

Note from the EDCTP Executive Director

I take this opportunity to extend our sincere thanks to all of you who over the past decade including the previous year have helped in making EDCTP the great success that it now is. Special thanks to the research participants who have been involved in EDCTP-funded research. Without their willingness to volunteer as research subjects none of the progress that has been made in improving clinical interventions would have been made. We also give thanks to all who have served in various capacities as scientific and strategic reviewers, advisors or policymakers. We thank Prof. Hannah Akuffo, the outgoing EDCTP General Assembly Chair for her leadership and commitment, and welcome Dr Mark Palmer, the new Chair.

As we welcome the New Year, we also look forward to a new era of EDCTP with the launch of the

second programme also known as EDCTP2. As you are all aware EDCTP2 is more ambitious in comparison to the previous programme. It is extended to cover all phases of clinical trials and includes neglected infectious diseases. Furthermore, it has also been agreed to change the legal entity of the Implementation Structure from a European Economic Interest Group (EEIG) to an Association under the Dutch law. This will open up membership to all European countries associated with Horizon 2020 as well as all sub-Saharan African countries, as long as they meet and fulfil membership requirements. Plans are underway to bring this giant step into force.

The EDCTP2 programme is expected to start with the launch of calls for proposals in the second quarter of 2014. These will be part of the 2014-2015 work plans that will include calls



Charles S. Mgone

on diagnostics, treatment and various capacity development activities. They will comprise integrated activities; participating states initiated activities; and joint activities with third parties.

I wish you all a happy and prosperous 2014.

Towards EDCTP2

Second High-Level Meeting on EDCTP2

A Second High-Level Meeting on EDCTP2 took place in Dakar, Senegal on 21 October 2013. The meeting was hosted by the Ministry of Health of Senegal, the European Commission and EDCTP. It followed up on the first High-Level Conference in Cape Town, South Africa on 5 November 2012. High-level representatives from African countries, delegates from European EDCTP member countries and other current or potential partners participated to reaffirm their commitment to EDCTP2. The objective of the meeting was to discuss ways of active and direct involvement of African partner countries in the EDCTP programme and governance.

The meeting was attended by government ministers and their delegations from the Republic of Congo, Senegal, South Africa, The Gambia, Uganda, and Zambia, while other countries were represented by senior officials: Cameroon, Burkina Faso, Gabon, Kenya, Mali, Mozambique, Niger, and Tanzania. Some governments sent their regrets about being unable to attend at ministerial level or send representatives: Angola, Ethiopia, Ghana, Malawi and Nigeria. This high-level representation was a clear indication of the continued commitment of African governments to EDCTP. The European Commission as well as the African Union

Commission of Social Affairs, the New African Partnership for Economic Development (NEPAD) and the World Health Organization Regional Office for Africa (WHO-AFRO) had high-level representation. The EDCTP General Assembly was represented by the Chair, the representative of Denmark and the High Representative.

At the meeting, representatives of the governments of South Africa, Tanzania, Uganda and Senegal indicated preference to join EDCTP as individual countries, while others favoured regional and sub-regional representation. As not all 48 African countries can send a representative, the challenge of

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finding a way of representing the interests of the countries not directly involved in the General Assembly was recognised. National and sub-regional representations were not considered to be mutually exclusive concepts. While there were different views on the mechanism of representation, the strong willingness of African countries to be represented on the EDCTP General Assembly was abundantly clear.

The report of the meeting has been published on the EDCTP website (www.edctp.org).

Towards EDCTP2 (continued from page 1)

Stakeholder meetings 2013 completed



The planned stakeholder meetings in preparation for the second EDCTP programme were successfully completed in 2013. Meetings on neglected infectious diseases (The Hague), HIV/AIDS (Lisbon), malaria (Vienna), tuberculosis and other mycobacterial infections (Paris), as well as meetings

on health research ethics review and regulatory affairs (Antwerp) brought together experts from research institutions, policymaker and representatives of product development partnerships, pharmaceutical industry and international organisations.

