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European & Developing Countries Clinical Trials Partnership

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EDCTP Newsletter

Note from the EDCTP **Executive Director**

The current newsletter fittingly reflects the present times as we are in transition getting ready for EDCTP2. As part of this preparation, EDCTP has been engaging with various stakeholders and partners to plan together the way forward including new ventures under its expanded scope. Some of these activities such as the high-level and post-approval programme meetings that took place in Cape Town in November 2012 are reported in this newsletter. Additionally, EDCTP has been undertaking landscape analysis to inform research programmes for EDCTP2. In the newsletter we also report on the Strategic Primer Grants that have been

awarded as pump priming to get the ground ready for EDCTP2. This scheme of grants has proven to be a big success.

Preparations for EDCTP2 include honing of governance and policy issues. To this end the current and potential new participating member states have been holding a series of meetings to discuss rules of participation including funding of the new programme as well as expansion of its membership. It is pleasing to state that the commitment from all partners from Europe and Africa as well as third parties is very strong and enthusiasm is running high. We do acknowledge that there

is still a lot of work ahead, but are confident that through joint effort we will come out triumphant and therefore, look forward to the expanded and stronger second programme of EDCTP.

Charles S. Mgone





EDCTP videos

EDCTP published two short videos on the second EDCTP programme. The most recent one presents the message of the High-Level Conference. The videos are available on the EDCTP YouTube channel (www.youtube.com/edctpmedia).

Towards EDCTP2

High-Level Conference on EDCTP2 in Cape Town

As part of the preparations for EDCTP2, a high-level conference was held in Cape Town, South Africa, on 5 November 2012. This conference was jointly organised by the Department of Science & Technology of South Africa, the European Commission and EDCTP. The objective of the conference was to provide a forum to discuss with African and

European stakeholders needs and expectations; and for African and European governments to endorse EDCTP2 and express fresh commitment to the programme. Invited participants included African and European ministers and senior representatives from governments, public and private product development partners,



Contents

Note from the EDCTP Executive Director

Towards EDCTP2

- High-Level Conference on EDCTP2
- Expansion of European membership

EDCTP Governance

- General Assembly
- Joint meeting of PB and DCCC
- New staff members

Calls and Grants

- Funded projects
- Strategic Primer Grants
- Senior Fellowships
- Member States Initiated Projects

Focus on EDCTP-Plus

- Pharmacovigilance meeting
- Agreement on Clinical Research Fellowship signed
- Mapping European and African research
- Extended support for PACTR
- EDCTP Financial Management Training in South Africa

Focus on Research Ethics Review in Africa

- Mapping research ethics review in Africa
- TRREE for Africa: online courses on research for ethics

Meetings

- World Health Summit Berlin 2012
- Δςτμη
 - Botswana site visit
- Africa-EU Science & Technology cooperation
- ASLM International Conference
- MMVC third Annual meeting
- Networking TB vaccine trials
- WHO Malaria Vaccine Technology Roadmap.

patient organisations and the research community. The 244 participants at the meeting heard presentations from 15 senior speakers and also two panel discussions, each of which was followed by contributions from the floor.

Towards EDCTP2 continued from page 1

The speakers were unanimous in praising the achievements of EDCTP so far and in welcoming the broadening of the remit of the second programme. Máire Geoghegan-Quinn - European Commissioner responsible for Research, Innovation and Science - described EDCTP as "a beacon of hope" and "a brilliant success story for EU-Africa research cooperation". She said the fight against poverty-related diseases was a global challenge in which Europe could and must make a major contribution. Appreciation and continued support for the work of EDCTP was also expressed by representatives from African and European countries, research institutions, the Bill & Melinda Gates Foundation, and GlaxoSmithKline.

Many speakers highlighted the importance of equality within the Partnership. For example, Maria da Graça Carvalho MEP, described EDCTP as, "a genuine partnership with Africa, in which African partners have retained a high degree of ownership and leadership". Nevertheless, the need for African governments to participate more actively was stressed by several speakers.

Also much referred to was the need to increase the involvement of other partners – including industry, charities and foundations, and communities themselves. It was regarded as essential that research supported by EDCTP should be translated into effective new products that reach those most in need. In February 2013, EDCTP published the conference proceedings on its website as well as a video capturing the conference and its main message.

