

Note from the High Representative

Dear Readers,

I am very gratified to introduce to you the June issue of the EDCTP newsletter for 2013. As the Partnership advances in its ninth year of existence and draws towards the end of its transition period, it is timely to tighten our belts and march forward with confidence into the second programme of EDCTP. This is an important milestone that comes with a price, all participating states and those aspiring to join the programme need to make fresh commitments coupled with action. I therefore call upon all EDCTP partners,

especially African governments and regional partners not to miss the opportunity for further investment in research, an essential ingredient for growth and development.

This issue highlights exciting activities in preparation for the second programme of EDCTP, the evolution of EDCTP governance, preparations for the seventh EDCTP Forum and second high-level conference, updates on projects and new calls, and policy dialogues.

Enjoy your reading.



Dr Pascoal Mocumbi,
EDCTP High Representative



EDCTP video

A new video about the EDCTP-funded TB-NEAT project is available on the EDCTP YouTube channel (www.youtube.com/edctpmedia).

EDCTP Forum

Seventh EDCTP Forum

The Seventh EDCTP Forum will be held at the King Fahd Palace Hotel in Senegal, Dakar from 21 to 24 October 2014. The theme is *The Partnership journey: New horizon for better health*. This Forum comes at a perfect time to share the story of our research partnership and will mark the watershed between the final years of the first EDCTP programme (EDCTP1) and the new vistas of the second

programme (EDCTP2). The Forum will bring together speakers and delegates from research institutions, universities, public-private partnerships, product development partnerships, like-minded organisations working on poverty-related diseases, governments, regional bodies and industry around the globe, especially from Africa and Europe. Information on the results of

projects that have been supported by EDCTP in collaboration with all of our partners will be presented. Practical experiences and lessons learned will be shared, and new strategic and scientific ideas will be captured that will contribute to EDCTP's future research and development agenda.

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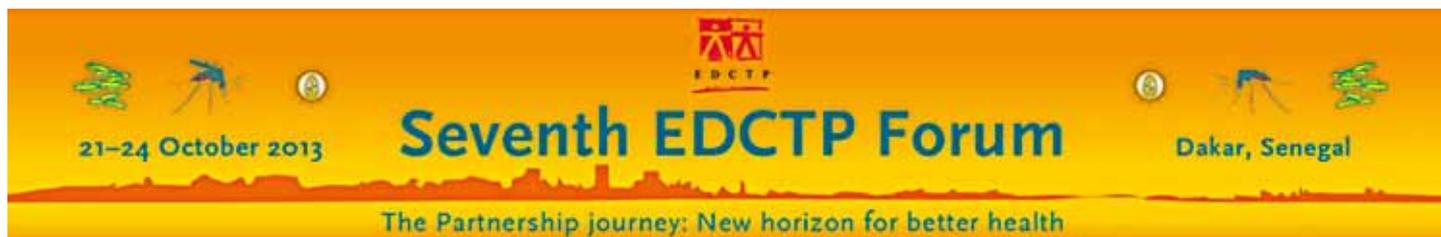
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The programme

The Forum programme comprises a wide range of topics including cutting-edge clinical research on HIV/AIDS, tuberculosis and malaria; interactions of these three major PRDs with neglected infectious diseases (NIDs); cross-cutting areas on health capacity development and networking, policy, ethics and regulatory affairs; and workshops on scientific publication and grant application writing, will be presented. The discussions will be based on real-life situations, experiences and practical examples. The format for presentations will include keynote addresses by invited speakers from North and South, oral presentations in plenary and parallel sessions, panel discussions, poster sessions, satellite meetings and a marketplace for research exhibitions. Moreover, the winners of the EDCTP Awards to Outstanding and Rising Star African Scientists will be awarded during the closing session of the forum.

Registration

The registration for the Forum is open. Please visit the Forum website (www.edctpforum.org) to submit your registration.

Scholarships

EDCTP will sponsor a limited number of individuals from sub-Saharan Africa, and where justified from Europe, to attend the Seventh Forum. The selection will be based on the scientific quality of the abstracts submitted.