Some of the reports and presentations of the meetings have been published on the EDCTP website (www.edctp.org) and others will be published early 2014.

The remaining stakeholder meeting on capacity building will be held on 3 July 2014 in Berlin.

EDCTP Awards 2013

Every two years EDCTP confers its awards for scientific excellence to African scientists. In November 2013, Dr Glenda Gray (University of Witwatersrand and Medical Research Council, South Africa) received the Outstanding African Scientist Award. Dr Graeme Meintjes (University of Cape Town, South Africa) was recognised with the Rising Star African Scientist Award. The awards consisted of a recognition trophy and a cash prize of 20,000 and 10,000 Euro respectively. The awards aim to further the research programmes of the winners. The award ceremony took place at the EDCTP Africa Office in Cape Town, South Africa.

Dr Glenda Gray is one of the world's foremost authorities on the HIV epidemic in sub-Saharan Africa. Her work on the epidemiology and biology of HIV as well as advocacy for improving the care of HIV-infected individuals are well recognised. She is also the recipient of the Nelson Mandela for Health and Human Rights Award for her instrumental work in reducing mother-to-child transmission of HIV-1. Dr Gray is the

founding Executive Director of the Perinatal HIV Research Unit in Cape Town, South Africa. She aims to use the prize to support two PhD projects led by young women scientists: "By supporting cutting edge research and early stage investigators, I am committed to developing African scientists of the future".

Dr Graeme Meintjes is an Associate Professor of Medicine and an Adult Infectious

Calls and Grants

Master's Fellowship in Epidemiology and Medical Statistics

The EDCTP Master's Fellowship in Epidemiology and Medical Statistics aims to build research capacity in sub-Saharan Africa by supporting the training and career development of junior researchers in the fields of epidemiology and medical statistics. Reliable data on the burden of diseases (HIV, tuberculosis, malaria, and neglected infectious diseases) and their epidemiological trends are essential for clinical research.

The scheme provides funds for the fellow to undertake a taught master's course in epidemiology or medical statistics at an internationally recognised centre of excellence and to conduct a field study of 6-12 months duration at an institution in sub-Saharan Africa to build practical skills. The maximum duration of the fellowship is two years.

The call for applications (MF.2013.40205) is funded by Sweden and the United Kingdom (EDCTP participating countries) and was open from August till November 2013. Fifty-two (52) eligible applications were received. Funding decisions for 5-10 awards will be finalised in March 2014.



Dr Glenda Gray, Dr Michael Makanga and Dr Graeme Meintjes at the EDCTP Awards ceremony in Cape Town, South Africa

Diseases physician based at the University of Cape Town (UCT). He was a Wellcome Trust Training Fellow from 2007 until 2011 and was awarded a 5-year Wellcome Trust Intermediate Fellowship in Public Health and Tropical Medicine in 2012. He jointly established and ran the

Infectious Diseases Unit at GF Jooste Hospital in Cape Town from 2004. In 2012 he became a full member of the Institute of Infectious Disease and Molecular Medicine at UCT. Dr Meintjes plans to continue developing his research on HIV-TB co-infection and other issues related to TB treatment.

EDCTP Governance

New staff

EDCTP welcomed several new staff members. Mariska Louw and Michelle Nderu joined the EDCTP Africa Office in Cape Town as Senior Administrative Officer and Project Officer respectively. **Mariska Louw** worked for many years at the Medical Research Council of South Africa. She is responsible for administrative duties at the Africa Office. **Michelle Nderu** has a Master of Science degree in Medicine and has pharmaceutical, research laboratory and research management experience.

In The Hague we welcomed **Lara Pandya** as North-North Networking Officer. Previously she worked at EDCTP as Project Officer and then at the International AIDS Vaccine Initiative (IAVI) and the Amsterdam Institute for Global Health and Development,

before moving back to EDCTP. **Lidwien van der Valk**, long-standing legal advisor to EDCTP, joined EDCTP full-time as Legal Officer. Moreover, two staff members employed on short term basis, **Christy Comeaux** and **Charlotte Hoekstra**, assumed administrative tasks in project document management.

