Note from the Executive Director

I am happy to inform you that following the launch of EDCTP2 on 2 December 2014 in Cape Town, the programme is now truly under way. The first Calls for Proposals were launched in December 2014 and are summarised in the current edition of the Newsletter. True to our intention of working very closely with other international development partners and the pharmaceutical industry one of our first calls was a joint action with TDR and the European Federation of Pharmaceutical Industries and Associations (EFPIA). In the current Newsletter we also call for proposals on Strategic Projects that are executed in partnership with other funders to finance large projects including phase III clinical trials.

I am also glad to inform our stakeholders that we are in the process of bringing to a close projects that were funded under the first programme. Most of the projects are now coming to an end and the results are being published. To facilitate the translation of these results into policy and their uptake we have published a call for proposals to facilitate this process.

Finally, I must mention that we have completed almost all of the projects that were funded by the European Union to support the transition from the first programme to the current one. A summary of these projects is given in this Newsletter.

With this good start the future is very promising. Let us continue to work together for a better health of the humankind.

Charles S. Mgone

Contents

First EDCTP2 calls for proposals

EDCTP launched the first calls for proposals based on its Workplan 2014 and 2015 under its second programme and Horizon2020.

Diagnostic tools for poverty-related diseases

Opened: 2 December 2014; two stages; first stage closing on 2 March 2015
Call budget: €15 million

The purpose of this call is to invest in validation of the clinical performance and/or implementation of new or improved diagnostic tools and technologies for detection of any of the poverty-related diseases, including as co-infections. These tools and technologies should improve the performance of diagnosis, prediction, monitoring, intervention or assessment of therapeutic response, with a significant impact on clinical decision and health outcomes.

Strategic projects with major cofunding

Opened: 28 January 2015; two stages; first stage closing on 16 April 2015
Call budget: 50% of eligible costs

The purpose of this call for proposals is to provide cofunding to strategically important, large-scale research projects with the potential to achieve rapid advances in the field of PRDs and to make a significant contribution to the objectives of EDCTP2. Projects that include phase III trials and/or address research areas not covered by other open or forthcoming EDCTP2 calls for proposals in 2015 are encouraged. Applications must demonstrate financial commitment from other funders.

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

Opened: 17 December 2014; closing on 16 March 2015
Call budget: €3 million

This call aims to accelerate translation of research findings from EDCTP-funded activities into policy and practice in order to maximise their public health impact in sub-Saharan Africa.

Improved treatment and clinical management of poverty-related diseases

Opened: 28 January 2015; two stages; first stage closing on 16 April 2015
Call budget: €35 million. Grants will not exceed €500,000.

This call for proposals is to provide funding for projects that will evaluate new or significantly improved drugs or drug regimens in humans or aim to optimise the efficacy and use of existing therapeutics for any of the poverty-related diseases, including co-infections of poverty-related diseases.

Go to the website for upcoming 2015 calls

Launch of EDCTP2

Captions

1 In his opening speech, Georg Schütte, State Secretary of the German Federal Ministry for Education and Research, illustrated the value of EDCTP from the point of view of a European member country and called for a courageous cultural shift in order to recognise the significance of Africa.

2 Carlos Moedas, European Commissioner for Research, Innovation and Science, visited the research and treatment clinic (site B) at Khayelitsha, Cape Town, accompanied by Dr Graeme Meintjes, coordinator of the EDCTP-funded clinical trial Pred-ART which studies possible treatment for TB-IRIS (Immune Reconstitution Inflammatory Syndrome) in TB-HIV co-infected patients starting antiretroviral therapy.

3 Commissioner Moedas addressed the participants of the meeting at the welcome reception on World Aids Day, 1 December 2014.

4 Naledi Pandor, Minister of Science and Technology, South Africa, delivering her opening address to the participants of the High-Level Launch Event for EDCTP2. She said South Africa was proud to be part of EDCTP and mentioned the increased commitment of African countries an exciting aspect of EDCTP2. Later, in her closing words at the end of the meeting, she urged EDCTP to be very ambitious.

5 The keynote speech by Rose Leke, Chair of the Board of the Cameroon National Medical Research Institute, discussed the critical challenges for the second programme and urged scientists to "dream big, bold and beyond our present horizons".

6 Peter Piot, Director of the London School of Hygiene & Tropical Medicine and Professor of Global Health, called in his key note address for "innovation for impact" and for a constant search for productive partnerships. He regarded South-South partnerships as "a potential game changer in the power structure of research".

7 Mark Palmer (MRC, United Kingdom), Chair of the EDCTP General Assembly, delivered the laudation for Pascoal Mocumbi, former Prime-Minister of Mozambique and EDCTP High Representative from 2003 until 2014 for his contribution to developing the support for EDCTP, especially from governments and international organisations of sub-Saharan Africa.

8 The third keynote speech on research challenges for EDCTP2 was delivered by Paul Stoffels, Worldwide Chairman of Janssen Pharmaceutical Companies of Johnson & Johnson, Belgium. He welcomed the second EDCTP programme as industry had the technology but would need collaboration with other institutions to be able to conduct trials quickly. He stress the need for urgency in addressing global health challenges and building the necessary research capacity including good laboratories.