Sponsorship opportunities

The Seventh EDCTP Forum invites interested organisations to sponsor the event. The

sponsorship packages offer the opportunity to support the Seventh EDCTP Forum and raise the visibility of the sponsoring organisation during the duration of the entire conference. The Forum is an excellent occasion for networking due to the multidisciplinary nature of the conference will gather representatives from different regions and research fields. More information about the sponsorship opportunities on the Seventh EDCTP Forum is available at www.edctpforum.org.

For more information about the Seventh EDCTP Forum and registrations, please visit www.edctpforum.org.

2013 EDCTP Awards to Outstanding African Scientists



EDCTP invites nominations for the 2013 Awards to Outstanding African Scientist. The awards will recognise an African Outstanding Scientist and a Rising Star (scientists ≤ 45 years of age) working on HIV/AIDS, tuberculosis and malaria in the scope of the EDCTP programme and will be extended at the Seventh EDCTP Forum in Dakar, Senegal on 24 October 2013.

The Rising Star Award recognises mid-career researchers who have significant achievements in

their field and who will continue to become leaders in their research field.

The Outstanding Scientist Award is for senior researchers who have outstanding achievements in their field and who are recognised as research leaders in Africa. In addition to their scientific excellence, the awardees will have made major contributions to the EDCTP objectives of strengthening clinical research capacity in Africa and supporting South-South and North-South networking.

Awards

The awards consist of a recognition trophy together with a cash prize of €10,000 for the Rising Star and €20,000 for the Outstanding Scientist. These awards will further the research programmes of the winners and may support activities such as study visits and training attachments to collaborating institutions, data collection for baseline studies, conference and meeting attendance, and other relevant research-related activities.

Eligibility

The awards are open to scientists from sub-Saharan Africa working in HIV/AIDS, tuberculosis and malaria within the scope of the EDCTP programme. Nominees should be scientists from sub-Saharan Africa who have spent the major part of their career in Africa. The Rising Star nominee must be 45 years of age or younger at the time of award on 24 October 2013.

Nominations to the EDCTP Awards should be sent by 28 June 2013 via email to award@edctp.org.

Please visit the EDCTP Forum (www.edctpforum.org) for more information about the Awards, eligibility and to submit nominations.

Second High-Level Conference on EDCTP2

A second High-Level Conference on EDCTP2 will be held in Dakar, Senegal on Monday 21 October 2013. The meeting will be hosted by the government of the Republic of Senegal and jointly organised by the European Union and EDCTP. The objective is to unite the countries participating in EDCTP and other (future) partners and to concretise their commitment to the second EDCTP programme. The conference will consolidate discussions and recommendations of the first High-Level Conference in Cape Town, South Africa on 5 November 2012. The participants will include policy-makers, product development partners and representatives of industry, non-governmental organisations and the research community. The High-Level Conference will be followed by the opening ceremony of the Seventh EDCTP Forum.

Towards EDCTP2

Stakeholder meetings

EDCTP will hold a series of thematic stakeholder meetings to shape its strategy and funding approach as part of the preparatory process for EDCTP2. Participants will include researchers from academia, representatives of product development partnerships and pharmaceutical industry, policy makers, funding agencies and other like-minded organisations as well as representatives of EDCTP and its constituencies. The meetings will be hosted by various countries participating in EDCTP.

The stakeholder meetings have themes based on disease (HIV/AIDS, tuberculosis, malaria and neglected infectious diseases) and interventions and have the following objectives:

1. To identify and review the current research issues, interventions, products in development and key players in the field
2. To ensure that EDCTP remains focused on the most pressing research needs, the most promising opportunities, and aligns its strategic planning and funding approaches accordingly
3. To identify priority areas for future calls for proposals
4. To identify potential partners to collaborate with in future EDCTP activities
5. To harness the efforts of EDCTP stakeholders in order to promote integration of national programmes of EDCTP European partner states and strengthen the partnership with African researchers.

Recommendations from the meetings will contribute towards the EDCTP strategic and operational business plan: priority research topics for calls for proposals; proposals for development of cooperative projects; identification of products in the pipeline for evaluation by EDCTP; focused capacity building initiatives; and proposals for funding partnerships.

