

Note from the Executive Director

Mission focus

It is an exciting, transformational and challenging time to take the helm of the EDCTP Executive Secretariat. The second EDCTP programme (EDCTP2) is steadily gaining momentum and all EDCTP constituencies are encouraged to stay the course and rise to the challenges of greater ambitions and higher expectations.

EDCTP2 is an ambitious programme that aims to fund large clinical trials, develop research capacity, and align national research efforts. Its remit includes many more poverty-related and neglected infectious diseases as well as all phases of clinical trials. The expanded remit of the programme increases the need for mission focus in diversity.

EDCTP's reason for existence remains the same: to contribute to the reduction of the social and economic burden of poverty-related diseases in sub-Saharan Africa. Our mission is to accelerate the clinical development of effective, affordable, safe and accessible

medical interventions against poverty-related infectious diseases.

International cooperation and coordination are vital for achieving our mission goals and are at the heart of the EDCTP approach. We expect the best results through alignment and coordination of national research programmes in partnership with the private sector and other stakeholders including international development partners. Capacity development in sub-Saharan Africa in the areas of clinical research, ethical review and regulatory functions remains an important element of this approach.

As an organisation we have started implementing a results-based management approach and our systems and processes have been strengthened to meet the requirements for effective delivery of EDCTP2. Measurable indicators for our performance and expected impact of the programme are being refined progressively.



Importantly, EDCTP is seeking for two High Representatives - one with a special focus in Africa and the other in Europe. As goodwill ambassadors they will increase our high-level visibility and support us in achieving wider collaboration with national governments, other funding agencies, industry and non-governmental partners.

I am confident EDCTP2 will satisfy the justifiable expectations and contribute to the hoped-for reduction of the burden of poverty-related diseases in sub-Saharan Africa. Above all - with a first evaluation of the programme already on the 2017 horizon - we need to focus on our mission.

Michael Makanga

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Calls & Grants

Pre-announcement: 2016 Call topics

Subject to the approval of the European Commission and EDCTP General Assembly, in 2016 EDCTP expects to launch calls for proposals on:

- Clinical trials aiming to accelerate the clinical development of new vaccines (preventive or therapeutic) against poverty-related diseases
- The establishment of a consortium for research and clinical management of patients in PRD epidemics in sub-Saharan Africa
- Strategic actions supporting large-scale clinical trials that have the potential to achieve rapid advances in the clinical development of new or improved medical interventions against PRDs
- Clinical trials and operational research studies to optimise the use of products for PRDs in mothers, new-borns, children and/or adolescents (RIA)
- Strategic actions supporting health systems/services optimisation research capacities in cooperation with development assistance initiatives, including the development of pharmacovigilance capacities in sub-Saharan Africa and the translation of research into policy and practice (CSA)
- Ethics and regulatory capacities to strengthen the functionality, recognition and performance of National Ethics Committees and National Regulatory Authorities in sub-Saharan African countries (CSA)
- EDCTP-TDR Clinical Research and Development Fellowships for junior to mid-career researchers or clinical staff from low- and middle-income countries to provide targeted training in research and development within pharmaceutical companies and product development partnerships
- Senior Fellowships to support the capacity development of potential African research leaders



Calls & Grants (continued)

- Career Development Fellowships to support junior to mid-career researchers to train and develop their clinical research skills
- Preparatory Fellowships to enhance the competitiveness of up and coming post-doctoral African scientists and clinicians aspiring to win international/regional/national fellowships or grant support.

