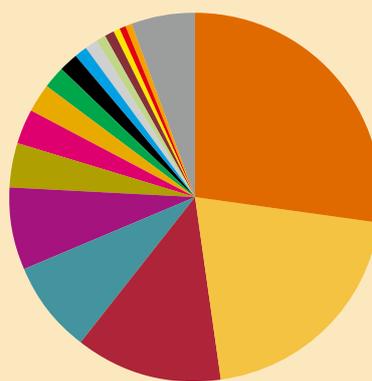
apresentam uma visão geral de como o financiamento da EDCTP tem sido distribuído entre as três doenças e entre as várias intervenções (dos medicamentos e vacinas às bolsas de ensaios não clínicos utilizadas para formação, reforço da ética e enquadramento regulamentar em África).

Financiamento EDCTP 2003 - 2009 por doença (€ 000)



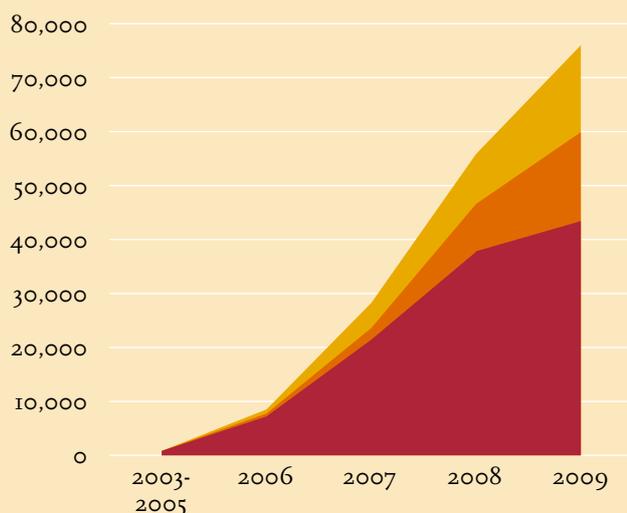
- VIH/SIDA € 54,244
- Tuberculose € 45,111
- Malária € 35,061
- Doenças não especificadas € 14,209

Financiamento de Terceiros às actividades da EDCTP 2003-2009 (€ 000)



- BMGF € 10,461
- Aliança Global contra a TB € 7,868
- Fundação Aeras Global para a Vacina contra a TB € 4,942
- RHRU € 3,164
- Sanofi Pasteur e Fundação EuroVacc € 2,800
- Parceria Internacional para os Microbicidas € 1,487
- Bayer AG € 1,200
- IAVI € 920
- SEQUELLA € 775
- ANRS € 600
- OMS € 469
- Sanofi Aventis € 376
- Rede Africana Contra a Malária (AMANET) € 335
- MRC-UVRI Uganda € 284
- Wellcome Trust € 264
- UVRI € 249
- MMV € 201
- Outros € 2175

Total de co-financiamento elegível dos Estados-membros no âmbito do programa comum da EDCTP para projectos financiados pela EDCTP de acordo com o tipo de contribuição (2003-2009) (€ 000)



- Co-financiamento em numerário
- Co-financiamento em numerário directo
- Co-financiamento em espécie

3.2 Contratos de bolsa assinados em 2009

Projectos integrados

1 Novos biomarcadores para medir a segurança dos microbicidas

Coordenador do Projecto Dr. Kishor Mandaliya
Instituição Centro Internacional para a Saúde Reprodutiva (ICRH-K) - Quênia
Doença-alvo VIH/SIDA (microbicidas)
Parceiros Bélgica, Quênia, Países Baixos, Ruanda, África do Sul, Tanzânia, Reino Unido e EUA
Orçamento € 3.994.112,00
 (€ 2.688.595,00 EDCTP)
Duração do projecto Abril 2009-Abril 2012

2 Reforço de capacidades no ensaio de vacinas contra o VIH na Tanzânia e Moçambique através de um conceito de vacina de ADN e MVA desenvolvido com novas tecnologias

Coordenador do Projecto Prof. Eligius Lyamuya
Instituição Universidade Muhimbili, Faculdade de Ciências da Saúde, Tanzânia
Doença-alvo VIH/SIDA (vacinas)
Parceiros Alemanha, Moçambique, Suécia, Tanzânia e Reino Unido
Orçamento € 6.367.429,00
 (€ 5.521.889,00 EDCTP)
Duração do projecto Novembro 2009-Junho 2014

3 Essai clinique international aléatoire de phase III destiné à étudier deux stratégies simplifiées d'entretien une fois par jour après une thérapie antirétrovirale initiale sur des bébés contaminés par le VIH en Afrique (MONOD)

