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EDCTP Newsletter

December 2015

Note from the Executive Director

After almost a decade at EDCTP, it is an appropriate time for me to move on. My tenure at the organisation has been very rewarding and enjoyable and I extend my sincere and unreserved gratitude to you for being part of this exciting journey.

During this period, EDCTP has grown into a model of a genuine partnership for responsibly and sustainably accelerating research and development (R&D) of medical interventions against povertyrelated and neglected infectious diseases. The organisation has funded nearly 250 projects including 100 clinical trials and diagnostic studies that were carried out in 30 different sub-Saharan African countries in collaboration with researchers from 14 European countries and other partners. Many of these broke new ground and contributed to new national and international guidelines, the registration of new medical products or regimens, and health research capacity development. The programme supported over 460 fellowships (including postgraduate training awards),

approximately 80 Ethics Review Committees and National Regulatory Authorities and established the Pan-African Clinical Trials Registry.

For its second programme, EDCTP has transformed itself from a European organisation governed by a group of European countries to an international association that is jointly owned and governed by European and African states. It has also expanded its mandate beyond HIV, malaria and tuberculosis to include other neglected infectious diseases and all phases of clinical trials including post registration trials and focused implementation research.

These achievements would not have been realised without the help of many who have dedicated their efforts to this cause. These include past and current members of the various EDCTP constituencies such as the Developing Countries Coordinating Committee, the European Networking Officers, the Partnership Board, the Scientific Advisory Committee, and the representatives in the General Assembly.



With every end comes a new beginning. Dr Michael Makanga, who has contributed immensely to the success of EDCTP, will take over as the new EDCTP Executive Director starting from 1 January 2016. Indeed, he is the most suitable person to take us to new horizons and we should all give him all our support.

I will remain in touch and continue to support and advocate for EDCTP and remain working in the global health space, particularly in health research capacity development, international cooperation, R&D partnerships, and health policy.

Charles S. Mgone

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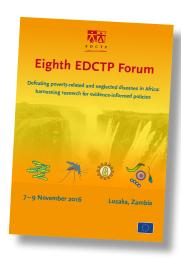
Publications

EDCTP published European and African clinical research: a bibliometric analysis of publications within the scope of EDCTP2 2003-2011. This bibliometric analysis provides the full background for the publication by authors from **EDCTP and Thomson Reuters** in PLOS neglected tropical diseases on August 11, 2015: 'Bibliometric assessment of European and sub-Saharan African research output on poverty-related and neglected infectious diseases from 2003-2011'.

Eighth EDCTP Forum

The Eighth EDCTP Forum will take place in Lusaka, Zambia from 6-9 November 2016. EDCTP invites all stakeholders to support and attend this conference and requests all interested parties to save this date.

The theme of the Forum will be: Defeating povertyrelated and neglected diseases in Africa: harnessing research for evidence-informed policies.





Dr Pascoal Mocumbi Prize

In November, EDCTP launched a call for nominations for the Dr Pascoal Mocumbi Prize. The prize will be awarded to an individual in recognition of his/ her outstanding achievements in advancing health research and research capacity development in Africa with significant impact on the wellbeing of the African population. The prize consists of a trophy and a cash prize of € 50,000. The cash prize shall be used by the award winner to

further the capacity development and networking activities contributing to the objectives of the EDCTP2 programme and promote international cooperation between Africa and Europe.

The prize is in recognition of Dr Pascoal Mocumbi, EDCTP's first High Representative and former Prime Minister of Mozambique. As High Representative (2004-2013), Dr Mocumbi assisted EDCTP in building political support for the programme, particularly in Africa. He was engaged in many international meetings with high-level representatives from Africa and Europe, including a meeting with the then President of the European Commission, José Manuel Barroso, and other stakeholders to discuss the challenges related to HIV/AIDS, tuberculosis and malaria. In 2011, he represented EDCTP at the Senior Officers Meeting of



the EU-AU dialogue. Moreover, he addressed the High-Level Meeting on the second EDCTP programme in Cape Town, South Africa (2012), and the Second High-Level Meeting on EDCTP2 in Dakar, Senegal (2013).