First funded projects of EDCTP2

Call: Maximising the impact of EDCTP research: translation of research results into policy and practice

Improving the impact of existing malaria products – ACTs (IMPACT)

Project coordination: Anja Terlouw / Liverpool School of Tropical Medicine, United Kingdom with partners from Malawi, South Africa and United Kingdom

Duration: January 2016 – December 2017 (24 months)

Grant budget: € 499,293

Grant agreement: CSA-2014-282

Maximising the public health impact of interventions to control malaria in pregnancy through the translation of EDCTP-funded evidence-based global policies to country-level policies and plans (IMPP-ACT)

Project coordination: Jenny Hill / Liverpool School of Tropical Medicine, United Kingdom with partners from The Gambia, Malawi, Mali and United Kingdom

Duration: January 2016 – December 2017

Grant budget: € 487,463

Grant agreement: CSA-2014-276

Tuberculosis: working to empower the nation's diagnostic effort (TWEENDE)

Project coordination: Wilber Sabiiti / University of St Andrews, United Kingdom with partners from Kenya, Tanzania and Uganda

Duration: January 2016 – December 2017

Grant budget: € 439,047

Grant agreement: CSA-2014-283

Improving HIV prevention and sexual and reproductive health care in high-risk women in Rwanda using lessons learnt from previous Rinda Ubuzima projects (WISH)

Project coordination: Janneke van de Wijgert / University of Liverpool, United Kingdom with partners from Belgium and Rwanda

Duration: January 2016 – December 2017

Grant budget: € 499,741

Grant agreement: CSA-2014-273

Call: Research capacity development in support of the EVD response

Enhancing capacity for phase 1 clinical trials in Uganda (Capa-CT)

Project coordination: Infectious Diseases Institute Ltd, Uganda with a partner from Ireland

Duration: February 2016 – January 2018

Grant budget: € 124,512

Grant agreement: CSA-Ebola-2015-353

Building research capacity in clinical management of infectious diseases at two main adult government hospitals in Freetown, Sierra Leone (Clinical Capacity)

Project coordination: King's College London, United Kingdom with partners from Sierra Leone

Duration: February 2016 – January 2018

Grant budget: € 249,938

Grant agreement: CSA-Ebola-2015-360

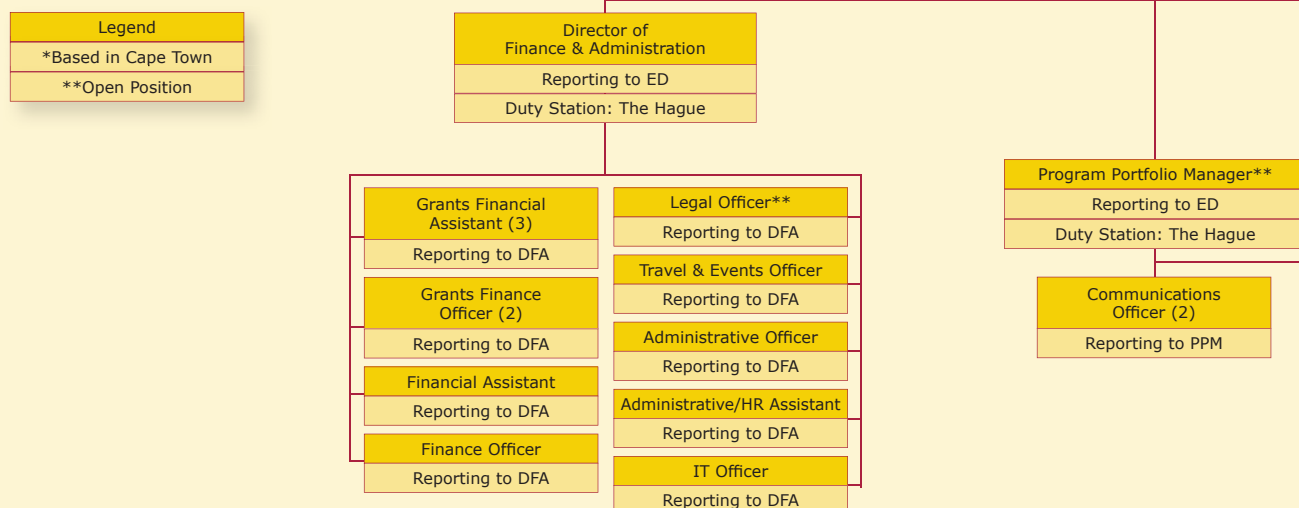
Enhancing individual and institutional infectious disease outbreaks response capacities of healthcare professionals to mitigate infectious emergencies in the Northern Uganda region (ENDORSE)

Project coordination: University of Milan, Italy with partners from Ireland, Italy and Uganda

Duration: February 2016 – January 2018

Grant budget: € 194,865

Grant agreement: CSA-Ebola-2015-337



EDCTP Governance

Programme Portfolio Manager

The second EDCTP programme is significantly larger than the first. With a bigger scope and a bigger budget came higher expectations of accountability and results. As an organisation EDCTP aims for a strong mission focus and results-based management of the activities. New functions will be created in the Secretariat that support this focus on results and key performance indicators.