Coordenador do Projecto Dra. Valériane Leroy
Instituição Inserm U897/Université Bordeaux 2/ ISPED, França
Doença-alvo VIH/SIDA
Parceiros Bélgica, Burquina Faso, Costa do Marfim, França, Luxemburgo e Ruanda
Orçamento € 3.442.969,00
 (€ 1.640.862,00 EDCTP)
Duração do projecto Dezembro 2009-Agosto 2013

4 Opções de avaliação da terapia de segunda linha em pacientes que rejeitam os regimes de primeira linha 2NRTI + NNRTI em África (EARNEST)

Coordenador do Projecto Prof. Peter Mugenyi
Instituição Centro de Investigação Clínica Conjunta, Uganda
Doença-alvo VIH/SIDA
Parceiros Bélgica, Irlanda, Itália, Malávi, Espanha, Uganda, Países Baixos, Reino Unido e Zimbabué
Orçamento € 4.872.368,00
 (€ 4.352.914,00 EDCTP)
Duração do projecto Setembro 2009-Setembro 2013

5 Desenvolver a capacidade de investigação e de trabalho em rede através da avaliação de duas estratégias de tratamento antiretroviral de segunda linha contra o VIH na África subsariana

Coordenador do Projecto Prof. Eric Delaporte
Instituição Université de Montpellier et Institut de Recherche pour le Développement (IRD), França
Doença-alvo VIH/SIDA
Parceiros Bélgica, França, Alemanha, Senegal, África do Sul, Suíça e Tanzânia
Orçamento € 4.040.244,00 (€ 2.007.885,00 EDCTP)
Duração do projecto Setembro 2009-Julho 2013

6 Crianças com VIH em África, Farmacocinética e Aceitabilidade/Cumprimento de Regimes Antiretrovirais Simples (CHAPAS-3)

Coordenador do Projecto	Dra. Veronica Mulenga
Instituição	Hospital Universitário, Lusaca, Zâmbia
Doença-alvo	VIH/SIDA
Parceiros	Irlanda, Itália, Países Baixos, África do Sul, Espanha, Uganda, Reino Unido e Zâmbia
Orçamento	€ 5.003.849,00 (€ 4.617.034,00 EDCTP)
Duração do projecto	Novembro 2009-Julho 2013

7 Apoiar a capacidade de investigação, trabalho em rede e gestão de projecto através da fase I–IIB de ensaios clínicos da vacina candidata contra a malária, a GMZ2

Coordenador do Projecto	Dr. Ramadhani Noor
Instituição	Rede Africana Contra a Malária, Tanzânia
Doença-alvo	Malária (vacinas)
Parceiros	Burquina Faso, Dinamarca, Gabão, Gâmbia, Quênia, Tanzânia, Uganda e Reino Unido
Orçamento	€ 9.863.901,00 (€ 5.140.147,00 EDCTP)
Duração do projecto	Janeiro 2009-Janeiro 2014

8 Consórcio de Vacinas de Vectores contra a Malária (MVVC)

Coordenador do Projecto	Dr. Egeruan Babatunde Imoukhuede
Instituição	Iniciativa Europeia da Vacina, Alemanha
Doença-alvo	Malária (vacinas)
Parceiros	Áustria, Burquina Faso, Gâmbia, Itália, Quênia, Reino Unido e Senegal
Orçamento	€ 9.543.310,00 (€ 7.882.536,00 EDCTP)
Duração do projecto	Dezembro 2009-Dezembro 2013

9 Tratamento antimalárico para as mulheres grávidas africanas

Coordenador do Projecto	Prof. Umberto D'Alessandro
Instituição	Instituto de Medicina Tropical, Bélgica
Doença-alvo	Malária (na gravidez)
Parceiros	Áustria, Burquina Faso, Gana, Malávi, Países Baixos, Ruanda, Reino Unido, Tanzânia e Zâmbia
Orçamento	€ 5.993.753,00 (€ 3.708.775,00 EDCTP)
Duração do projecto	Fevereiro 2009-Maio 2013

10 Rede da África Ocidental para Ensaios Clínicos de Medicamentos Antimaláricos (WANCAM)

Coordenador do Projecto	Dr. Abdoulaye Djimde
Instituição	Universidade de Bamaco, Mali
Doença-alvo	Malária
Parceiros	Burquina Faso, França, Alemanha, Guiné, Mali Países Baixos, e Reino Unido
Orçamento	€ 5.359.268,00 (€ 4.699.208,00 EDCTP)
Duração do projecto	Setembro 2009-Março 2013

11 Avaliação das interações farmacocinéticas entre ACT e antiretrovirais e estratégias de doseamento com base na idade para ACT