Dr Ole F. Olesen joined EDCTP in September 2013 as **Director of North-North Cooperation**. He studied at the universities of Aarhus (Denmark) and Cambridge (United Kingdom) as well as at the Copenhagen Business School. Dr Olesen holds a Masters and PhD degree in Molecular Biology and an HD degree in international economics. Dr Olesen worked in the pharmaceutical industry for 10 years and has considerable experience in managing large international



Dr Ole F. Olesen

projects in pharmaceutical product development. He also worked as assistant professor in pharmacology at Copenhagen University. Before joining EDCTP, Dr Olesen was Principal Scientific Officer for Global Health at the European Commission's Directorate-General for Research & Innovation, where he was responsible for research in neglected infectious diseases and vaccine research activities.

Meetings of Interim Strategic Advisory Committee and General Assembly

The interim Strategic Advisory Committee convened on 10-11 October. The discussion focussed on the work plans for 2014-2015 of the member states and EDCTP in order to prepare for the start of EDCTP2. The General Assembly (GA) met on 7-8 November 2013 and continued its deliberations with the European Commission on the governance structure of EDCTP2 and the various funding mechanisms. The GA elected Dr Mark Palmer (United Kingdom) as the new Chairperson. He will take over from Prof. Hanna Akuffo (Sweden) on 1 January 2014. Moreover, two new Vice-Chairpersons were elected: Dr Detlef Böcking (Germany) and Prof. Stefano Vella (Italy).

EDCTP Plus

Evaluation of EDCTP Ethics grants programme

In 2013, EDCTP commissioned a comprehensive evaluation of the EDCTP 'Ethics' grants programme for strengthening research ethics review in sub-Saharan Africa. All 75 EDCTP funded ethics projects were analysed.

The desktop review covered all 75 projects and included analysis of project proposals, profiles, and annual reports. Visits were made to Botswana, Cameroon, Ethiopia, Nigeria and South Africa, and included face-to-face interviews with 15 grantees. Seventeen (17) key informants from 17 funded projects across sub-Saharan Africa were interviewed by telephone. Self-administered surveys were distributed to beneficiaries using an internet-based system. The training quality survey was completed by 200 beneficiaries. The assessment on the functionality of ethics committees was completed by 18 ethics committees.

The evaluation focused on each EDCTP funding area: a) mapping of ethics review and trial regulatory capacity in sub-Saharan Africa (MARC); b) establishment and strengthening of National Ethics Committees (NECs) and Institutional Review Boards (IRBs); c) research ethics review training activities (including the development of online training programmes).

The MARC project achieved its proposed objectives, went above and beyond the call and can be considered a great success. MARC mapped 166 IRBs in 34 African countries and developed professional social network and discussion function

on the MARC website (www.healthresearchweb.org). Additionally, MARC Phase 1 developed an online information management system (RHinnO Ethics software). This resource aims to provide IRBs and medicines regulatory authorities with a secure, fully web-based solution for submitting, managing and tracking the process of research applications.

The main purpose of the IRB and NEC related projects was to enable them to be functional through support for office infrastructure development, training, development of Standard Operating Procedures (SOPs) and improved quality of protocol review. Funding enabled ethics committees to address the considerable challenges faced. However, limited human resources are

still a threat to the sustainability of NECs and IRBs. Online ethics training activities were the most used and convenient form of training. It provided value for money and reached the highest number of beneficiaries. The data shows a high level of efficacy in NECs and IRBs and supports the conclusion that ethics has made a solid entrance into research ethics in Africa.

(Based on the report summary by Creative Consulting & Development Works, Cape Town, South Africa.)

Focus on Projects

Joint Programme Activities call: all projects completed

In 2013 all projects from the Joint Programme Activities call published in 2008 and 2009 were completed. The call resulted in four projects with a total grant value of €1,095,154. The aim was to identify and strengthen joint programme activities and contribute to the integration of the clinical trial efforts within the remit of EDCTP of the European participating countries. It also sought to reduce duplication and improve collaboration within or among African institutions and research centres.