Under the supervision of the Executive Director, the Programme Portfolio Manager will be responsible for the management of the communication, monitoring and evaluation functions in the organisation. The Programme Portfolio manager will be supported by a Monitoring and Evaluation officer. An important aspect of the function will be the implementation of results-based management (RBM) with the aim of improving effectiveness and accountability by clearly defining expected results, monitoring progress toward the achievement of expected results, integrating lessons learned and reporting on performance. Moreover, creating greater

awareness of EDCTP-supported activities and project outputs and outcomes will be important as well as keeping all EDCTP stakeholders regularly informed of developments at EDCTP.

EDCTP staff



Dr Christy Comeaux started working as Project Officer at EDCTP in December 2015. Previously, she worked as a physician in the Department of Obstetrics and Gynaecology at an academic hospital in The Netherlands. Throughout her study and training, Christy has had an ongoing interest in infectious diseases as well as maternal and child health in low- and middle-income countries. Christy Comeaux was born and raised in the United States. After obtaining a Bachelor's of Science degree in Biomedical Engineering at Johns Hopkins University in Baltimore, Maryland, she moved to Boston, Massachusetts for her

graduate studies. Her major research areas were tuberculosis and malaria. She earned her PhD in Biological Sciences in Public Health (Harvard, 2009) for a study of epigenetic regulation of virulence factors in the human malaria parasite *Plasmodium falciparum*. She received her medical degree in 2012 from Harvard Medical School.



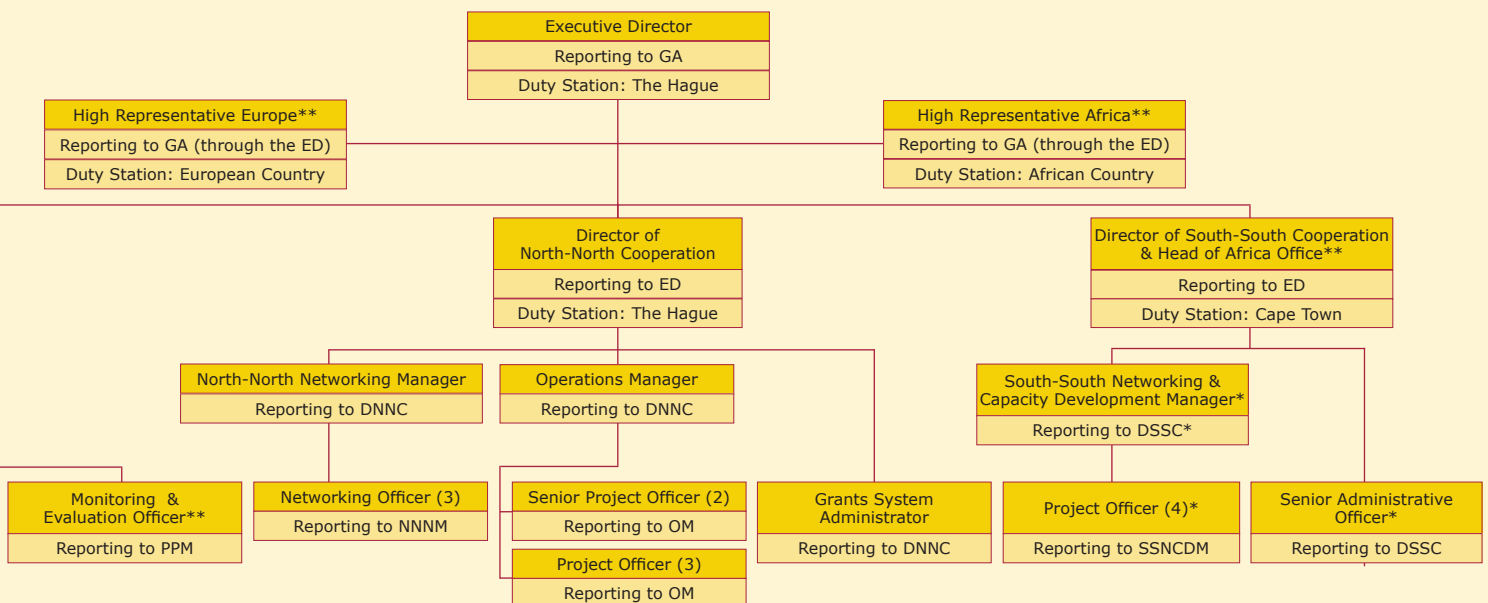
Dr Michelle Helinski joined EDCTP in December 2015 as Project Officer. Prior to joining EDCTP, Michelle worked as a Vector Control Specialist with the NGO Malaria Consortium in Uganda where she provided technical support to vector control-related activities and operational research projects in sub-Saharan Africa. She obtained a Master's in Biology and PhD in Medical Entomology from Wageningen University in the Netherlands before conducting post-doctoral studies at Cornell University in

