

Note from the Executive Director

Gaining momentum

As 2016 unfolds, EDCTP is steadily gearing up as we extend our boundaries and stretch our tent cords, while maintaining focus on our primary programme objectives. Our second programme (EDCTP2) is a continuation of EDCTP's core mission with an extended scope and this also means new opportunities. We have updated our visual brand identity with a fresh and clean style which you will see applied to all means of communication in the coming months. We also warmly welcomed new members to the Executive Secretariat. Most importantly, the newly signed grant agreements, and many that are to follow in the course of this year, clearly signal that EDCTP2 is gaining momentum.

It is equally rewarding to see the high-impact results that continue to come from the various projects funded under our first programme and the transitional programme EDCTP-Plus. Just to name a few: the recently published PregACT trial results will contribute towards improved health care practices for pregnant women with malaria.

A stellar result from EDCTP-Plus is the international accreditation (ISO 15189) of three African laboratories: the Medical Research Council Unit Routine Diagnostics Laboratory in The Gambia, the Medical Research Council/Uganda Virus Research Institute Clinical Laboratory, and the Laboratory of Bacteriology Virology based at the University Hospital A. le Dantec in Dakar, Senegal.

From July 2016 onwards, after the final approval of the annual work plan, there will be a staggered launch of the 2016 calls for proposals. A general overview of what can be expected is included in this newsletter. In preparation for the 2017 work plan as we cautiously include new areas, EDCTP will organise two stakeholder meetings. Experts and other partners will be consulted on diarrhoeal diseases and lower respiratory tract infections that are priorities for sub-Saharan countries. The meetings will take place on 5 and 6 July 2016 and the reports will be published.

In conclusion, I would like to invite all our partners to participate in the Eighth EDCTP



Forum. It is practically on the horizon and will take place in Lusaka, Zambia from 6-9 November 2016. The conference will unite all EDCTP stakeholders: researchers and policy makers from Africa and Europe as well as international funding organisations, product development partnerships, pharmaceutical and biomedical companies, and development organisations.

Michael Makanga

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Eighth EDCTP Forum

Participate, contribute, or sponsor the Eighth EDCTP Forum! It will take place in Lusaka, Zambia on 6-9 November 2016. It is organised in collaboration with the Ministry of Health of the Republic of Zambia, one of the African members of the EDCTP Association. The Forum offers a broad range of scientific and policy-oriented sessions on diagnosis, treatment and

prevention of poverty-related diseases, research capacity development as well as ethics and regulatory topics. The Forum website www.edctpforum.org provides on-line services for registration, abstract submission and sponsoring. Deadline for abstract submission (as well as requests for scholarships) is 24 June 2016.

Stakeholder meetings 5-6 July

As the second EDCTP programme includes an extended range of neglected infectious diseases, two EDCTP stakeholder meetings are organised to consult experts on diarrhoeal diseases and lower respiratory tract infections. The stakeholder

meetings will inform EDCTP's strategy and future workplans. Participation in the one-day stakeholder meetings is by invitation only. The meetings on diarrhoeal diseases and lower respiratory tract infections will take place on 5 and 6 July respectively.

Calls & Grants

Newly signed grants

Call: Research capacity development in support of the EVD response

Strengthening laboratory capacities in the St. Joseph's Catholic Hospital (Monrovia) for clinical trials on infectious diseases (SELeCT)

ISGlobal-Barcelona Institute for Global Health (Spain) with partners from Liberia and Spain

Starting date: 1 February 2016

Duration: 18 months

Grant budget: EUR 249,554

Grant agreement: EDCTP-CSA-Ebola-334

Call: Diagnostic tools for poverty-related diseases

Diagnostic tools for human African trypanosomiasis (DiTECT-HAT)

Institut de recherche pour le développement (IRD, France) with partners from Belgium, Burkina Faso, Democratic Republic of Congo, Guinée, Côte d'Ivoire and United Kingdom

Starting date: 1 February 2016

Duration: 48 months

Grant budget: € 2,999,006

Grant agreement: DRIA-2014-306

Integrating the diagnosis and management of HIV-associated central nervous system infections into routine health services in low and middle income countries (DREAMM)

Project coordination: St George's, University of London (United Kingdom) with partners from Cameroon, France, Malawi, Tanzania and United Kingdom

Duration: 48 months

Grant budget: € 1,887,717

Grant agreement: DRIA-2014-314

A one-stop shop for the same day diagnosis and management of TB and HIV (Stop TB/HIV at One)

Project coordination: Liverpool School of Tropical Medicine (United Kingdom) with partners from Ethiopia, Moldova, Nigeria and Spain.