Strengthening capacity at the College of Medicine, Malawi

The project to develop clinical trial management and infrastructure at the College of Medicine in Malawi, led by Dr Gertrude Kalanda (University of Malawi) resulted in the establishment of the Clinical Trials Unit at the Research Support Centre (RSC-CTU). The project improved clinical trial management capacity through training in: Foundations in Clinical Research, Project Management, Good Clinical Laboratory Practices, Trial Site Management and Standard Operating Procedures. Generic courses in clinical research through mentorship and train-the-trainer courses were developed. These courses transmitted expertise from the Liverpool School of Tropical of Medicine and the former Vienna School of Clinical Research which mentored the RSC-CTU team, provided the required training, and permitted the RSC to benefit from wide networks with other African partners. Using the skills

gained by the clinical trial management team, RSC now offers courses in Basic Good Clinical Practice (GCP) and Advanced GCP.

Quality control systems related to *P. falciparum* culture

This project led by Dr Benjamin Mordmüller (Institute of Tropical Medicine, University of Tübingen, Germany) was a joint programme of Gabon, Germany and the Netherlands to implement and standardise *in vitro* culture of clinical *Plasmodium falciparum* isolates at two research centres in Gabon. It enabled two sites in Gabon to perform continuous cell culture of *P. falciparum*.

The Medical Research Laboratory of the Albert Schweitzer Hospital is one of the few institutions in Central Africa with international visibility in clinical research on malaria and other infectious diseases. However, important laboratory services had to be outsourced to Northern partners.

The outcome of the project was a shift towards performance of laboratory studies on site and the inclusion of a less developed centre in Fougamou for studies on parasite biology and growth properties. Additionally, contact was established with other research networks and regional institutions.

TB diagnostic and prognostic tools

Dr Thomas Schön (Kalmar County Hospital, Sweden) led a project that focused on improving tools for clinical diagnosis, prognosis and follow-up of patients with tuberculosis (TB) for potential use in highly endemic areas. A clinical scoring model was validated in both Ethiopia and Guinea Bissau in an effort to refine the scoring system which could aid triaging in the early weeks of treatment. TB cultures from retreatment cases were tested for susceptibility to second-line drugs by a novel strategy of simultaneously testing 8-10 TB-drugs with a good correlation to standard methods. Chest x-rays including follow-up and clinical outcome data have been collected from 400 TB patients and are evaluated with a new grading system.

The first randomised clinical trial on deworming in tuberculosis

patients showed that infection by intestinal worms (helminths) suppresses an adequate immune response against TB which could be reversed by deworming. This project has led to capacity building and continued collaboration between Denmark, Sweden, Ethiopia and Guinea Bissau.

Training and IT infrastructures

The aim of the project led by Professor Anders Sönnerborg (Karolinska Institute, Sweden) was to strengthen the capacities of the African partners to conduct genotypic HIV-drug resistance testing (GRT), analyse viral sequences from African patients, and to retrain the EuResist predictive system on African data.

African trainees were educated in GRT, database management, IT-tools and statistics in three workshops. A strategy, "the split procedure", was developed and evaluated in which all steps of GRT, except sequencing, were performed locally. Sequences were generated from patients at baseline and therapy failure. Only limited transmitted drug resistance was identified while failing patients showed in general the expected pattern of mutations. More sequences are aimed at in order to allow reliable retraining of the EuResist predictive engine.

EDCTP Forum

Rescheduled Seventh EDCTP Forum

Following the EDCTP General Assembly's approval, the Seventh EDCTP Forum has been rescheduled to take place in Berlin, Germany from 30 June to 2 July 2014. The Forum will be hosted by the German Federal Ministry of Education and Research. The theme for the Forum remains 'The Partnership journey: new horizon for better health'. The three-day Forum will be

followed by the one-day EDCTP Stakeholder meeting on Capacity Building.