The schedule for the meetings is as follows:

Date	Research field	Location
27-28 June 2013	Neglected infectious diseases	The Hague, Netherlands
3-4 September 2013	HIV	Lisbon, Portugal
19-20 September 2013	Malaria	Vienna, Austria
28-29 October 2013	Tuberculosis and other mycobacterial infections	Paris, France
28-29 November 2013	Ethics and regulatory affairs	Antwerp, Belgium

An additional stakeholder meeting focussed on capacity building will be held in the second quarter of 2014. The format of the stakeholder meetings will include scene-setting plenary sessions and open discussion sessions in order to produce meeting recommendations. Participation at these face to face meetings is by invitation only but a platform will be provided to collect views and contributions from a broader range of stakeholders. For more information, please visit the Stakeholder meetings page on the EDCTP website (www.edctp.org/Stakeholder_meetings.863.0.html).

New partnership EU and Gates Foundation

On 10 June 2013, the European Union and the Bill & Melinda Gates Foundation signed a new strategic agreement to work together to fight poverty-related diseases.

The press release from the European Commission states that the EC and the Gates Foundation "will jointly fund clinical development of new tools to treat and prevent HIV, tuberculosis, malaria and other neglected infectious diseases such as diarrhoeal diseases, Buruli ulcer, trachoma, lymphatic filariasis and sleeping sickness.

Much of this work will be carried out through the European and Developing Countries Clinical Trials Partnership (EDCTP), a flagship initiative of the European Union".

See EU press release http://europa.eu/rapid/press-release_IP-13-517_en.htm



Commissioner Geoghegan-Quinn and Bill Gates, Co-Chair of the Bill & Melinda Gates Foundation, signing the Memorandum of Understanding to fight poverty related diseases in Paris, 10 June 2013.

Calls and Grants

Upcoming call for proposals: EDCTP Master's Fellowship in Epidemiology and Biostatistics

The Master's Fellowship scheme aims to build research capacity in sub-Saharan Africa by supporting the training and career development of upcoming researchers in the fields of epidemiology and statistics. The scheme provides funds for the fellow to undertake a Master's course in Epidemiology or Medical Statistics taught at an internationally recognised centre of excellence and to conduct a field study at their

home institution in sub-Saharan Africa. The maximum duration of the fellowship is two years. Proposals that include south-south and north-south partnerships between sites with established epidemiological research platforms and sites with limited capacity are encouraged. The call will be launched in July 2013. More information will be available on the EDCTP website at www.edctp.org.

Focus on EDCTP-Plus

MSc scholarships for six African scientists involved in EDCTP-funded research

Six scientists from sub-Saharan Africa involved in EDCTP-funded vaccine development projects have been awarded a scholarship for the Master's Programme in Vaccinology and Pharmaceutical Clinical Development (III edition) at the University of Siena, Italy.

The Master's programme is offered by the University of Siena Medical School, Novartis Vaccines and Diagnostics, Novartis Vaccines Institute for Global Health (NVGH), and ADITEC (Advanced Immunization Technologies). The scholarships are offered through Novartis and the EU FP7 ADITEC programme. The programme commences in May 2013 and offers a one-year course at the University of Siena in Italy followed by a six-month internship at Novartis.

The selected candidates are working in different institutions in six African countries, including: Kumasi Hospital (Kumasi, Ghana); Kenya Medical Research Institute/ U.S. Centres for Disease Control and Prevention (Kisumu, Kenya); Rwanda Biomedical Centre (Kigali, Rwanda); Cheikh Anta Diop University (Dakar, Senegal); The Aurum Institute (Klerksdorp, South Africa), and Ifakara Health Institute - Bagamoyo Research and Training Centre (Bagamoyo, Tanzania).

Physicians working in vaccine development projects funded by EDCTP are eligible for the programme as a result of collaboration between Novartis and the European Commission. The initiative is part of a broader EDCTP effort to foster cooperation of public and private partners for clinical research on poverty-related diseases and neglected infectious diseases.