Expansion of European membership

EDCTP actively seeks to promote a wider European membership of EDCTP2 to be able to integrate further the European clinical research effort regarding poverty-related and neglected infectious diseases. Part of the ongoing dialogue to expand the European membership of EDCTP was the one-day meeting of current and prospective EDCTP partner countries held in Copenhagen on 15 May 2012.



The meeting was organised by EDCTP and the European Commission and hosted by the Statens Serum Institut with support from the Danish Presidency of the European Union. The report is now available on the website.

EDCTP Governance

General Assembly

Prior to the High-Level Conference, the EDCTP General Assembly met in Cape Town, South Africa for a regular meeting on 1-2 November 2012. The Assembly was updated on EDCTP projects and activities. Extensive discussion was dedicated to EDCTP2 on topics including the legislative process, the governance structure and the mechanisms of cofunding in the EDCTP2 programme.

Joint and last meeting of PB and DCCC

On 29 and 30 October 2012, the Partnership Board (PB) and the Developing Countries Coordinating Committee - EDCTP's scientific advisory bodies - convened in The Hague for their last and joint meeting. Prof. Charles Mgone, the EDCTP Executive Director, provided an overview of the proposed governance structure for EDCTP2. This would include the establishment of a streamlined scientific and strategic advisory body, the Scientific Advisory Committee (SAC) to replace the DCCC and the PB. As setting up the SAC should begin soon, an interim advisory body, the interim SAC has been constituted as precursor to the SAC. This interim committee includes a selected representation from both the former DCCC and PB membership, with scope to recruit several representatives with expertise in the EDCTP2 expanded remit. The interim SAC is chaired by Professor Shabbar Jaffar.



New staff members

Rafael Taguas Sánchez Financial Assistant



Rafael Taguas Sánchez temporarily joined EDCTP in October 2012. He was born in France, but grew up in Madrid where he earned a degree in Sociology and a Master's degree in International Trade. Early in his career, Rafael held positions in the area of international trade. In 2001, he made a career switch to finance. Most recently, he worked as an Accounting Assistant at the Technical Centre for Agricultural and Rural Cooperation (CTA), a joint international institution of the African, Caribbean and Pacific (ACP) Group of States and the European Union. He will leave in March 2013.

Ralph Buchrnhornen Grants Financial Assistant



Ralph Buchrnhornen started working as a temporary Grants Finance Assistant at EDCTP in November 2012. He completed a Bachelor's degree in Accountancy in 2005. Shortly after graduating, Ralph joined KPMG as an Auditor. Ralph left KPMG in 2009 in order to establish himself as an independent consultant so as to gain broader experience with various organisations. Over the past years, Ralph has worked in several companies in different financial roles. Prior to joining EDCTP, Ralph worked as an Assistant Controller at Floresteca. He will leave in April 2013

Calls and Grants

Funded projects

EDCTP is pleased to announce funding of the following projects:

Call: EDCTP Strategic Primer Grants

Safety and Immunogenicity of P27A, a novel candidate bloodstage malaria vaccine, in malaria exposed African adults Project Coordinator: Dr Salim Addulla (Ifakara Health Institute, Dar-es-Salaam, Tanzania) Budget: €799,480 Duration of the project: 1 December 2012 - 30 November 2014

Preparing for clinical trials of interventions to improve the reproductive health of adolescent girls in sub-Saharan Africa Project Coordinator: Prof. Anne Buvé (Institute of Tropical Medicine, Antwerp, Belgium) Budget: €921,385 Duration of the project: 1 December 2012 - 30 November 2014

Preparing for clinical trials with vaginal rings that protect women from HIV and unintended pregnancy Project Coordinator: Dr Tania Crucitti (Institute of Tropical Medicine, Antwerp, Belgium) Budget: €590,462 Duration of the project: 1 December 2012 - 30 November 2014

Innovative approaches to diagnose and monitor patients with TB to facilitate conducting clinical trials for the communitybased treatment of MDR-TB Project Coordinator: Dr Luis Eduardo Cuevas (Liverpool School of Tropical Medicine, Liverpool, United Kingdom) Budget: €848,469 Duration of the project: 1 December 2012 - 30 November 2014

Biomarker extension programme

(PANBIOE) Project Coordinator: Prof. Stephen

Gillespie (University Court of the University of St Andrews, United Kingdom) Budget: €794,012 Duration of the project: 1 December 2012 - 30 November 2014