The Seventh Forum in Berlin expects to accommodate a maximum of 300 participants. Participation at the Forum will be by invitation only. The Forum programme will consist mainly of oral presentations of results by researchers involved in EDCTP-funded projects.

Because of limited capacity, the Forum in Berlin will not include poster presentations.

Initially, the Seventh EDCTP Forum was planned to take place in Dakar, Senegal from 21-24 October 2013. The event was cancelled due to unforeseen circumstances that had led the Senegalese government to host the Heads of State summit of ECOWAS

(Economic Community of West African States) on the same dates at the King Fahd Palace Hotel in Dakar, the venue that was meant for the EDCTP Forum.

More information about the Seventh EDCTP Forum in Berlin will be available at www.edctpforum.org from January 2014.

Focus on Networks of Excellence

Laboratory accreditation process

EDCTP initiated a laboratory strengthening programme for selected laboratories within its four regional Networks of Excellence (TESA, WANETAM, CANTAM and EACCR). The project is funded as part of the Coordination and Support Action grant received from the European Commission. The project targets the systematic

development of 26 clinical research and public health laboratories involved in EDCTP-funded studies towards internationally-recognised accreditation.

To achieve this, the WHO-AFRO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) is used.

This accreditation process provides a framework to establish an effective quality management system for medical laboratory testing.

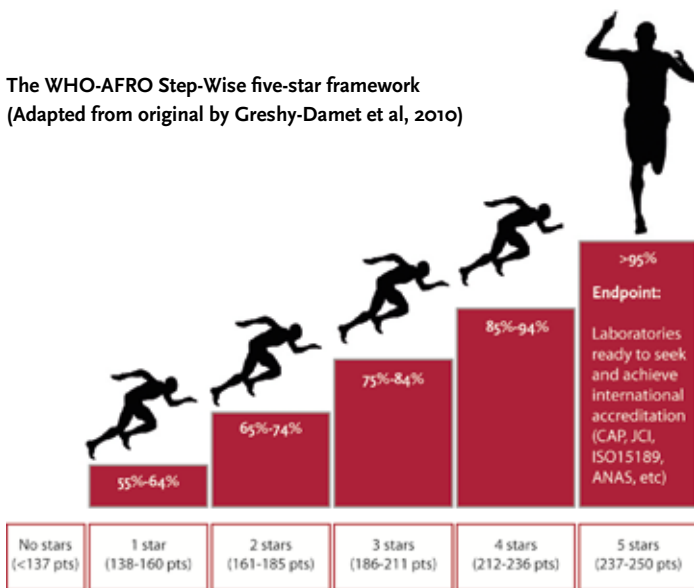
Following assessment, laboratories are recognised on a 0 to 5-star scale (Greshy-Damet et al., 2010).

Under the second phase of the project, 26 NoE laboratories located in 19 African countries were audited for their initial, baseline quality management systems and general laboratory capacity by LQT Consulting, a company based in Senegal. This audit established the baseline level for 26 laboratories on the SLIPTA scale: 13 at 0-star; 4 at 1-star; 1 at 2-stars; 6 at 3-stars; 1 at 4-stars and 1 at 5-stars. All laboratories are now aware of non-compliance gaps and the steps required improving their overall quality, management and performance.

The baseline audit provided the gap analysis and corroborated the importance of sustaining continuous activity at the laboratories and continuous employment for laboratory personnel in order to develop and maintain internal quality standards.

The next phase of this EDCTP initiative will be conducted by the African Society for Laboratory Medicine (Ethiopia) and Quintiles Africa (South Africa), both firms with significant expertise in strengthening laboratories in the sub-Saharan African region. Between January 2014 and December 2014, they will re-audit all 26 laboratories, address all non-compliance gaps and prepare each laboratory for accreditation through implementation of mentorship programmes, training schemes and internal quality assessments.

The WHO-AFRO Step-Wise five-star framework
(Adapted from original by Greshy-Damet et al, 2010)



European-African partnership meetings for NoEs

In preparation of EDCTP2 the Networks of Excellence prepared two European and African partnership meetings in order to collaboratively initiate the establishment of health research and capacity building priorities for the Networks of Excellence under EDCTP2.