EDCTP Governance

EDCTP work plan 2015

The EDCTP work plan for 2015 was approved by the European Commission on 3 September 2015 and by the General Assembly of the EDCTP Association on 5 October 2015. The work plan describes activities under EDCTP in 2015, including the PSIA's (Participating State Initiated Activities), which are funded and implemented directly by one or more EDCTP member countries and are considered an integral part of the EDCTP2 programme.

Scientific Advisory Committee

The Scientific Advisory Committee (SAC) met in The Hague on 8-9 October for its autumn meeting. It discussed updating the EDCTP Strategic Business Plan, possible Eighth **EDCTP Forum programme** topics and the EDCTP Work plan 2016, among other topics. The SAC also discussed future stakeholder meetings as well as the 2017 work plan.

General Assembly meeting

The EDCTP-EEIG and EDCTP Association General Assembly meetings took place in The Hague on 12-13 November

2015. The GA decided that the Eighth EDCTP Forum would take place in Lusaka, Zambia 2016. The meeting (which was attended for the first time by the representative of the new member country Gabon, Dr Ayola Akim Adegnika) also discussed the work plan for 2016 and approved the decisions made by the Association Board.

EDCTP staff



Ms. Shingai Machingaidze joined EDCTP Africa Office as Project Officer on 1 September 2015. She is an epidemiologist by training, with a particular interest in vaccines and vaccination programmes, as well as the translation of research into policy and practice.

Before joining the EDCTP, Ms Machingaidze worked as a researcher at the University of Cape Town (UCT), South Africa, for five years with the South African TB Vaccine Initiative (SATVI), as well as with the Vaccines for Africa Initiative.



She was born and raised in Harare, Zimbabwe. She studied at UCT and completed a Master of Public Health in epidemiology in 2011. Currently, she is finalizing her PhD in International Health with the Centre for International Health (CIH), University of Munich (LMU).



Former EDCTP Project Officer Dr Michelle Singh returned to the Africa Office as dedicated Project Officer for the EDCTP participation in the TRUST project (see p. 4), also as of 1 September 2015. Prior to worked at EDCTP, the South African Medical Research Council and the University of KwaZulu-Natal where she

managed maternal and child health research studies and clinical trials, with a strong focus on prevention of perinatal HIV transmission.

Michelle Singh was born in Durban, South Africa. She graduated with a Master of Biomedical Science (2003) and obtained a PhD from the University of KwaZulu-Natal in 2010.



At the office in The Hague, Project Officer Mr Pete Murphy moved to the newly established position of Grants Management System Administrator, effective re-joining EDCTP, Michelle Singh from 12 October 2015. This new role is related to the new grants application system that was adopted for the second EDCTP programme in 2014.

Calls & Grants

Calls for Proposals: new calls since October 2015

In October and November 2015, EDCTP launched the following calls for proposals:

- Ethics and regulatory capacities
- EDCTP-TDR Clinical Research and Capacity Development Fellowships
- EDCTP Regional Networks
- · Senior Fellowships
- Career Development Fellowships

The launch of these calls followed the approval of the EDCTP work plan for 2015 by the European Commission on 3 September 2015 and the General Assembly of the EDCTP Association on 5 October 2015.

Ethics and regulatory capacities

The purpose of this Call for Proposals is to support sub-Saharan African countries to establish and develop robust national medicines regulatory systems and capacities for ethical review of clinical research and use of medicinal products and technologies for use in humans. This scheme targets both National Ethics Committees (NECs) and National Regulatory Authorities (NRAs).

Type of action: Coordination & Support Action (CSA)

Call budget: € 1.5 M **Funding maximum:** € 300,000

Funding level: 100% of eligible costs
Opening date: 15 October 2015, 17:00
Closing date: 21 January 2016, 17:00

EDCTP-TDR Clinical Research and Development Fellowships

The purpose of this Joint Call for Proposals is to support researchers and key members of clinical trial research teams from low- and middle-income countries to acquire specific skills in clinical research and development through placements in pharmaceutical companies and PDPs.

Placements are for 6 months up to 24 months, followed by a re-integration period of 6 months according to an approved plan.

Type of action: Training & Mobility Actions (TMAs)

Call budget: € 3 M

Funding level: 100% of eligible costs

Stage 1 (Proposal):

Opening date: 22 October 2015, 17:00 Closing date: 28 January 2016, 17:00

Stage 2 (Training plan - EDCTP only):

Opening date: 14 June 2016 Closing date: 21 July 2016

EDCTP Regional Networks

The purpose of this Call for Proposals is to support regional networking in sub-Saharan Africa in order to build and strengthen regional, national, institutional and individual capacities to conduct clinical trials in line with the international guidelines for Good Clinical Practice (ICH-GCP).