A phase I/IIa clinical trial of HIV-1 vaccines pSG2.HIVconsv, MVA.HIVconsv and ChAdV63. HIVconsv in combined regimens in healthy HIV-1/2-negative adults in Nairobi (HIV-CORE004) Project Coordinator: Prof. Tomáš Hanke (University of Oxford, United Kingdom) Budget: €796,658 Duration of the project: 1 December 2012 - 30 November 2014

Epidemiology of PZA resistance in TB Clinical trials in Africa - an essential prerequisite for evaluating novel TB drug combinations Project Coordinator: Prof. Michael Hoelscher (Ludwig-Maximilians University München, Munich, Germany) Budget: €430,808 Duration of the project: 1 December 2012 - 30 November 2014

Field trials of a new combination malaria vaccine in West-African adults and children (MVVC2) Project Coordinator: Dr Egeruan Babatunde Imoukhuede (European Vaccine Initiative, Heidelberg, Germany)

Budget: €1,101,415 Duration of the project:

1 December 2012 - 30 November 2014

A randomized controlled trial of lithium carbonate in individuals with HIV clade C-associated neurocognitive impairment: a proof of principle

Project Coordinator: Prof. John Joska (University of Cape Town, South Africa) Budget: €352,956

Duration of the project:

1 December 2012 - 30 November 2014

Preventing tuberculosisassociated immune reconstitution inflammatory syndrome in high-risk patients: a randomised placebo-controlled trial of prednisone

Project Coordinator: Prof. Graeme Meintjes (University of Cape Town, South-Africa) Budget: €616,102 Duration of the project:

1 December 2012 - 30 November 2014

Platform for controlled human malaria infection studies for development of new malaria vaccines, drugs and diagnostics in Africa Project Coordinator: Dr Bernards Ogutu (CREATES - Strathmore University, Nairobi, Kenya) Budget: €794,640 Duration of the project: 15 December 2012 -30 November 2014

Factors affecting HIV susceptibility in the adolescent genital tract Project Coordinator: Dr Jo-Anne Shelley Passmore (University of Cape Town, Cape Town, South Africa) Budget: €900,000 Duration of the project: 1 December 2012 - 30 November 2014

Promoting infant health and nutrition in sub-Saharan Africa – Evaluation of innovative tuberculosis diagnostic tests (PROMISE-TB)

Project Coordinator: Prof. Philippe Van de Perre (Université Montpellier 1, France)

Budget: €452,402 **Duration of the project:**

1 December 2012 - 30 November 2014

Call: Senior Fellowships

Baseline study of epidemiological and sociological aspects of malaria in the four natural regions of Guinea Project Coordinator: Dr Abdoul Habib Beavogui (Centre National de Formation et de Recherche en Santé Rural Jean Sénécal de Maférinyah, Conakry, Guinea) Budget: €178,580 Duration of the project:

1 November 2012 - 31 October 2014

Functional characteristics of effector and memory NK cellular responses and their comparison with adaptive T cell responses in HIV-vaccinated subjects and risk populations

Project Coordinator: Dr Sabelle Jallow (Medical Research Council, Banjul, The Gambia) Budget: €199,461 Duration of the project:

1 December 2012 - 30 November 2014

A prospective study to evaluate a pharmacogenetic-guided dosing algorithm based on patient CYP2B6 genotype compared to the empirical standard dose in the safe and efficacious use of efavirenz in HIV/AIDS patients in Zimbabwe Project Coordinator: Dr Collen Masimirembwa (African Institute of Biomedical Science and technology, Harare, Zimbabwe) Budget: €199,135

Duration of the project: 1 November 2012 - 31 October 2014

Clindamycin plus quinine for treating uncomplicated falciparum malaria: an open-label randomized trial

Project Coordinator: Dr Charles Owuora Obonyo (Kenya Medical Research Institute, Nairobi, Kenya) Budget: €199,333

Duration of the project: 1 November 2012 - 31 October 2014

Improving retreatment success in Tuberculosis

Project Coordinator: Dr Nesri Padayatchi (Centre for the AIDS Programme of Research in South Africa (CAPRISA), Durban, South Africa) Budget: €200,000

Duration of the project: 2 January 2013 - 31 December 2014

Evaluating pharmacokinetic interactions between artemisininbased therapies and rifampicinbased tuberculosis treatment in African patients