EDCTP and EFPIA: joint webinar on Clinical Research Fellowship scheme

On 12 June 2013, EDCTP and the European Federation of Pharmaceutical Industries and Associations (EFPIA) will host a webinar to introduce the EDCTP-EFPIA Clinical Research Fellowship scheme. The scheme aims to promote research capacity for conducting clinical trials in Africa. The webinar is to inform pharmaceutical companies engaged in research, development and manufacturing of medicinal products. It will be moderated by Mélanie Yammine, Manager Global Health at EFPIA.

The webinar will provide an opportunity for pharmaceutical companies interested in hosting an EDCTP-EFPIA Fellow to interact directly with the programme coordinator, Dr Gabrielle Breugelmans, North-North Networking Manager at EDCTP. Plans for EDCTP2 will be presented and the following topics will be addressed:

- Call for applications and selection process
- Roles and responsibilities of host institutions
- Reporting mechanisms and evaluation
- Logistical and practical requirements.

The Fellowships will be awarded through open calls for proposals published by EDCTP in coordination with EFPIA and the pharmaceutical companies. Candidates will be selected by EDCTP. The pharmaceutical companies that have expressed interest in specific candidates and EDCTP will jointly decide on the final selection.

EDCTP Governance

Strategic Advisory Committee: call for experts

The Strategic Advisory Committee (SAC) is the principal advisory body for EDCTP. It provides strategic and scientific advice to the EDCTP General Assembly as well as the Executive Secretariat. It oversees the scientific integrity of the EDCTP programme.

EDCTP is calling on high-level experts from across multiple fields and sectors to apply for membership of the SAC from 1 January 2014. The SAC will comprise up to 12 members: the Chair, two Vice-Chairs and up to nine ordinary members. Applications are requested not later than 30 August 2013.

Experts should have skills, knowledge, expertise and standing in one or more of the following fields with clinical trials' experience: HIV/AIDS; tuberculosis; malaria; neglected infectious diseases. In addition to disease specific

requirements, expertise in the following fields is sought:

- Ethics/clinical regulatory affairs
- Industry product development experience
- Post registration safety and effectiveness programmes
- Health services and implementation research
- Public health (including epidemiology, biostatistics, health economics and planning)
- Social and behavioural sciences within the disease remit of EDCTP2
- Research capacity strengthening and training.

How to apply

Please refer to the detailed advertisement on the EDCTP website for details on how to apply and further information about this call and the mandate of the SAC members (www.edctp.org/Call_for_Experts_EDCTP_Strategi.860.0.html).

Focus on Projects

Scholarships for MSc Clinical Trials by distance learning

Since 2007 EDCTP supports postgraduate trainees to undertake a distance learning Master in Clinical Trials offered by the London School of Hygiene and Tropical Medicine (LSHTM). The course was designed to offer flexibility to train for the Master's degree while working. Students may complete the Master's training within a period of two to five years at a pace appropriate to their own circumstances and their employing institution's needs. A postgraduate diploma based on completion of four core modules can be awarded after a minimum of one year.

By the end of 2012, 24 Master's students were funded via this grant, of which eight in the meantime have obtained their Master's degree.

A second training grant coordinated by the LSHTM has supported the establishment of an MSc in Clinical Trials course at the University of Ghana (conducted in English) and an MSc in Clinical Trials course at the University of Bobo-Dioulasso in Burkina Faso (conducted in French).

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Strengthening African Research Ethics Committees/SARETI



In 2008 Professor Douglas Wassenaar received a grant for 'Strengthening African Research Ethics Committees' capacity for ethical review of HIV prevention research'. This project aimed to strengthen African research ethics committees (RECs), specifically in the review of HIV prevention research. This was done by inviting selected African REC members to participate in intensive ethics training modules provided by the South African Research Ethics Training Initiative (SARETI) based at the University of KwaZulu-Natal, South Africa (<http://sareti.ukzn.ac.za>).

Participation in the training programme was open to all African REC members but the selection criteria required applicants to serve on a REC in an African country that at the time was or would be hosting HIV prevention trials. Based on calls for applications, EDCTP funded the participation of 15 REC members from ten African countries. Preference was given to individuals with some basic training and a four-year degree.