the USA. Her research focused on the reproductive biology of disease transmitting mosquitoes and the feasibility of applying the Sterile Insect Technique for the control of African malaria vectors.



Erica Bass joined the EDCTP team as temporary Communications Officer in November 2015. Erica is from South Florida, USA and has lived and worked in the Netherlands since April 2014. Erica brings years of experience in the areas of marketing, public relations, and company branding. She obtained a degree in Advertising and Media Studies from the University of Florida in Gainesville, Florida, USA.

In January, two long-time staff members - **Jing Zhao** (Grants Financial Officer) and **Hager Bassyouni** (Networking Officer) left EDCTP for the next step in their professional careers.



Updating the organisational chart

Focus on the EDCTP Member Countries

Participating States' Initiated Activities

The EDCTP Association currently has 14 European and 14 African countries as members. These 28 countries are formally known as the Participating States and they fund and implement a broad array of national research activities that are in the scope of the second EDCTP programme and contribute to its objectives. While funded and implemented independently from EDCTP, these activities are - under certain conditions - considered an integral part of the EDCTP programme and are very important for the funding of the activities initiated by EDCTP under Horizon 2020.

As members of the EDCTP Association, the Participating States are required to contribute at least € 400,000 within a two-year period to EDCTP. This contribution consists of cash contributions as well as the fair value of

in-kind contributions. The in-kind contributions comprise non-cash resources allocated either directly to EDCTP, to EDCTP-funded projects or to activities that fall in the scope of EDCTP2 but that are financed and managed by the countries themselves, the so-called Participating States' Initiated Activities or PSIAAs.

These PSIAAs therefore have an important role to play in achieving the objectives of the EDCTP programme:

- All PSIAAs count towards the minimum membership amount required in the EDCTP Association.
- PSIAAs implemented and funded by European Participating States count towards the matching of funds by the European Union. PSIAAs are therefore an important means of ensuring that the maximum EU contribution of € 683 million

can actually be used to fund EDCTP Calls for Proposals.

- PSIAAs also promote research collaboration in Europe and sub-Saharan Africa.
- PSIAAs support EDCTP in achieving its objective of promoting international research cooperation and integration of national research programmes and activities.

To develop the PSIAAs as a strong and transparent instrument for achieving the EDCTP2 objectives, the Participating States submit their PSIAAs annually in time for incorporation in the next EDCTP annual work plan. The proposals provide essential project information such as objectives, deliverables, alignment with the EDCTP2 programme, collaborating African and European partners as well as an indication of the total value of national public

funding commitments. This identification in advance of PSIAAs facilitates an independent peer review by a committee established by the European Commission. This committee provides an opinion on the eligibility of the PSIAAs for inclusion in the EDCTP2 annual work plan. Final acceptance of the projects as in-kind contribution to the EDCTP2 programme is dependent upon approval by the European Commission of technical and financial reports by the Participating States. If approved and provided they are publicly labelled as part of the EDCTP programme, the PSIAAs will be counted as in-kind contributions and its value will be matched by cash contributions from the European Union to EDCTP2.