The networks should build on results from former EDCTP-funded regional networking actions.

Type of action: Coordination & Support Actions (CSAs)

Call budget: € 12 M **Funding maximum:** € 3 M

Funding level: 100% of eligible costs
Opening date: 5 November 2015, 17:00
Closing date: 18 February 2016, 17:00

Senior fellowships

The purpose of this Call for Proposals is to support the careers of potential African research leaders who will serve as long-term trainer-of-trainers and mentors for junior researchers with emphasis on hands-on research training linked to clinical trial activities.

Type of action: Training & Mobility Action (TMA)

Call budget: € 2.5 M **Funding maximum:** € 500,000

Funding level: 100% of eligible costs

Opening date: 12 November 2015, 17:00

Closing date: 4 February 2016, 17:00

Career development fellowships

The purpose of this Call for Proposals is to support junior and mid-career researchers to train and develop their clinical research skills.

Type of action: Training & Mobility Action (TMA)

Call budget: € 1.5 M **Funding maximum:** € 150,000

Funding level: 100% of eligible costs
Opening date: 12 November 2015, 17:00
Closing date: 4 February 2016, 17:00

Grants for Ebola research capacity

Six institutions in Africa and Europe have been awarded funding to strengthen capacity in sub-Saharan Africa to conduct high quality health research during health emergencies and/or epidemic outbreaks. The proposals were developed in response to the Ebola virus disease (EVD) outbreak in West Africa, and they address individual, institutional, national and regional capacity.

"The broader goal of sustainable health system preparedness requires a stronger research base in sub-Saharan Africa. Research capacity in African countries with a good balance of suitable infrastructure and human resources is essential for sustainable health system resilience, research uptake and the future health of African populations." - Dr Michael Makanga (Director of South-South Networking and Head of Africa Office)

A total of 37 admissible proposals were received. After independent review, six proposals were approved for funding. All projects are funded contingent on satisfactory contract negotiations. Three recipients are based in Africa and three are in Europe, working in Africa and with African partners. The projects range from enhancing capacity for clinical trials to health system rebuilding. TDR (the Special Programme for Research and Training in Tropical Diseases) and EDCTP will provide the €1.49 million of funding. Visit the EDCTP website for an overview of grantees and projects.

Focus on Projects

TRUST: global ethics consortium

TRUST is a global ethics consortium coordinated by Prof. Doris Schroeder, Director of the Centre for Professional Ethics, University of Central Lancashire (UCLan) and funded from the Horizon 2020 programme of the European Union. This is a threeyear coordination and support action project that aims to catalyse a global collaborative effort to improve adherence to high ethical standards in research in low- and middleincome countries.

The project's strategic outputs include three sets of tools based on participatory engagement covering all continents: 1) a global code of conduct for funders, 2) an online tool enabling fair research contracting, and 3) a compliance and ethics follow-up tool.

The TRUST kick-off meeting was co-organised by UNESCO (the United Nations Educational, Scientific and Cultural Organization) and UCLan and took place at the UNESCO Headquarters in Paris, France from 5-6 October 2015. EDCTP was represented by Dr. Michael Makanga (Director of the South-South Cooperation and Head of the Africa Office) and Dr. Michelle Singh (Project Officer). The TRUST consortium plans to meet again in May 2016 in Nairobi, Kenya.

EDCTP's role in this exciting project includes leading and establishing the funder's platform within TRUST by developing an inventory of large research funders, organizing funder workshops, funder engagement and contributing towards ethics policy briefs emanating from this project.

TRUST offers a global perspective on ethics through its diverse and interdisciplinary group of partners, advisors and stakeholders. These include: Action contre la faim, the

Council on Health Research for Development, EDCTP, European Commission, the Forum for Ethics Review Committees in India, Foundation Global Values Alliance, l'Institut national de la santé et de la recherche médicale, Partners for Health and Development in Africa, Sanofi, Signosis, South African San Institute, UCLan, UNESCO, the University of Cape Town, the University of the Witwatersrand and the Wellcome Trust.