Project Coordinator: Dr Mohammed Lamorde (Infectious Diseases Institute Ltd, Mulago Hospital Complex, Kampala, Uganda) Budget: €198,507 Duration of the project:

1 November 2012 - 31 October 2014

Call: Member States Initiated Projects

The utility of intensified case finding combined with a package of novel TB diagnostics performed at community-based clinics in Africa - a multi-centric prospective cohort study (XACT study) Project Coordinator: Prof. Keertan

Dheda (University of Cape Town, South Africa) Budget: €564.575

Duration of the project: 1 November 2012 - 30 June 2013

Focus on EDCTP-Plus

The activities highlighted in this section - as well as in the section Towards EDCTP2 are part of the support action project 'EDCTP-Plus' which is funded through the Seventh Framework Programme grant from the European Commission (FP7-304786).

Pharmacovigilance meeting

EDCTP published the report



Sharina responsibility of the meeting on 'Post-Registration Medicinal Products Safety Monitoring in sub-Saharan Africa'. It was

held in Cape Town, South Africa on 4 November 2012 as part of preparations for EDCTP2. Its aim was to discuss opportunities to address issues of safety and effectiveness following the approval and deployment of new medicinal products with other stakeholders. Invited participants included African and European experts from the research community, the pharmaceutical industry, product development partnerships, regulatory agencies, funders as well as policymakers.

As an introduction Dr Alex Doodo (University of Ghana Medical School; International Society of Pharmacovigilance) gave an overview of the current drug and vaccine pharmacovigilance activities in Africa. This was followed by a discussion of the comprehensive post-registration programme GlaxoSmithKlein Biologicals developed for the first malaria vaccine RTS, S/AS. These presentations were followed by discussion of a wide range of issues, such as capacity development, good governance, safety data sharing and the collection of baseline data.

The safety of new medicinal products should be assessed during their complete life-cycle. In the majority of African countries there is clearly a greater need to monitor the safety and effectiveness of new drugs and vaccines. For the second programme EDCTP – supporting the complete life-cycle approach - will seek to define its role in

phase IV studies. One aspect of that role is to be a broker bringing together all pertinent partners and also to participate in the required capacity development relevant to improve post-registration safety monitoring of medicinal products in sub-Saharan Africa.

Agreement on Clinical Research Fellowship signed

On 24 January 2013, EDCTP and the European Federation of Pharmaceutical Industries and Associations (EFPIA) signed a memorandum of understanding for a Clinical Research Fellowship scheme. The Fellowship grant will give sub-Saharan African researchers the possibility to be placed in a European-based pharmaceutical company for up to two years to develop skills in clinical AIDS, tuberculosis, malaria and trial research. The aim is to further promote research capacity for conducting clinical trials in Africa.

Richard Bergström, the Director General of EFPIA said that the fellowship scheme was "a great opportunity for all parties involved. EFPIA's members will benefit from interaction with African scientists from diverse backgrounds. We hope Trial registration in the PACTR to help them acquire skills relevant to achieving their research and professional goals". Professor Charles Mgone, EDCTP Executive Director said that "it is critical that more African researchers are sufficiently trained and equipped with skills and expertise in clinical trials research in the fight against diseases that severely impact the social and economic development of sub-Saharan Africa."

The Clinical Research Fellowships will be awarded through open calls for proposals published by EDCTP in coordination with pharmaceutical companies. Candidates will be selected by EDCTP. After completion of their training, fellows will return to their countries. The first call for applications is expected in the first quarter of 2014. The text of the memorandum of understanding is available on the EDCTP website.

Mapping European and African research

Two research mapping projects that will contribute to the aims of increased collaboration and cooperation in the second EDCTP programme have recently started. The projects will also enable EDCTP to identify potential partners and opportunities for partnership, especially as the disease remit will be expanded and the scope of EDCTP2 extended to phase I clinical studies as well as phase IV post-registration studies. These projects are part of a larger mapping project.

The first study is a bibliometric analysis of African and European research programmes, partnerships, activities and capacities in the fields of HIV/ neglected infectious diseases over the period 2003-2011.

Extended support for PACTR

The EDCTP-funded Pan African Clinical Trials Registry (PACTR) is the only WHO-endorsed primary registry in Africa. portal (www.pactr.org) meets the requirements of the International Committee of Medical Journal Editors (ICMJE) and feeds information to the WHO International Clinical Trials Registry Platform (ICTRP). The PACTR registry facilitates understanding of regional

Thomson Reuters Evidence, London, United Kingdom, a firm specialised in bibliometric citation analysis, will conduct this study. The project results should be available in the second quarter of 2013.