Austria: UNESCO chair for bioethics

Dr Christiane Druml, the representative of Austria in the EDCTP General Assembly, has

become the holder of the UNESCO Chair for Bioethics at the University of Vienna. The

inaugural lecture was held on 26 January 2016. Dr Michael Makanga, EDCTP Executive

Director, was present at the ceremony. It is the first chair in bioethics at an Austrian University; its offices will be in the Institute for the History of Medicine and the Collections of the Medical University of Vienna.



Dr Christiane Druml with (left to right) Wolfgang Schütz (former Rector of the Medical University of Vienna), Markus Müller (Rector of the Medical University of Vienna), Manfred Nowak (Vice-president of the Austrian UNESCO-Committee), Michael Makanga (Executive Director EDCTP), Peter Kremsner (Director of the Institute for Tropical Medicine, University of Tübingen), Nada Al-Nashif (Assistant Director General UNESCO).

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The next four years Dr Druml will cooperate with the UNESCO Bioethics programme and develop a network of researchers with its European, African and Asian partners in this field. One of the main objectives will be to reinforce and increase capacity in the area of ethics research and of ethics education. Other important issues are the cooperation with African researchers and the promotion of ethics capacity in North-South research as well as the strengthening of the position of women in bioethics.

Interview with Charles Mgone *By Daniela Pereira*

Born in Tanzania, Charles Mgone initially trained as a clinician in Tanzania and the United Kingdom, practicing and teaching paediatrics as well as conducting research. In the UK he earned a PhD in Medical and Molecular Genetics, a discipline which he continued to pursue through the study of various infectious diseases.

"I was looking at the pathogenesis of infectious diseases, looking at why individuals are susceptible or not to certain diseases, mostly tropical infectious diseases. That is how it all started. Gradually I was working more and more on malaria and HIV, and later tuberculosis also."

In this period Prof. Mgone served as the Deputy Director and later Acting Director of the Papua New Guinea Institute of Medical Research. Once back in Africa, he became the Network Director of the African Malaria Network Trust (AMANET) responsible for accelerating the development of



malaria vaccines and other interventions. In this role, he was responsible for developing and overseeing capacity development of African institutions and scientists conducting clinical trials.

"After three years working with AMANET, I was invited to join EDCTP. The programme was a big and interesting challenge for me. EDCTP allowed me to work with the three major infectious diseases as I did before – HIV, TB and malaria – and on all interventions."

Initially, he was appointed as Head of the EDCTP Africa Office

in Cape Town in 2005. In 2007, Prof. Mgone became the EDCTP Executive Director.

"The very concept of EDCTP was a big challenge. The idea was to make European countries work together and integrate their programmes of HIV, TB and malaria. But the problem was that quite a lot of them didn't have any programmes at all. And secondly the concept was to work in partnership with sub-Saharan African countries. Many European countries did not have a tradition of working with African countries. The third challenge was to have a buy-in from partners in the private sector."

In 2007, under his leadership, EDCTP introduced the grant scheme for integrated projects. In this approach projects have to integrate capacity building, networking and project management activities in the core activity of the clinical trials. The objective was to develop African research capacity for conducting clinical trials. The integrated projects also required the participation of at least two sub-Saharan African countries in each project.

"Where there was no pharmacologist, we trained one. Where there was no data manager, we trained one and on the job. I think this worked very well and I see it as a huge achievement. Putting this framework together, and getting the partnership to work, building the trust and the capacity for Africans to apply themselves without waiting for European partners – that was one of the more important achievements, one of the biggest."

With EDCTP2, the governance has also fundamentally changed with sub-Saharan African countries sitting as full members in the governing body.