Coordenador do Projecto	Dr. Victor Mwapasa
Instituição	Wellcome Trust Malávi-Liverpool, Malávi
Doença-alvo	Malária
Parceiros	Áustria, Bélgica, Malávi, Moçambique, Espanha, Reino Unido e Zâmbia
Orçamento	€ 5.082.545,00 (€ 3.863.808,00 EDCTP)
Duração do projecto	Julho 2009-Julho 2014

12 Realização da fase II de ensaios de vacinas contra a TB do nível ICH-BPC em populações de alto risco em África

Coordenador do Projecto Dr. Mark Doherty
Instituição Statens Serum Institut, Dinamarca
Doença-alvo Tuberculose (vacinas)
Parceiros Dinamarca, Etiópia, Guiné-Bissau e Países Baixos
Orçamento € 8.411.556,00
 (€ 4.164.136,00 EDCTP)
Duração do projecto Março 2009-Março 2014

13 Fase IIb de um ensaio de eficácia para avaliar a eficácia preventiva da vacina potenciadora MVA85A administrada a adultos saudáveis infectados com VIH na África do Sul, Senegal e Gâmbia

Coordenador do Projecto Dr. Martin Ota
Instituição Conselho de Investigação Médica, Gâmbia
Doença-alvo Tuberculose (vacinas)
Parceiros Bélgica, Senegal, África do Sul e Reino Unido
Orçamento € 13.177.720,00
 (€ 9.473.720,00 EDCTP)
Duração do projecto Agosto 2009-Agosto 2014

14 Uma nova vacina contra a TB para as crianças africanas

Coordenador do Projecto Prof. Gregory Hussey
Instituição Universidade da Cidade do Cabo, África do Sul
Doença-alvo Tuberculose (vacinas)
Parceiros Áustria, Países Baixos, Espanha, Suíça, Quênia, Moçambique, África do Sul, Suécia, Uganda e EUA
Orçamento € 7.706.813,00
 (€ 3.411.368,00 EDCTP)
Duração do projecto Maio 2009-Agosto 2014

15 Avaliação Rápida da Moxifloxacina na Tuberculose (PanACEA – REMoxTB)

Coordenador do Projecto Prof. Stephen Gillespie
Instituição University College London, Reino Unido
Doença-alvo Tuberculose
Parceiros Quênia, África do Sul, Tanzânia, Reino Unido e Zâmbia
Orçamento € 7.382.511,00
 (€ 5.913.631,00 EDCTP)
Duração do projecto Setembro 2009-Fevereiro 2014

16 Estudos clínicos com doses elevadas de rifampicina e desenvolvimento da capacidade de investigação clínica em África (PanACEA – HIGHRIF)

Coordenador do Projecto Dr. Martin Boeree
Instituição Universidade de Radboud, Nijmegen, Países Baixos
Doença-alvo Tuberculose
Parceiros Países Baixos, África do Sul, Suíça, Tanzânia, Uganda e Reino Unido
Orçamento € 4.640.849,00
 (€ 3.122.842,00 EDCTP)
Duração do projecto Junho 2009-Dezembro 2013

17 Avaliação de uma nova droga contra a TB (SQ109) para reduzir e simplificar o tratamento da TB (PanACEA–SQ109)

Coordenador do Projecto Dr. Michael Hoelscher
Instituição Departamento de Doenças Infecciosas e Medicina Tropical, Hospital Universitário de Munique (LMU), Alemanha
Doença-alvo Tuberculose
Parceiros Gabão, Alemanha, África do Sul, Tanzânia, Países Baixos, Reino Unido, EUA e Zâmbia
Orçamento € 6.012.526,00
 (€ 1.136.761,00 EDCTP)
Duração do projecto Junho 2009-Junho 2014

Bolsas de Estudo para Quadros Superiores

1 Avaliação da resistência aos medicamentos antiretrovirais em crianças infectadas com VIH em África

Coordenador do Dra. Cissy Kityo

Projecto

Doença-alvo VIH/SIDA

Parceiros Centro de Investigação Clínica Conjunta, Uganda, e Conselho de Investigação Médica, Reino Unido

Orçamento € 196.900,00

Duração do projecto Novembro 2009-Novembro 2011

2 O efeito da co-infecção por VIH na resposta imune à *Mycobacterium tuberculosis* no pulmão

Coordenador do Dra. Wendy Burgers

Projecto

Doença-alvo Tuberculose

Parceiros Universidade da Cidade do Cabo, África do Sul, Universidade de Stellenbosch, África do Sul, e Centro de Investigação Borstel, Alemanha

Orçamento € 199.980,00

Duração do projecto Outubro 2009-Outubro 2011

3 Síndrome Inflamatória de Reconstituição Imune (SIRI) em doentes com esquistossomíase submetidos à terapêutica HAART

Coordenador do Dra. Pauline Mwinzi

Projecto

Doença-alvo Tuberculose

Parceiros Instituto de Investigação Médica do Quênia (KEMRI), Quênia, e o Instituto de Medicina Tropical Príncipe Leopoldo, Bélgica