CHAPAS-3: high efficacy of paediatric **ART**

The EDCTP-funded CHAPAS-3 trial, coordinated by Dr Veronica Mulenga (University Teaching Hospital, Zambia), is the first randomised controlled trial in African children to compare three 'backbones' for antiretroviral treatment (ART) regimens. All regimens were shown to have low toxicity and good clinical, immunological, and virological responses. This trial provides strong evidence to support the WHO guidelines for first-line paediatric ART. The trial allays concerns of reduced efficacy raised by observational studies. The results, published in The Lancet Infectious Diseases in October 2015, support clinicians and policy makers in implementing the current WHO guidelines for ART in children.

The CHAPAS-3 (Children with HIV 1 in Africa, Pharmacokinetics and Adherence/Acceptability of Simple Antiretroviral Regimens) was an open-label randomised phase II/III trial conducted in Zambia and Uganda to evaluate new solid, dispersible scored antiretroviral fixed-dose combination and single drugs in African children. A total of 478 children (age 1 month to 13 years) were randomised to study arms which received fixed-dose combination tablets of one of the three NRTIs (abacavir, stavudine, or

zidovudine) plus lamivudine in combination with nevirapine or efavirenz. All combinations were dosed according to WHO weight bands. The trial included 365 ART-naive children and 113 virologically suppressed ART-experienced children on a stavudine-containing first-line regimen for 2 years or more. The and efficacy of the artemisinintrial compared the pharmacokinetics, toxicity, acceptability, adherence, efficacy and costeffectiveness of these first-line antiretroviral regimens. The study drugs were donated by CIPLA Pharmaceuticals, India.

Publication: The Lancet Infectious Diseases, 6 October 2015: V. Mulenga et alii, Abacavir, zidovudine, or stavudine as paediatric tablets for African HIV-infected children (CHAPAS-3): an open-label, parallel-group, randomised controlled trial. DOI: 10.1016/ S1473-3099(15)00319-9

WANECAM: repeat treatment with Pyramax approved

The West African Network for Clinical Trials of Antimalarial Drugs (WANECAM) trial, a large, phase IIIb/IV multicentre clinical study, led by Prof. Abdoulaye Djimdé, University of Science, Techniques and Technologies of Bamako, Mali, was designed to evaluate the safety and effectiveness of two new ACTs,

namely Eurartesim® and Pyramax®. Over a 2-year period, patients were randomised and treated with the same antimalarial each time they had a malaria episode.

Data from the Pyramax® sub-study showed the safety based combination therapy (ACT) Pyramax® (pyronaridineartesunate) when used for the re-treatment of adults and children (over 5 kg body weight). The results, published in The Lancet Infectious Diseases, were subsequently used to support a successful application for a label change to allow for re-treatment with the Pyramax® medicine and support its use in all malaria-endemic regions including sub-Saharan Africa, where the global burden of malaria weighs most heavily.

On 20 November, 2015, The European Medicines Agency (EMA) published a positive scientific opinion on Pyramax® under the EMA's article 58 process (evaluation of medicinal products intended exclusively for markets outside the European Community) Pyramax® was developed by Shin Poong Pharmaceutical and Medicines for Malaria Venture. The new label allows it to be used for treating multiple episodes of malaria in the same person after registration in malaria-endemic countries.



Focus on Projects (continued)

Even more excitingly, the child-friendly fixed-dose ACT Pyramax® Granules is the first paediatric antimalarial to be approved by the EMA.

"We congratulate the study team and the MMV-Shin Poong partnership with this important result. Multiple episodes of malaria in the same person are a common occurrence in high-endemic areas, especially in Africa. This study provides valuable safety data to address this challenge. Moreover, a child-friendly formulation is made available for use in this high-risk patient population."

- Dr Michael Makanga

The WANECAM trial budget with a total value of almost €12.5M was mainly funded by MMV and EDCTP. Other funders are the UK Medical Research Council, Swedish International **Development Cooperation** Agency, German Ministry for Education and Research, University Claude Bernard (Lyon, France), Malaria Research and Training Centre (Bamako, Mali), Centre National de Recherche et de Formation sur le Paludisme (Burkina Faso), Institut de Recherche en Sciences de la Santé (Bobo-Dioulasso, Burkina Faso), and Centre National de Formation et de Recherche en Santé Rurale (Republic of Guinea).