Asked for his wishes for the future of EDCTP, Prof. Charles Mgone said that he would like to see even stronger ownership by

the African and European countries. "Not every European country is pulling its weight in equal measure. Ownership requires real money directly into EDCTP. African countries also should directly engage in financing the programme. The ideal thing would be for EDCTP to become more autonomous, so that even without the European Union funding the programme can work."

Prof Mgone especially praised the various advisory bodies that served and serve EDCTP and

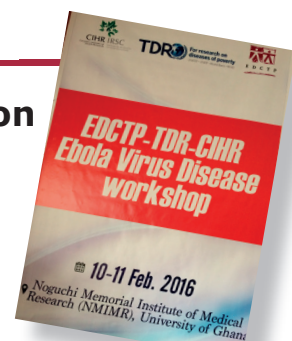


pointed to the crucial role of the scientists. "They are the ones doing the work. Whatever achievement we had, we could not have done it without the scientists. And the scientists could not have done their work without the volunteers who participate in the studies. EDCTP is where it is because of the work and efforts of many different important parties. They all pulled their weight."

Focus on projects

International collaboration on Ebola research

Six grantees funded by EDCTP, UK Medical Research Council, National Health Research Institute Carlos III, and TDR (the Special Programme for Research and Training in Tropical Diseases) and another 12 grantees funded under a separate grant scheme of the Canadian Institutes of Health Research (CIHR) met for a workshop at the University of Ghana on 10-11 February 2016. The workshop is a result of coordination between the funders in keeping with the objectives of the GLOPID-R (Global Research Collaboration for Infectious Diseases Preparedness). These grantees were recently selected to conduct a range of research projects from basic science to implementation research, including capacity development and models of clinical care. Each project comprises collaborative activities between institutions in African and in Europe and Canada. Thirty-two researchers from 18 projects met for an Ebola Virus Disease (EVD) workshop to share their planned studies, identify possibilities of collaboration and finalise project plans. The workshop was hosted by the Noguchi Memorial Institute of



Medical Research at the University of Ghana and chaired by Dr Thomas Nyirenda (EDCTP) and Dr Marc Ouellette (CIHR). Each grantee presented their project plans and case studies and lessons learnt from the Ebola crisis, mainly in West Africa, were also summarised. Dr Francis Kateh, Deputy Minister of Health Services & Chief Medical Officer for Liberia, presented on Liberia's Ebola outbreak management, post-outbreak efforts and the need for greater research capacity there. Professor Fred Binka, Foundation Vice-Chancellor of the University of Health and Allied Sciences in Ghana, reviewed ethical and regulatory dilemmas that had been encountered in Ghana with early phase clinical trials during the recent EVD outbreak and emphasised the importance of strategic community engagement and the education of all stakeholders from an early stage in the research planning and its conduct.

Meetings

Challenges in vaccine development

EDCTP Project Officer Jean Marie Vianney Habarugira presented on EDCTP2 and co-moderated a session at a workshop in the Institut Pasteur, Paris on 2-3 December 2015. The workshop was co-organised by CoReVac-PalSud. Its topics were the scientific and economic challenges in the development of vaccines for the South.

46th Union Conference

The 46th Union World Conference on Lung Health was held in Cape Town, South Africa from 2-6 December 2015. The conference was attended by Dr Monique Surette (Project Officer), Hager Bassyouni (Networking Officer), Dr Thomas Nyirenda (South-South Networking and Capacity Development Manager), and Dr Ole Olesen (Director of North-North Cooperation). Communication Officer Gert Onne van de Klashorst provided information in the EDCTP booth.



The conference theme of the five-day scientific programme was "A New Agenda: Lung Health Beyond 2015". The 4,000 attendees included clinicians and public health workers, health programme managers, researchers and advocates. Delegates took part in more than 230 postgraduate courses and workshops, symposia, plenary sessions, abstract-driven and poster-related sessions, meet-the-expert sessions and 2 late-breaker sessions on TB and HIV.