Duration: 36 months

Grant budget: € 1,413,749

Grant agreement: DRIA-2014-309

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

Translating Research into Practice (TRIP): Evaluating and speeding up the adoption of an evidence-based innovative REMSTART package to reduce mortality in advanced stage HIV patients starting antiretroviral therapy in Tanzania

National Institute for Medical Research (NIMR), Dar es Salaam (Tanzania) with partners from Tanzania and the United Kingdom

Starting date: 1 March 2016

Duration: 36 months

Grant budget: € 499,433

Grant agreement: CSA-2014-279

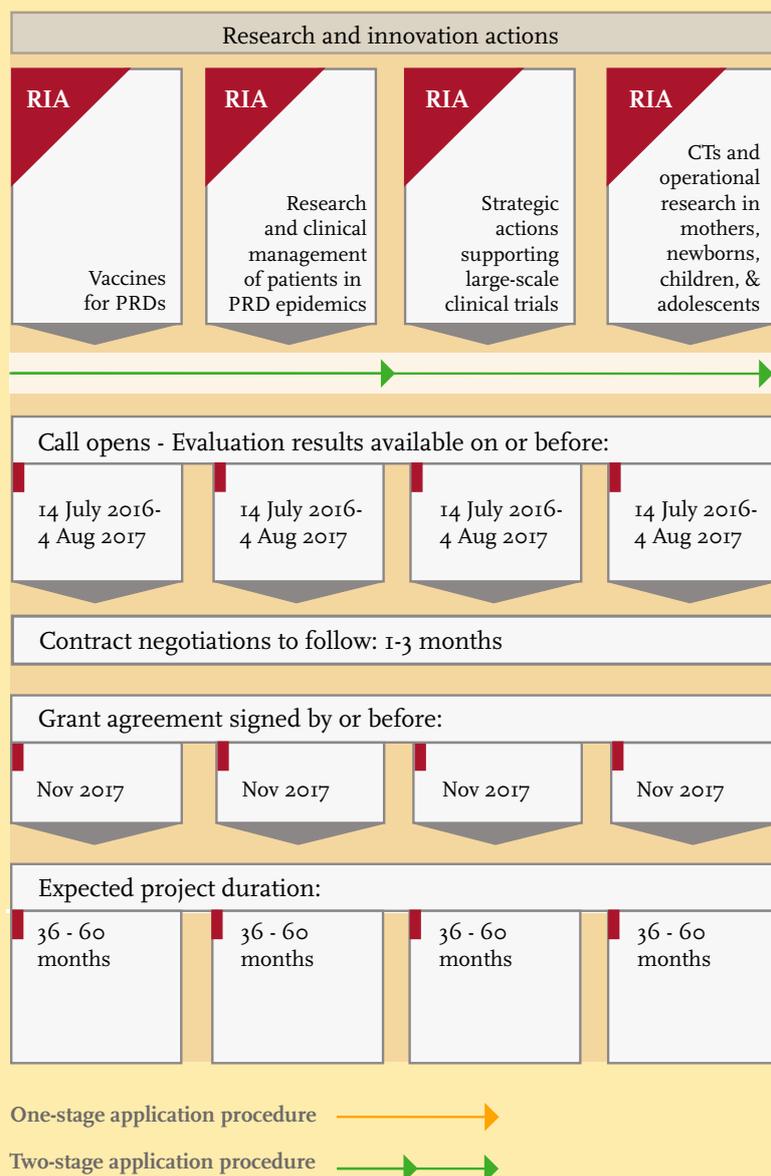
EDCTP Governance

Scientific Advisory Committee

The EDCTP Scientific Advisory Committee (SAC) met from 31 March – 1 April 2016 in The Hague. The SAC's input was sought on key topics, such as EDCTP's 2017 work plan, Strategic Business Plan, upcoming stakeholder meetings on diarrhoeal and lower respiratory tract infections and the Eighth EDCTP Forum (6-9 November 2016). An analysis of EDCTP2 calls

launched so far and the peer-review process was presented and discussed. The SAC will also take on a new role in the monitoring and evaluation of EDCTP2 grants by looking at grant progress and outputs for approved large consortia projects. It should be noted however that review of grant applications is done by independent panels of reviewers separate from SAC. The next SAC meeting will take place on 1-2 September 2016.