Publication: Issaka Sagara, PhD et alii, Safety and efficacy of re-treatments with pyronaridine-artesunate in African patients with malaria:

a substudy of the WANECAM randomised trial *The Lancet Infectious Diseases* 22 October 2015, DOI: http://dx.doi.org/10.1016/S1473-3099(15)00318-7

PROMISE-PEP: Successful protection of infants during breastfeeding

Final results from the PROMISE-PEP/ANRS12174 study show that two liquid formulas of HIV drugs are safe and highly effective at protecting infants from infection while they are breastfed by their HIV-positive mothers, including in the 6-12 month period after birth which has not been studied in previous research. The clinical trial was coordinated by Professor Philippe Van de Perre (INSERM, Montpellier, France) and funded by ANRS (France Recherche Nord&Sud Sida-HIV Hépatites), the Research Council of Norway/University of Bergen as well as EDCTP.

"EDCTP applauds the study team for their research output with important results. This study demonstrates the value of research towards the protection of children at their most vulnerable age. It addresses the important challenge of improving maternal and child health in Africa."

- Dr Michael Makanga

The PROMISE-PEP was a randomised controlled clinical trial, conducted in Burkina Faso, South Africa, Uganda and Zambia. It compared two prophylactic treatment regimens to prevent transmission of HIV from mother to child during 12 months of breastfeeding from day 7 until 4 weeks after cessation of breastfeeding (maximum duration of prophylaxis: 50 weeks for a recommended maximum duration of breastfeeding of 49 weeks). Between November 2009, and May 2012, 1273 infants were enrolled and 1236 were analysed; 615 assigned to lopinavir-ritonavir and 621 assigned to lamivudine. The HIV-infected mothers involved were not receiving ARV therapy after giving birth as per WHO guidelines at the time of recruitment. A total of 17 HIV infections were diagnosed in the study period resulting in cumulative HIV-1 infection of 1.4% and 1.5%, respectively. Infection rates did not differ between the two drug regimens.

Publication: Nicola Nagot et alii, Extended pre-exposure prophylaxis with lopinavirritonavir versus lamivudine to prevent HIV-1 transmission through breastfeeding up to 50 weeks in infants in Africa (ANRS 12174): a randomised controlled trial. *The Lancet*, 18 November 2015. DOI: http://dx.doi.org/ 10.1016/ S0140-6736(15)00984-8

strategy 2016-2030, the WHO End TB strategy, and the new 2015-2023 business plan of the Drugs for Neglected Disease *initiative*, among many other topics.

Country visit: The Gambia/Guinea Bissau

Dr Ole Olsen (Director, North-North Cooperation) and Dr Thomas Nyirenda (South-South Networking and Capacity Development Manager) visited EDCTP-funded research projects in The Gambia and Guinea Bissau from 28 September to 2 October 2015.

The Gambia joined the EDCTP Association in 2014 and the EDCTP team met with the Minister of Health and Social Welfare, Hon Omar Sey.

Subsequently, discussions were held at the ministry on the country's EDCTP-related work plans for 2015 and 2016.

EDCTP was also invited to the annual joint meeting of the ministry and the MRC The Gambia Unit on 30 September 2015.



The Bandim Project in Guinea Bissau is the site of studies in the areas of TB vaccines and diagnostics, HIV vaccines, and for capacity development (WANETAM Plus). EDCTP assessed the research facilities and clinics.

Financial standards for not-for-profit sector

On 5-6 October 2015, EDCTP Director of Finance and Administration, Mr. Abdoulie Barry, participated in meetings at the Wellcome Trust, held in London, United Kingdom. The meetings aimed to contribute to the development of

Meetings

9th ECTMIH 2015

The European Congress on Tropical Medicine and International Health was held in Basel from 6-10 September 2015. The 2000 participants from 102 countries discussed the most pressing global health problems, including the spread of drug resistance, dealing with sporadic infectious diseases such as Ebola, and the new UN sustainability goals. EDCTP was represented by Dr Gabrielle Breugelmans (North-North Networking Manager), Dr

Montserrat Blázquez (Senior Project Officer) and Daniella Pereira (Communications Officer) who organised the EDCTP information booth.

Highlights of importance to EDCTP were the draft malaria

Meetings (continued)

international financial reporting and quality standards for the not-for-profit sector as well as standards for Good Financial Grant Practice (GFGP). For more information see www.mango.org.uk and www.aasciences.org.