9 Francois Bompart, Chair of the Global Health Initiative at the European Federation of Pharmaceutical Industries and Associations, and Vice-President and Medical Director of Access to Medicines at Sanofi, France, one of several industry representatives at the meeting. The second EDCTP programme aims for extensive collaboration with industry and private funders.

10 The first panel discussion on addressing global and national health challenges through EDCTP with (left to right): George Schütte (chair; Federal Ministry of Education and Research, Germany), Nkando Luo (Minister of Chiefs and Traditional Affairs, Zambia), Glenda Grey (MRC South Africa), Roger Genet (Ministry of Higher Education and Research, France), Sarah Louise Barber (WHO South Africa), Marcellino Lucas (Ministry of Health, Mozambique), John Gyapong (representing the Minister of Health of Ghana), and Mountaga Tall (Minister of Higher Education and Research, Mali, with Prof. Abdoulaye Djimde interpreting).

11 Minister Pandor and Robert-Jan Smits, Director-General for Research and Innovation, European Commission, interviewed for the e.TV Sunrise programme before the start of the launch meeting.

12 Second panel discussion on connecting the health delivery chain with: Bruno Itoua (Minister of Science, Technology, and Innovation, Congo) speaking and (left to right) Hassan Mshinda (chair; Tanzanian Commission for Science and Technology, Tanzania), Samuel Okware (representing the Prime Minister of Uganda), Martin Ota (WHO Regional Office for Africa), and Leonor Parreira (Ministry of Education and Science, Portugal). Not visible panellists: Paul Lartey (Federation of African Pharmaceutical Manufacturers Associations, Ghana), K. Sikwese (African Community Advisory Board, Zambia).

13 The third round table discussion on social responsibility, partnership and long-term investments was joined by (left to right): co-chairs Tumani Corrah (MRC The Gambia) and Bernadette Murgue (IMMI/Aviesan, France) and Trevor Mundel (Bill & Melinda Gates Foundation), Isabel Mota (Calouste Gulbenkian Foundation, Portugal), William Mwatu (Tried Approach Ltd, Kenya and former Chair of the Federation of East African Pharmaceutical Manufacturers), François Bompart (European Federation of Pharmaceutical Industries and Associations), and Shiva Dustdar (European Investment Bank).

EDCTP Governance

EDCTP-Plus: mission accomplished

General Assembly

The General Assembly met on 1 December 2015 in Cape Town, South Africa on the eve of the High-Level Launch Event for EDCTP2. The main points of business were the adoption of the approved Workplan 2014 and the approval of the application for membership of the EDCTP Association by the Republic of Mali and Burkina Faso. All members in attendance approved their admittance and the required unanimous approval of all 24 members was then established by written procedure. Currently, 13 African and 13 European countries are members of the EDCTP Association.

EDCTP Staff

In 2014, Jean Marie Vianney Habarugira, an EDCTP Calls and Grants team member was awarded a Master's degree by the European Programme of Pharmacovigilance and Pharmacoepidemiology (Eu2P). Part of his research involved a study that focused on the reporting and follow-up of Serious Adverse Events (SAEs) from EDCTP-funded clinical trials. Key findings were published in November 2014 in the *Journal of Pharmacovigilance* (doi: 10.4172/2329-6887.1000148).

EDCTP Delegation agreement

In December 2014, European Union and the EDCTP Association signed the final agreement for EDCTP2. With this Delegation Agreement the European Union entrusts budget implementation tasks regarding the second programme to the EDCTP Association as the so called EDCTP2 Implementation Structure.

In 2012, EDCTP received funding from the European Union for a programme of activities. This EDCTP-Plus programme aimed to lay the foundation for implementing and managing the second EDCTP programme (EDCTP2) while ensuring the EU-Africa research partnership remained strong in the process. The activities were funded under the European Framework Programme 7 through a Support Action Grant (FP7-304786) and were completed in December 2014. A selection of these activities is highlighted below.

Mapping research

Several projects aimed at getting extensive information on research partners, research policies and research (published as well as planned) which would be relevant to the strategy and workplans of EDCTP2. First, a desk review of research programmes in the EDCTP member countries was conducted by the EDCTP Executive Secretariat.

A bibliometric analysis of African and European research programmes, partnerships, activities and capacities was commissioned in 2012 in order to analyse the fields of HIV/AIDS, tuberculosis, malaria and neglected infectious diseases over the period 2003-2011. The report, *Bibliometric analysis: European and African research output within the scope of EDCTP2 2003-2011*, was finalised in 2013 and included a supplementary analysis of intra-European research collaboration in each of the disease areas, an evaluation of the impact of EDCTP-funded research and an overview of leading sub-Saharan African researchers based on research outputs and citations.

A second study commissioned under EDCTP-Plus mapped research in poverty-related and neglected infectious diseases in the European EDCTP member countries. The report *Charting research: EDCTP Member State programmes and activities in the scope of EDCTP2* presents a summary overview of

activities and programmes relevant to the scope of EDCTP2. It highlights available capacities such as research infrastructure and expertise.