2016 Calls for proposals



EDCTP Governance (continued)



Back row, from left to right: Prof. Clara Menéndez Santos, Mr Jean Marie Talom, Prof. Simon Croft, Prof. Knut Fylkesnes, Prof. Moses Bockarie, Dr Martin Ota, Dr Salim Abdulla, Prof. Marie-Louise Newell, Prof. Gita Ramjee, Dr Monique Rijks-Surette, Dr Pauline Beattie, Dr Gabrielle Breugelmans, Prof. Stefan Kaufmann, Dr Thomas Nyirenda, Prof. Maria Fraga Oliveira Martins and Dr Ole Olesen. **Front row, from left to right:** Prof. Tumani Corrah, Dr Michael Makanga, Prof. Eleni Aklillu and Prof. Ali Zumla.

EDCTP Secretariat



Dr Anne-Laure Knellwolf joined EDCTP as Programme Portfolio Manager in April 2016, bringing broad experience in clinical trial project management. As Deputy Representative for Italy to the General Assembly (2012-2014), she actively participated in the preparations for EDCTP2. She holds a Medical Degree from Montpellier University and a Master's in Integrative Biology and Physiology with a specialisation in Clinical and Experimental Pharmacology from the Paris-Sorbonne University. For 10 years Dr Knellwolf worked in the private sector in R&D project management (Novartis/Switzerland and GlaxoSmithKline-Beecham/France). Moving to the public sector in 1998, she continued coordinating clinical trials and was co-responsible for setting up the first public clinical research unit in Paris public hospitals. In 2004, she became Scientific Project Manager at the Italian National Institute of Health. She led the monitoring, evaluation and reporting of several biomedical research projects funded by the European Commission such as NEAT (European network of excellence in HIV/AIDS clinical research) and EUCO-Net (European Network for global cooperation in the field of AIDS & TB).



Ms. Gauri Deoras joined EDCTP as an intern in April 2016. Her main task is to analyse the research projects which are

All calls are contingent on the approval of the EDCTP 2016 work plan by the European Commission and the EDCTP Association.



More information on the three types of grants (RIA, CSA, and TMA) can be found on the EDCTP website (<http://www.edctp.org/funding-opportunities/grant-types/>).

Focus on the EDCTP Member Countries

conducted independently by the member countries of EDCTP but are accepted to be integral to its remit (PSIAs). Her review aims to identify opportunities for further research and capacity development collaboration between EDCTP members. Ms. Deoras completed a BSc in Biochemistry at King's College London (United Kingdom) and received a Master's in Drug Innovation from Utrecht University (The Netherlands).



Mrs. Neodia Flores-Mensing was appointed to the EDCTP Finance team as Grants Finance Assistant as of May 2016. Her main tasks will be to review the financial reporting on grants and support grantees in this. She was born in the Philippines where she obtained a Bachelor's degree in commerce and accounting; after she moved to Hong Kong she continued to work and study. She has a Master's degree in business administration (Hong Kong 2003) and a Master's from the University of Amsterdam (Netherlands) in Accountancy and Control (2009).



Mr. Robert Netten joined the EDCTP Finance team as Grants Finance Assistant on a temporary basis. Previously, he delivered services as a Senior Financial Officer for various companies. Before that he worked at KPMG Management Services in many different projects for 16 years. He has extensive experience in various aspects of financial administration, payments, payroll and reporting.

Mozambique: Manhica Foundation Symposium

On the occasion of the 20th anniversary of the Manhica Health Research Centre (CISM), the Manhica Foundation organised an international global health symposium with a focus on the 'Role of African Health Research Institutions for the achievement of the Sustainable Development Goals'. The conference took place in Maputo, Mozambique from 7-9 March 2016.

Participants representing important health research centres in Africa and key international partners reflected on the future challenges and opportunities for African health research centres. EDCTP Executive Director, Dr Michael Makanga, delivered the opening keynote speech. From the perspective of research in Africa, he elaborated on North-South partnerships for African research centres, funding mechanisms for research in Africa and the crucial importance of supporting African scientists to develop their careers.