The second study, a mapping and analysis of African health research activities, capacities and public resources in our disease areas of focus, will describe how these relate to African national disease control programmes and the mission of EDCTP. This study will be carried out by RAND Europe, Cambridge, United Kingdom, an independent not-for-profit research institute whose mission is to help improve policy and decision making through research and analysis. The results are expected to be published in late 2013.

research patterns, enables the identification of research gaps for future studies, and facilitates the investigation of the scope, quality and funding patterns of African trials. In preparation for the second EDCTP programme, EDCTP has provided more support to develop the registry further. Thus PACTR will offer an increasingly comprehensive instrument for monitoring the clinical trial environment in Africa.



Focus on research ethics review in Africa

Mapping research ethics review in Africa

The EDCTP-funded project Mapping African Research Ethics and Drug Regulatory Capacity (MARC) ran from 2009 until end of June 2012. This project continues with resources from COHRED. The main objective of the MARC project were to develop an interactive and continuously updated map of Africa's health research ethics committees (HRECs) and (national) regulatory authorities for medicines. The second aim was to provide a web-based platform for the improvement of communication between HRECs and between HRECs and the regulatory authorities.



The MARC project was implemented through collaboration between the Council on Health Research for Development (COHRED) in Geneva, Switzerland and the South African Research Ethics Training Initiative (SARETI) at the University of KwaZulu-Natal, South Africa. MARC identified 166 HRECs operating in Africa with a great variation in skills, membership and efficiency. A website

(www.researchethicsweb.org) was developed to offer an overview of the mapped information.

Moreover, an information management platform was developed with feedback and support from the MARC project. The Research for Health and Innovation Organiser (RHinnO Ethics, www.rhinno.net) facilitates efficient ethical review clearance through a simple yet sophisticated, fully web-based system as an alternative to the currently widely used and complex paper-based systems for research ethics review.

Since its launch in April 2012, RHInnO Ethics is used by the national ethics committee in Tanzania, and will soon be used by institutionally based HRECs in Mozambique, South Africa, Senegal and Tanzania. Other countries of the West African Health Organisation (WAHO), including Guinea Bissau, Liberia, Mali and Sierra Leone, expressed interest in the platform. Adoption of RHInnO Ethics by a majority of HRECs in Africa will bridge the gaps in the ethical review processes and will lead to harmonisation and standardisation of the ethical review process.

MARC data are also fed into COHREDs Health Research web (HRWeb), a website offering an overview of health research systems including national institutions and governments, funders and HRECs/Institutional Review Boards (IRBs). The website provides ethics information per country as well as up to date information on research ethics activities, events and opportunities.

TRREE for Africa: online courses on research for ethics

TRREE for Africa (Training and Resources in Research Ethics Evaluation for Africa) is a web-based training and capacity building programme that provides an introduction and access to regulations, ethical guidelines and internationally recognised human rights standards relevant to health research. Local issues and perspectives relevant to North-South research partnerships are integrated in the courses. The TRREE portal (www.trree.org) offers e-learning programmes tailored to the needs of members of health research ethics committee (HREC), investigators and other healthcare professionals.

Funded by EDCTP, TRREE was launched in 2009 focusing mainly in Africa. The platform has now been expanded to the Americas, Asia and Europe. As of January 2013, there are over 3,800 participants from 178 countries, 49% of whom are from Africa and 4% from Asia. More than 4,000 participants successfully completed at least one TRREE module. The programme available on the portal consists of modules at four levels: 1) introduction to research ethics; 2) research ethics evaluation; 3) informed consent; 4) national supplements. These modules are available in English, French, German and Portuguese. A new level three module on Good Clinical Practice (GCP) was launched in December 2012 and another one on ethical issues related to HIV vaccine testing is under development. A new national supplement for Burkina Faso was published in February 2013.