Orçamento € 185.669,00

Duração do projecto Novembro 2009-Novembro 2011

4 Um ensaio controlado aleatório da terapia de ferro oral para o tratamento da anemia por deficiência de ferro pós-malária das crianças do Malávi comparando o tratamento imediato após a alta com o tratamento retardado do consumo de ferro e resposta hematológica

Coordenador do Dr. Kamija Phiri

Projecto

Doença-alvo Malária

Parceiros Wellcome Trust Research Programme Malávi-Liverpool, Malávi, Centro Médico Universitário de Groningen, Países Baixos e Universidade de Liverpool, Reino Unido

Orçamento € 199.145,00

Duração do projecto Setembro 2009-Setembro 2011

Redes de Excelência

1 Rede de Excelência da África oriental para a Investigação e Prática Clínicas (EACCR)

Coordenador do Dr. Pontiano Kaleebu

Projecto

Instituição Instituto de Investigação de Vírus do Uganda (UVRI), Uganda

Parceiros Etiópia, Alemanha, Quênia, Países Baixos, Noruega, Sudão, Suécia, Tanzânia, Uganda Reino Unido e EUA

Orçamento € 3.499.200,00
(€ 2.499.200,00 EDCTP)

Duração do projecto Maio 2009-Maio 2012

2 Reforço de capacidades para preparar os locais da África Ocidental para ensaios clínicos do VIH/SIDA, TB e Malária

Coordenador do Prof. Soleymane Mboup

Projecto

Instituição Université Cheikh Anta DIOP de Dakar (UCAD), Senegal

Parceiros Burquina Faso, France, Gâmbia, Gana, Guiné-Bissau, Mali, Nigéria, Senegal, Reino Unido e EUA

Orçamento € 3.499.921,00
(€ 2.499.921,00 EDCTP)

Duração do projecto Julho 2009-Maio 2012

3 Ensaios de Excelência na África Austral (TESA)

Coordenador do Dr. Alexander Pym

Projecto

Instituição Conselho de Investigação Médica da África do Sul (MRC), África do Sul

Parceiros Botswana, França, Alemanha, Malávi, Moçambique, Países Baixos, África do Sul, Reino Unido, Zâmbia e Zimbabué

Orçamento € 2.640.548,00
(€ 2.337.304,00 EDCTP)

Duração do projecto Novembro 2009-Novembro 2011

Reforço Ético e Regulamentar

1 Reforçar a capacidade das Comissões Éticas de investigação africanas para a revisão ética da investigação na prevenção do VIH

Coordenador do Universidade de KwaZulu-Natal

Projecto (Prof. Douglas Wassenaar)

País África do Sul

Orçamento € 49.935,00

Duração do projecto Novembro 2009-Novembro 2012

2 O projecto Mzadi : reforçar a capacidade ética de investigação na República do Congo e na República Democrática do Congo

Coordenador do Centre Interdisciplinaire de

Projecto Bioéthique pour L'Afrique Francophone (CIBAF) (Dr. Bavon Mupenda)

País República Democrática do Congo

Orçamento € 40.800,00

Duração do projecto Dezembro 2009-Dezembro 2012

3 Criação de uma comissão ética nacional de investigação e reforço dos recém-criados CRI/CEN no Gana

Coordenador do Universidade do Gana (Dr. Okyere

Projecto Boateng)

País Gana

Orçamento € 49.808,00

Duração do projecto Dezembro 2009-Dezembro 2012

4 Reforço de capacidades para a revisão ética e monitorização de projectos aprovados no Instituto de Investigação Médica do Quénia

Coordenador do Instituto de Investigação Médica do

Projecto Quénia (KEMRI) (Dra Christine Wasunna)

País Quénia

Orçamento € 49.500,00

Duração do projecto Dezembro 2009-Dezembro 2012

5 Programa para o reforço da Comissão Ética Nacional de Investigação do Senegal (CNRS) e promoção da consciência ética no Senegal e na África Ocidental

Coordenador do Conseil National pour la Recherche en

Projecto Sante (CNRS) (Dr. Samba Cor Sarr)

País Senegal

Orçamento € 50.000,00

Duração do projecto Dezembro 2009-Dezembro 2012

Actividades do Programa Comum

1 Investigação sistemática de isolados clínicos de *Plasmodium falciparum*

Coordenador do Dr. Benjamin Mordmüller

Projecto

Instituição Universidade Eberhard Karls, Tübingen, Alemanha

Doença-alvo Malária

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