The Manhica Health Research Centre was created in 1996 and its development has been guided by a bilateral programme between the governments of Mozambique and Spain. CISM's activities are in three connected areas: biomedical research on HIV, tuberculosis, malaria and other infectious diseases as well as maternal, infant and reproductive health; training of young scientists; and delivery of technical services. CISM has strong international partnerships, including with the University of Barcelona, the Barcelona Centre for International Health Research (CRESIB) and the EDCTP Network of Excellence TESA (Trials of Excellence in Southern Africa). Its main funders have been the Spanish Agency for International Cooperation (AECID), The Path Malaria



HE Joaquim Chissano gives Dr Pascoal Mocumbi an award in recognition for his work.

Vaccine Initiative, the Bill & Melinda Gates Foundation and EDCTP.

The closing session of the conference was a tribute to Dr Pascoal Mocumbi. Laudations were delivered by the Hon. Nazira Abdula, the Minister of Health of Mozambique, the HE Joaquim Chissano, the second President of Mozambique, Dr Pedro Alonso, Director of the WHO Global Malaria Programme and Dr Michael Makanga. In his long political career as Minister of Health, Minister of Foreign Affairs and Prime-Minister of Mozambique and afterwards as President of the Manhica Foundation, Dr Mocumbi played an important role in fostering international partnerships in health research and supporting research capacity development in Africa. From 2004-2014, Dr Mocumbi also was the High Representative for EDCTP that in 2015 created the Dr Mocumbi Prize in recognition of his outstanding contribution to research diplomacy and strengthening African research capacity.

Joep Lange Institute inaugurated

On 15 March 2016, the Joep Lange Institute (JLI) – dedicated to develop solutions

for global healthcare issues – was officially inaugurated in Amsterdam, The Netherlands. High-level speakers and participants from civil society, industry, politics and global health research backgrounds attended. Dr Michael Makanga, Executive Director of EDCTP was very pleased "this important initiative was launched and we congratulate all stakeholders. We are looking forward to collaborate with the Joep Lange Institute and its partner organisations". At the inauguration EDCTP was represented by Dr Gabrielle Breugelmans, North-North Networking Manager.

The goals of the JLI are to make health markets work for the poor in countries where the (health care) system fails the people. The JLI aims to come up with "concrete solutions for healthcare quality, delivery and finance. We develop and test these on the ground, to see what works and what doesn't". The institute is closely linked to the Amsterdam Institute for Global Health and Development (AIGHD). Over the last two decades, AIGHD and PharmAccess, both founded by Joep Lange, have been pioneers in the delivery of HIV/AIDS treatment in Africa, and in working with the private sector in the public interest.

Focus on Projects

PREGACT: malaria treatments for African pregnant women

The results of the PREGACT study were published in the *New England Journal of Medicine* on 10 March 2016. This clinical trial was conducted to compare four antimalarial drug combinations for treating pregnant women. The authors concluded that based on safety and efficacy, dihydroartemisinin with piperaquine (DHAPQ) seems the most suitable treatment for uncomplicated malaria in pregnancy. The results are expected to inform WHO treatment guidelines, particularly regarding the performance of DHAPQ for which due to lack of data no recommendation could be made previously.

Malaria in pregnancy is a major public health problem in endemic countries. Its harmful effects during pregnancy make it extremely important to adequately treat malaria. However, few studies on antimalarial drugs have been carried out in pregnant women.

They are usually excluded from clinical trials for fear of study drugs causing physical malformations (teratogenicity). This has hindered the development of evidence-based recommendations for the prevention and treatment of malaria during pregnancy.

The PREGACT trial was led by Professor Umberto D'Alessandro (MRC The Gambia Unit) and completed in 2014. For the trial 3,428 pregnant women with confirmed malaria infection were recruited in four countries (Burkina Faso, Ghana, Malawi and Zambia) in order to test the safety and efficacy of four artemisinin-based combination therapies when administered to pregnant women with *P. falciparum* infection during the second and the third trimester. The clinical trial was funded by EDCTP and the Malaria in Pregnancy Consortium, which is funded through a grant from the Bill & Melinda Gates Foundation to the Liverpool School of Tropical Medicine. In addition, it benefited from the support of partners in Belgium, the

Netherlands, and the United Kingdom. EDCTP contributed almost €3 million to the total project budget of €6.5 million. The study drugs were provided by the Drugs for Neglected Diseases initiative (Geneva), Novartis (Basel), Sanofi Aventis (Paris, France), and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A (Roma, Italy).