Participants completed two research ethics courses which had been taught and developed

by SARETI since 2002 and are run by experts in the topic areas. Each course is formally examined by written assignment and evaluated by participants. The second course exposed participants to the complexities and controversies associated with ethical issues in complex multinational trials of HIV prevention products, and covered relevant international and local ethical guidelines.

Kenya country visit

From 18-20 March 2013, an EDCTP team consisting of Mr Abdoulie Barry (Director of Finance and Administration), Ms Nuraan Fakier (Ethics Projects Officer) and Dr Thomas Nyirenda (South-South Networking and Capacity Development Manager) visited several projects at the Kenya Medical Research Institute (KEMRI) and the University of Nairobi: three projects related to research ethics, four clinical trial sites and the EDCTP Network of Excellence EACCR (East African Network of Excellence in Clinical Research and Practice). The team also visited the Strathmore

Dr Amina Jindani on RIFAQUIN



Dr Amina Jindani

Dr Amina Jindani is Honorary Senior Lecturer at St George's University of London, United Kingdom and has vast experience in tuberculosis (TB) research. In the 1960s, Dr Jindani coordinated the first East African/British Medical Research Council trial of short-course chemotherapy for TB in Africa. "When I first started working on tuberculosis, the standard TB treatment was 18 months," says Dr Jindani. "Then the development of new drugs such as rifampicin and pyrazinamide suggested that treatment in humans could be shortened". The trial paved the way to the standard regimen used today.

The standard six-month course of four antimicrobial drugs to treat tuberculosis recommended by the World Health Organization (WHO) is very effective – it has over 95% cure rate. Dr Jindani: "But we still have a very high global incidence and prevalence of tuberculosis, and one of the reasons for this is that the six-month treatment is too long". The long-course treatment involves substantial costs in terms of time and administration to both patients and treatment

University in Nairobi which received EDCTP funds to establish an Institutional Review Board at the Centre for Research in Therapeutic Sciences (CRETES) in collaboration with KEMRI.

The EDCTP country visits in sub-Saharan Africa are conducted to establish personal contact and dialogue with the teams implementing the funded projects in the field; to technically assess the progress made in achieving objectives; to assess financial controls; and to further inform partners in the visited countries about the objectives of EDCTP2.

services. Additionally, daily drug taking is not always observed by patients. It is necessary to reduce treatment duration.

Funded by EDCTP, Dr Jindani coordinated the RIFAQUIN clinical trial to shorten or simplify the treatment of TB. Treatment services and adherence to treatment would greatly benefit if the length of treatment could be shortened to four months, or if treatment administration could be simplified (for example, once or twice weekly rather than daily). The project started in 2006 and was completed in March 2013. The trial assessed whether a combination treatment that included rifapentine (a rifamycin) and moxifloxacin (a quinolone), when given together, can achieve these objectives. It investigated both a four-month and a six-month rifapentine/moxifloxacin combination against the standard six-month TB treatment. The trial enrolled 827 patients and involved sites in Botswana, South Africa, Zambia and Zimbabwe.

The results showed that it is possible to simplify the treatment administration through combination treatment that includes rifapentine, administered only once a week. However, as Dr Jindani explains: "As this regimen stands it can't be adopted by national treatment programs because the drugs are very expensive and it requires to be taken with a small meal. The regimen will have to be modified to reduce costs". Unfortunately the study did not show a possibility to shorten treatment duration.

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Vaccinations started in a phase IIb trial of candidate malaria vaccines

The Malaria Vectored Vaccine Consortium (MVVC) has started recruitment for the phase IIb clinical trial of the AdCh63/MVA ME-TRAP vaccines at the site in Banfora, Burkina Faso. The study aims to assess the safety, immunogenicity and efficacy of the candidate malaria vaccines in prime-boost regimes in healthy sub-Saharan African children and infants.