G7 Science ministers commit to fight NTDs and PRDs

On 8 and 9 October 2015, the G7 Ministers of Science discussed in Berlin, Germany the coordination of research efforts regarding global issues of health. In their statement, the Ministers of Science expressed their resolve to support the fight against neglected tropical and poverty-related infectious diseases in line with the declaration of the G7 Leaders at their meeting in Elmau, Germany on 8 June 2015. EDCTP was indicated as one of the mechanisms to be built upon.

It is possible not only to control most of these diseases, but even to eradicate many of them."

World Health Summit Berlin 2015

At the World Health Summit (Berlin, Germany 11-13 October 2015), Dr Michael Makanga (Director of South-South Cooperation and Head of Africa Office) was a speaker at the workshop on 'Sustainable research capacity strengthening: aiming beyond outbreaks and emergencies'. He presented the EDCTP strategy for developing research capacity in sub-Saharan Africa.

EU response to the 2015 Ebola outbreak

From 12-14 October, Dr Michael Makanga also participated as a speaker at the EU Conference on 'Lessons learned for public health from the Ebola outbreak in West Africa: how to improve



The main health research action points decided on were:

1) Fighting Neglected Tropical Diseases (NTDs); 2) Maximising research impact by better coordination of on-going and planned research on Poverty-Related Diseases (PRDs); and 3) Continued financial support for relevant R&D and operational research on PRDs and NTDs.

EDCTP Executive Director, Prof. Charles Mgone, was invited to present the EDCTP programme on 8 October 2015. In his speech he stressed that: "... the battle against neglected and poverty-related diseases can be won.

preparedness and response in the EU for future outbreaks' organised under the Luxembourg Presidency. The conference was well attended (360 delegates) with high level political representation as well as strong representation from the international R&D and humanitarian partners involved in the fight against Ebola. Dr Makanga was invited to speak on the role of EDCTP and was a member of the discussion panel.. The role of EDCTP was specifically recognised in the recommendations on R&D that ultimately will be passed on to the European Council of Ministers.

European ESTHER Alliance annual conference of the

Dr Gabrielle Breugelmans attended the annual meeting of the European ESTHER Alliance (EEA) in Dublin, Ireland on 13 October 2015. The ESTHER initiative contributes to the implementation of its member states' policies for health sector development aid. The organisation counts 12 members. Currently, its scope encompasses most global health priorities including capacity development, notably through its North-South hospital twinning.

In light of the new EEA Strategic Framework 2015–2020 EDCTP was invited to present its programme and discuss opportunities for collaboration, e.g. operational research. See also www.esther.eu.

Institut Pasteur International Network

Dr Ole Olesen (Director of North-North Cooperation) attended the annual scientific symposium – Paving the way for research on Global Health and One Health – which was organised by the Institut Pasteur International Network in Paris on from 14-16 October. He cochaired a plenary session on 'Global Health Education'. More information on www.pasteur-network-meeting2015.org.

Ethics symposium at ASTHM 2015

Wellcome Trust and EDCTP organised a symposium on health research ethics at the

annual conference of the American Society for Tropical Medicine and Hygiene (ASTMH) in Philadelphia USA from 25-29 October 2015. For EDCTP Prof. Charles Mgone, Dr Pauline Beattie (Operations Manager) and Ms Nuraan Fakier (Project Officer) attended.

The symposium, held on 28 October, consisted of four talks by speakers with extensive knowledge of ethical issues around clinical trials in disease-endemic countries. The programme focussed on informed consent. The meeting concluded with recommendations for ethical research and best practices in conducting trials in low- and middle-income countries.

ANDI: 5th stakeholder meeting

The African Network for Drugs and Diagnostics Innovation (ANDI) held its 5th Stakeholder Meeting in Nairobi, Kenya, from 23-25 November 2015. The event focused on 'Partnerships and Financing for Transformative, Accessible and Sustainable Health Technologies in Africa'.

EDCTP was represented by Dr Ole Olesen, who is also a member of ANDI's Scientific and Advisory Committee. He gave a plenary presentation about the EDCTP programme on 23 November and chaired the plenary session about the ANDI Strategic Plan for 2016-2020 on 25 November.

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 0690 Fax: +27 21 938 0569

Web: www.edctp.org

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