The Central African NoE CANTAM and the West-African NoE WANETAM co-organised a meeting in Dakar, Senegal on 24-25 June 2013. The meeting was attended by 55 delegates from partner research institutions of the two NoE, African government representatives, EDCTP Secretariat, other networks and delegates from France and UK. An important

objective was to identify opportunities to better integrate EDCTP activities in the sub-Saharan francophone

countries and existing networks. The conclusion of the meeting was an agreement by

WANETAM, CANTAM and their partners on the priority areas of research to pursue under EDCTP2.



Participants of the NoE meeting in Dakar, Senegal

European-African partnership meetings for NoEs (continued from page 5)

The second meeting was organised by the Southern African NoE (TESA) and the East African NoE (EACCR) which was hosted by the Ministry of Science and Technology of South Africa and took place in Johannesburg,

South Africa on 18-19 July 2013. Like the first meeting, it was attended by the European research partners (France, Sweden and UK) as well as policymakers from various African and European countries and organisations. The

strategic objective of the meeting was to define concrete common research and capacity development plans for clinical trials and closely linked health research of Eastern and Southern Africa under EDCTP2 in partnership with the East

African Community (EAC), the Southern African Development Community (SADC) and their European partners. Agreement on research and capacity building priorities was achieved for the different diseases and interventions.



Participants of the NoE meeting in Johannesburg, South Africa

Meetings

EDCTP visits to Malawi and Mozambique

EDCTP country visits are focussed on countries where substantial financial investments have been made. After Botswana, Gabon, Senegal, Tanzania and Zimbabwe (2012) and Kenya (2013), EDCTP teams visited Malawi and Mozambique. The objectives of the visits are to establish personal contacts and dialogue with the teams implementing the funded projects. They involve also assessments of technical progress and financial controls.

In **Malawi**, a team comprised of Mr Abdoulie Barry, Director of Finance and Administration, Dr Thomas Nyirenda, South-South Networking and Capacity Development Manager, and Dr Montserrat Blázquez-Domingo, Project Officer, conducted a visit from 3-7 June 2013. Clinical trial research centres and field sites of nine on-going projects in Blantyre and Zomba were visited, including the MiP trials (malaria in pregnancy), the EARNEST-trial (Eastern and Southern Africa Research Network for Evaluation of Second Line Therapy in HIV infection) as well as centres involved in activities of one of the Networks of Excellence TESA (Trials of Excellence in Southern Africa).

From 26-30 August 2013, Mr Abdoulie Barry, Dr Thomas Nyirenda, Dr Pascoal Mocumbi, EDCTP's High Representative and Dr Monique Rijks-Surette, Project Officer, conducted a visit to **Mozambique**, which had seen an important increase in the number of EDCTP-funded projects between 2004 and 2011. Twelve completed and on-going projects were evaluated and several institutions were visited including the Ministry of Health, the Eduardo Mondlane University, the National Institute of Health, and the Manhica Health Research Centre, which all demonstrated a strong mutual working relationship. The TaMoVac-01 and TaMoVac-02 trials – the first HIV vaccine trials conducted in Mozambique –

were amongst the EDCTP-funded projects that were evaluated. EDCTP funding helped improve research oversight in the country. Throughout its existence and with the help of EDCTP funding, the National Ethics Committee of Mozambique has helped in the formation and endorsement of seven Institutional Review Boards.



Researchers in the laboratory of the Centro de Investigação em Saúde de Manhica



The MALARID study team in Zomba Hospital and Dr Thomas Nyirenda

EDCTP – Europe Office

P.O.Box 93015, 2509 AA The Hague
The Netherlands
Tel: +31 70 344 0880
Fax: +31 70 344 0899

E-mail: info@edctp.org

EDCTP – Africa Office

P.O.Box 19070, Tygerberg 7505,
Cape Town – South Africa
Tel: +27 21 938 0819
Fax: +27 21 938 0569

Web: www.edctp.org

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