Publication: DOI: [10.1056/NEJMoa1508606](https://doi.org/10.1056/NEJMoa1508606)

TB Diagnostics: LAM TB

The results of the LAM TB diagnostics study, part of the EDCTP-funded TB-NEAT project, were published in *The Lancet* on 19 March 2016. The study team assessed a urine-based, lateral flow, point-of-care, lipoarabinomannan assay (LAM) and the effect of a LAM-guided strategy for the initiation of antituberculosis treatment on mortality.

EDCTP invested significantly in the development of TB treatment, prevention and diagnostics. One of the diagnostics projects was the TB-NEAT study led by Prof.

Keertan Dheda, Cape Town University, South Africa which comprised a study of the Xpert MTB/RIF test in regular healthcare settings and the LAM-TB trial of a urine-based test for rapid diagnosis of TB in HIV-infected patients.

The LAM TB study was a multicentre trial conducted in 10 hospitals in Africa: 4 in South Africa, 2 in Tanzania, 2 in Zambia, and 2 in Zimbabwe. The study showed that bedside LAM-guided initiation of anti-tuberculosis treatment in HIV-positive hospital inpatients with suspected tuberculosis was associated with reduced 8-week mortality.

The authors concluded that implementation of LAM testing is likely to offer the greatest benefit in hospitals where diagnostic resources are most scarce and where patients present with severe illness, advanced immunosuppression, and an inability to self-expectorate sputum.

Publication: DOI: [http://dx.doi.org/10.1016/S0140-6736\(15\)01092-2](http://dx.doi.org/10.1016/S0140-6736(15)01092-2)

Meetings

AARCHD

Dr Thomas Nyirenda, EDCTP South-South Networking and Capacity Development Manager, attended the 30th meeting of the

WHO African Advisory Committee for Health Research and Development (AARCHD) in Cape Town, South Africa from 10-11 March 2016. The role of AARCHD is to advise WHO

African Region on the research agenda in relation to health and development.

DiTECT-HAT consortium

The DiTECT-HAT project kick-off meeting took place in Montpellier, France from 15-17 March. It is funded through the 'Diagnostic tools for poverty-related diseases' call and aims to implement and validate diagnostic tools for human African trypanosomiasis (HAT) elimination and clinical trials in Africa. EDCTP's Project Officer Dr. Michelle Helinski attended the meeting which brought together consortium partners from Belgium, Burkina Faso, Côte d'Ivoire, DR Congo, France, Guinea, and the United Kingdom.

The meeting was used to discuss the project's objectives and critical implementation steps. Go to www.ditect-hat.eu for more information.

Clinical trial data sharing

Dr Pauline Beattie, EDCTP Operations Manager, participated in a meeting on the 'Future of Clinical Trial Data Sharing' at the Wellcome Trust in London from 21-22 March 2016. At this invitation-only meeting, the Multi-Regional Clinical Trials (MRCT) Center and collaborators presented plans to launch a new not-for-profit organisation charged with directing, implementing and governing a global clinical trial data-sharing platform.



From left to right: Enock Matovu (External Advisory Board); Michelle Helinski (EDCTP); Philippe Büscher (ITM, Belgium); Mamadou Camara (PNLTHA-MoH, Guinea); Eric Fèvre (UoL, UK); Pere Simarro (External Advisory Board); Hamidou Ilboudo (CIRDES, Burkina Faso); Bruno Bucheton (IRD, France; PNLTHA, Guinea); Veerle Lejon (IRD, France); Alicia Bert (IRD, France); Dramane Kaba (IPR, Ivory Coast). Attended the meeting but not in the picture: Dieudonné Mumba Ngoyi (INRB, DRC); Crispin Lumbala wa Mbuyi (PNLTHA, DRC).

Meetings (continued)

APPG TB and APPG Global Health

Ahead of World Tuberculosis Day (on 24 March 2016), Dr Michael Makanga, EDCTP Executive Director, participated in an event to commemorate World TB Day in the House of Commons, London, United Kingdom on 22 March 2016. The invitation was extended by the very active All-Party Parliamentary Group on Global Tuberculosis and Aeras. The theme for the discussions was 'Preventing the world's leading infectious killer: the case for TB vaccine research and development'. A meeting between EDCTP and the All-Party Parliamentary Group on Global Health was confirmed for 6 September 2016.