An EDCTP editorial on childhood TB was accepted for publication

in the International Journal of TB and Lung Disease. The Global TB Summit was attended by Hager Bassyouni during which close to 50 parliamentarians from 30 countries pledged their support to move tuberculosis up the political agenda in their respective countries.

Maternal and Newborn Health

The European Commission's Directorate General for Research, Science and Innovation with involvement of the Directorate General for International Cooperation and Development convened the conference 'Together for the Next Generation: Research and Innovation for Maternal and Newborn Health' in Brussel on 8 December 2015. Dr Michael Makanga participated in the meeting which explored the possibilities of recent innovations to improve the health of mothers and their new-born children. Another theme addressed how to improve research in order to facilitate uptake of innovations.

ECSA-HC Forum

Dr Michael Makanga attended the 9th Forum on best practices of the East Central and Southern Africa Health Community (ECSA-HC), the 25th meeting of its Directors' Joint Consultative Committee and the 62nd Health Ministers Conference in Port Louis, Mauritius from 30 November to 4 December 2015.

Scientific Days and ESSENCE meeting

The Institute for Tropical Medicine and Hygiene in Lisbon, Portugal, organised a Scientific Day on 11 December 2015 at which EDCTP was represented by Dr Makanga. He then attended the Science Day organised by the Swedish International Development Agency (Sida) on 14 December in Stockholm, Sweden and the meeting of the health research funders group ESSENCE in Amsterdam, The Netherlands on 15 December.

ERA-LEARN Annual Joint Programming Conference

Networking Officer Lara Pandya represented EDCTP at the Annual Joint Programming Conference of ERA-LEARN, the support platform funded under Horizon 2020 for Public-Public Partnerships on 14-15 January 2016. The theme of the meeting was: 'Building and Sustaining Commitment to Public-Public Partnerships'. She was a panelist in the workshop: 'Internationalisation of Public-Public Partnerships beyond Europe'.

CAAST-Net Plus in Khartoum

On 17 January 2016, CAAST-Net Plus – the network for Science, Technology and Innovation Cooperation between Sub-Saharan Africa and Europe - partnered with EDCTP to deliver an information session on Horizon 2020 in Khartoum, Sudan. For EDCTP, Dr Thomas Nyirenda presented on EDCTP at the event attended by 150 participants and hosted by the Ministry of Higher Education and Scientific Research of Sudan. Prof. Ahmed Hassan Fahal of the University of Khartoum, who was recently appointed as the first Sudanese National Contact Point for Horizon 2020, supported the event's organisation, alongside the EU science counsellor to the African Union, Mr. Stéphane Hogan.

Chatham House, London

The think-tank Chatham House organised an expert roundtable on 14-15 January 2016.

Dr Michael Makanga was invited to participate in the sessions. The topic of the meeting was: 'Infectious Disease Risk Assessment and Management (IDRAM): From the Ebola outbreak in West Africa to a One Health approach to shared preparedness and response for health emergencies'. The roundtable focused on partnerships that extractive companies and public sector groups can establish to improve prevention as well as preparedness and response capacities in regions where extractive operations are active.

17th ADVAC Scientific Committee meeting

From 21 to 22 January 2016, the 17th ADVAC Scientific committee meeting was held in Paris, France. Dr Michael Makanga participated in the meeting. The committee advises the ADVAC organisation on the important annual advanced course in vaccinology, a two-week training programme for decision-makers, including academia, industry, governmental and non-governmental agencies, in all fields related to vaccines and vaccination.

Stakeholder presentation in Austria

On 26 January, Dr Michael Makanga gave a presentation on EDCTP for stakeholders in Austria. Dr Hemma Bauer, deputy representative in the General Assembly, was instrumental in arranging the meeting with stakeholders in ministries, developing agencies and the Austrian research community.

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The EDCTP Newsletter is available in English, French and Portuguese in electronic format on our website (www.edctp.org). To receive the electronic format, please subscribe online. The next Newsletter will be published in April 2016.

The EDCTP programme is supported under Horizon 2020, the European Union's Framework Programme for Research and Innovation.