Following the proliferation of e-learning programmes in research ethics, TRREE is currently coordinating an initiative to develop standards for e-learning programmes. Such an evaluation tool would be useful for individuals or groups who wish to use, recommend or accredit such programmes. A workshop for developing standards for high quality e-learning programmes in research ethics and regulation in North-South partnerships is planned for January 2013. (http://elearning.trree.org)



Meetings

World Health Summit Berlin 2012

At the Berlin Health Summit in October 2012, Dr Gabrielle Breugelmans, EDCTP North-North Networking Manager, participated in the panel of the partner symposium on 'EU Global Health R&D: impact and return on investment' organised by DSW (Deutsche Stiftung Weltbevölkerung) on 23 October 2012.

ASTMH

EDCTP Executive Director Prof. Charles Mgone participated in the annual conference of the American Society of Tropical Medicine and Hygiene (ASTMH) in Atlanta (USA) on 12-16 November 2012. He delivered a presentation on the EDCTP programme and the principles of capacity building for clinical trials in Africa for the Global Health pre-meeting course 'Building Global Public Health and Research Capacity: a discussion of three case studies and lessons learned' on 11 November 2012.

Botswana site visit

From 17-19 November 2012, a small EDCTP team consisting of Abdoulie Barry, Director of Finance and Administration, and Dr Tom Nyirenda, South-South Networking and Capacity Development Manager visited several project sites in Botswana: three projects related to research ethics, two clinical trial sites and the EDCTP Network of Excellence TESA (Trials of Excellence in Southern Africa).

The objectives of EDCTP site visits are: to establish personal contact and dialogue with the teams working in the field; to do a technical assessment of progress made; to assess finance systems, internal controls, reporting, and information technology capacity; to inform managers, researchers and their teams about the goals of EDCTP. Site visits also offer opportunities for strategic dialogue with policy makers, regulators, and ethics review committee/board members, and for identifying potential areas of future collaboration.

MMVC third Annual meeting

From 14 to 17 January 2013, the EDCTP-funded Malaria Vectored Vaccines Consortium (MVVC) held its third annual meeting as well as the kick-off meeting for the MVVC2 project for which an EDCTP Strategic Primer Grant agreement has been signed recently. The meetings took place in Dakar, Senegal. EDCTP was represented by the Project Officer. Participants heard updates from the phase-I and phase-II clinical trials and presentations by five of the seven post-graduated trainees involved in the project.

WHO Malaria Vaccine Technology Roadmap

EDCTP was represented by Dr Michael Makanga in the Consultation on the Updated Vision and Strategic Goals of the Malaria Vaccine Technology Roadmap in Geneva, Switzerland on 5 February 2013. This meeting brought together independent experts, experts from industry and academic institutions as well as from major funders of malaria vaccine research. The updated Malaria Vaccine Roadmap will offer recommendations on global strategic areas of investment to accelerate the development of malaria vaccines.

Africa-EU Science & Technology cooperation

From 3 to 4 December the third CAAST-Net stakeholder conference took place in Accra, Ghana in collaboration with PAERIP. The CAAST-Net and PAERIP projects are funded by the European Union under FP7 and aim to promote cooperation between Africa and the European Union on science and technology and research infrastructure, respectively.

Dr Michael Makanga, EDCTP Director of South-South Cooperation, presented EDCTP as a case study in cooperation highlighting its impact on the infrastructure for clinical trials in sub-Saharan Africa. The outcome of the conference will be presented to policymakers, specifically those responsible for the governance of the Africa-EU science, information society and space partnership. Contributions can be downloaded from the CAAST-Net website (www.caast-net.org).

Networking TB vaccine trials

The annual meeting of the TBTEA project followed by a TBVI symposium on current TB vaccine development took place in Switzerland on 28-29 January 2013. EDCTP was represented by the Project Officer. The EDCTP-funded TBTEA project aims to implement a sustainable platform as interface between independent TB vaccine trials (i.e. the ongoing trials VPM1002, H1/IC31, MVA85A and the future trials MTBVAC and HBHA), where integration, improvement and broadening of the capacity to clinically evaluate TB vaccines in Africa and Europe will be stimulated.

ASLM International Conference

The African Society for Laboratory Medicine held its first international conference in Cape Town, South Africa, 1-7 December 2012. In a plenary session EDCTP Executive Director Prof. Charles Mgone held a presentation on 'Preparing Africa for High Level Research and Clinical Trials'. EDCTP has a keen interest in improving research laboratory capacity in sub-Saharan Africa and accelerating the process toward accreditation to pave the way for the establishment of regional reference laboratories within the EDCTP Networks of Excellence.

European & Developing Countries Clinical Trials Partnership

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