Africa-EU

In association with the African EU High-Level Policy Dialogue on Science, Technology and Innovation, a stakeholder meeting was convened on the implementation of an African-EU Research and Innovation Partnership on Food and Nutrition Security and Sustainable Agriculture. The forum was held in Addis Ababa, Ethiopia from 5-6 April 2016. Dr Ole Olesen, EDCTP Director of North-North Cooperation, presented EDCTP as a working model for long-term, equal research partnerships between Africa and Europe.

TB drug conference and TB funders meeting

The 8th Critical Path to TB Drug Regimens workshop (CPTR) was held in Washington DC from 4-7 April 2016 and attended by more than 160 participants including top TB drug and diagnostics researchers from all over the world. The theme of the workshop was "Evolving TB Drug Regimen and Diagnostic Development: Where Innovation Meets Implementation". EDCTP was represented by Senior Project Officer Dr Monique Rijks-Surette.

She also represented EDCTP at the first TB Funder Forum on Capacity Building which was organised by WHO on 7 April. This meeting was organised as a follow-up to the recent WHO publication *Global Action Framework for TB Research*, which proposed that regular fora be organised to assemble key TB Research & Development (R&D) funders to discuss strategies to maximise the impact of invested funding and for supporting research in TB-endemic countries.

NTD Network kick-off

Dr Ole Olesen participated in the kick-off meeting for the new Neglected Tropical Diseases Network in Montpellier, France, on 7-8 April 2016. The meeting was a follow-up of the G7 Ministers of Research meeting in Berlin 2015 and organised by Aviesan, the French National Alliance for Life Sciences and Health. The meeting's purpose was to elaborate mission, strategy and goals of the network. On 8 April, Dr Olesen participated as a speaker in the round-table session with French and European funders.

Senegal: Financial & project management training

EDCTP organised a financial and project management training for grantees in Dakar, Senegal from 11-13 April 2016. The EDCTP team consisted of Abdoulie Barry, Director of Finance and Administration, Dr Ole Olesen and Mrs. Mary Jane Coloma-Egelink, Grants Finance Officer.

European Parliament: STOA workshop

The Science and Technology Options Assessment (STOA) panel is an integral part of the structure of the European Parliament. The panel has the task to independently assess the impact of new science and technologies. In this way it assists the Members of the European Parliament in their

policy making with independent information.

On 19 April 2016, a STOA workshop was held on investing in health in the developing world. The main topics were the shortage of health workers, the burden of infectious diseases and the economic benefits of investing in health. Dr Michael Makanga, EDCTP Executive Director, was one of the panelists on the specific support that could be provided by the European Union. Dr Makanga stressed the importance of research and development for poverty-related and neglected infectious diseases in order to achieve Sustainable Development Goals. Implementation research for interventions is needed in order to improve access to health care.

Gates Foundation: Product Development Challenge

The Bill & Melinda Gates Foundation organised the Global Health Product Development Challenge in Seattle, USA from 26-28 April 2016. Around 250 selected leaders from the global health product development community participated, including Dr Ole Olesen on behalf of EDCTP. A series of small creative workshops were intended to develop actionable solutions to six global health challenges, including more efficient and faster implementation of new interventions and exploring the role of sex and gender in clinical trials.



10th INTEREST: Dr Catherine Hankins (Amsterdam Institute for Global Health and Development, Netherlands; Scientific Chair), and Prof. Sinata Koulla-Shiro MD (Ministry of Health, Cameroon; Local Chair 2016; Representative for Cameroon in the EDCTP General Assembly)

Cameroon: 10th INTEREST workshop

The 10th INTEREST workshop (the International Workshop on HIV Treatment, Pathogenesis and Prevention Research in Resource-Limited Settings) took place in Yaoundé, Cameroon from 2-6 May 2016. The workshop is an important event for African HIV researchers. EDCTP North-North Networking Officer Lara Pandya presented EDCTP2 in one of the sessions and on 6 May, conducted a workshop on EDCTP2.

Screen TB kick-off

The kick-off meeting for ScreenTB, one of the six EDCTP grants funded under the 2014 'Diagnostics for poverty-related diseases' call for proposals, took place from 2-3 May 2016. As the assigned project officer, Dr Monique Rijks-Surette was invited to participate. ScreenTB is a consortium of four African and four European partners, led by Professor Gerhard Walzl from Stellenbosch University in South Africa. ScreenTB builds upon the work from the EDCTP1-funded AE-TBC grant, which identified six host biomarkers for active TB regardless of HIV status of the patient. ScreenTB will implement this set of six biomarkers into a rapid, laboratory-free point-of-care test.

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