The phase IIb trials were also conducted at two additional sites in Kenya and Senegal in adults volunteers. In Burkina Faso, a lead-in safety study was first conducted in 30 children, and for this efficacy study a total of 700 children and infants are expected to be enrolled. On 25 March 2013, the first group of children received the first dose of the vaccine regime. To date 400 children from 5-17 months of age have been vaccinated. The Centre National de Recherche et de Formation sur le Paludisme (CNRFP) is conducting the trial in Burkina Faso as a member of the MVVC consortium funded by EDCTP.

The antigen utilised in this vaccine is ME-TRAP, the complete *Plasmodium falciparum* pre-erythrocytic thrombospondin-related adhesion protein (TRAP) fused to a string of T cell multiple epitopes. For the prime, a recombinant vaccine based on the chimpanzee adenovirus ChAd63 is given. The subsequent boost stage uses the same antigen in a modified vaccinia virus Ankara (MVA).



Researcher working in the laboratory for the MVVC project

Meetings

EAC health and science meeting in Rwanda

The 4th annual East African Health and Scientific Conference, organised by the East African Community, was held in Kigali Rwanda on 27-29 March 2013. Dr Tom Nyirenda, EDCTP South-South Networking and Capacity Development Manager, presented the EDCTP perspective. This key note address was entitled 'Advancing regional health research priorities for evidence-based health policy formulation and interventions in Africa: EDCTP perspective'.

The path from research to policy in Africa was characterised as a winding road with many different problems including lack of research agendas, a widening gap between researchers and research users, ineffective communication of research findings to policy makers, inability to handle and use large volumes of research publications and general lack of research funding. The EAC countries were encouraged to address the problems mentioned. One of the steps could be to complement EDCTP2 efforts by producing country and regional specific research plans and agendas.

EVI: 15th anniversary symposium

The European Vaccine Initiative held its 15th Anniversary Symposium on Global health and diseases of poverty in Heidelberg, Germany on 26 February 2013. The Professor Charles Mgone, EDCTP Executive Director was one of the speakers. He summarised the achievements of EDCTP and presented an outlook on EDCTP2 which is expected to obtain a higher level of funding, have an expanded scope and foster stronger relationships with partners from the private sector and international development.

Gates Foundation/NIH: Schistosomiasis elimination strategy

The Bill & Melinda Gates Foundation and the US National Institutes of Health hosted a meeting on 'Schistosomiasis Elimination Strategy and Potential Role of Vaccine in Achieving Global Health Goals'. The meeting was convened in Seattle, United States from 12-13 March 2013 to consider current control program strategies, unmet needs, and

the potential role of schistosomiasis vaccines. It brought together approximately 60 researchers, implementers, and policy-makers from around the world. Several research groups at various stages of developing potential vaccines against schistosomiasis presented their projects. EDCTP Executive Director, Prof. Charles Mgone attended the meeting.

Third Global Forum on TB vaccines

The Third Global Forum on TB Vaccines was held in Cape Town, South Africa from 25 to 27 March 2013. EDCTP was one of the sponsors of the event which brought together researchers, policymakers, donors, civil society and other stakeholders interested in the development of new TB vaccines. The main objectives of the conference were to review

progress in the field and discuss strategies to advance vaccine development; share the latest data and findings on key issues in TB vaccine research; and promote collaboration among stakeholders. Prof. Charles Mgone presented the plans for EDCTP2 during the final plenary session on financing the global TB vaccine portfolio.

Consultation on collaboration with South Africa

South Africa, through the Strategic Partnership Directorate of the Department of Science & Technology, is currently one of the African countries that co-finance EDCTP projects. A follow-up meeting to the High-Level Conference in November 2012 was organised in Cape Town on 26 March 2013. The meeting involved representation from the European Commission, EDCTP, the Medical Research Council and the Department of Science and Technology of South Africa.

The objective of the meeting was to have a strategic discussion on collaboration between the European Union, EDCTP, South Africa and other African countries. South African's perspective on national investments in clinical trials, research, innovation and capacity-building was presented. The European Commission and EDCTP emphasised the need for African co-ownership of EDCTP2, and the need to scale up African involvement of African countries in preparation for EDCTP2.

European & Developing Countries Clinical Trials Partnership

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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