In collaboration with RAND Europe and Baird's CMC, EDCTP mapped sub-Saharan African health research activities and capacities and analysed how these relate to national funding commitments, health research policies and the mission of EDCTP. The report *Africa mapping: Current state of health research on poverty-related and neglected infectious diseases in sub-Saharan Africa* shows the significant regional differences in the health research of sub-Saharan (volume, development and funding). The report highlights the importance of political will in African governments to contribute financially to establishing an adequate and sustainable research environment in sub-Saharan Africa. Currently, clinical research in the majority of sub-Saharan Africa countries relies heavily on international funding. According to many of the respondents interviewed, the main challenges are increasing its funding and improving awareness of most policymakers of the benefits and importance of research.

Stakeholder meetings

EDCTP held a series of thematic stakeholder meetings in preparation for the second EDCTP programme. Meetings on neglected infectious

diseases (The Hague), HIV/AIDS (Lisbon), malaria (Vienna), tuberculosis and other mycobacterial infections (Paris), as well as meetings on health research ethics review and regulatory affairs (Antwerp) and capacity development (Berlin) brought together experts from research institutions, policymaker and representatives of product development partnerships, pharmaceutical industry and international organisations.

These meetings aimed to identify and review the current research issues, interventions, products in development and key players in the field; ensure that EDCTP remains focused on the most pressing research needs and the most promising opportunities; identify priority areas for the current and future calls for proposals; identify interested and potential partners to collaborate; harness the efforts of EDCTP stakeholders in order to promote integration of national programmes of EDCTP European Participating States and strengthen the partnership with African researchers.

Evaluation of the first EDCTP programme

A comprehensive external evaluation of the first EDCTP programme was conducted by the external consultancy firm Technopolis group as part of the preparations for the second programme. The report *Assessment of the performance and impact of the first programme of the European & Developing Countries Clinical Trials Partnership* (September 2014) was published on the EDCTP website (www.edctp.org) in February 2015.

Evaluation of EDCTP ethics grants programme

A comprehensive evaluation of the EDCTP grants programme

EDCTP-Plus: mission accomplished (continued)

for strengthening research ethics review in sub-Saharan Africa was also commissioned.

The evaluation of all 75 EDCTP-funded ethics projects focused on the three funding areas: the mapping of ethics review and clinical trial regulatory capacity in sub-Saharan Africa (MARC); establishing or strengthening of National Ethics Committees (NECs) and Institutional Review Boards (IRBs); and training (including the development of online training programmes) for research ethics review.

The MARC project, executed by the Council on Health Research for Development (COHRED), was deemed to be a great success. MARC mapped 166 IRBs in 34 African countries and developed professional social network and discussion functions on the MARC website.

The main purpose of the IRB and NEC-related projects was to give operational support for office infrastructure development, training, development of standard operating procedures and improved quality of protocol review. This funding helped the ethics committees which face considerable personnel, systems and infrastructural challenges. Online ethics training activities provided a good return on investment. The data also shows a high level of efficacy in NECs and IRBs and supports the conclusion that ethics has made a solid entrance into research ethics in Africa. Limited human resources and limited local financial support remain a threat to their sustainability.

Extended support for PACTR

In preparation for the second EDCTP programme, EDCTP has provided more support to develop the Pan African Clinical Trials Registry (PACTR). It is the only WHO-endorsed primary registry in Africa and trial registration in the PACTR portal (www.pactr.org) meets the requirements of the International Committee of Medical Journal Editors (ICMJE) and feeds information to the WHO International Clinical Trials Registry Platform (ICTRP). The PACTR registry facilitates understanding of regional research patterns, enables the identification of research gaps for future studies, and facilitates the investigation of the scope, quality and funding patterns of African trials. There was exponential growth in clinical trials registration with PACTR during 2014 with 388 clinical trials registered by end of the year.

Preparing for laboratory accreditation

EDCTP supported the development of the laboratory capacity of its Regional Networks of Excellence (NoEs). Through a consultative process, the four NoEs (CANTAM, EACCR, TESA and WANETAM) selected 24 clinical research and public health laboratories actively involved in EDCTP funded clinical trials in 18 sub-Saharan African countries. The selected laboratories have been systematically developed towards future accreditation by international laboratory accreditation agencies. The initial assessment was based on frameworks established by the International Organisation for Standardisation (ISO) and the World Health Organisation-African Region (WHO-AFRO) stepwise Laboratory Quality Improvement Process (SLIPTA).

The next phase of this EDCTP initiative was executed by the African Society for Laboratory Medicine (Ethiopia) and Quintiles Africa (South Africa) in 2014. They performed on-site gap analysis on all 24 laboratories. They proceeded to work with these laboratories to develop each laboratory forward in the process towards accreditation through mentorship programmes, training schemes and internal quality assessments.

Raising private and public commitment to EDCTP

Strong foundations for future EDCTP collaboration with the private sector and Product Development Partnerships have been established. Key events such as the 'Pharmaceutical Industry Workshop' (2012, The Netherlands), the 'Post-Registration Medicinal Products Safety Monitoring in sub-Saharan Africa' meeting (2012, South Africa), as well as individual meetings with stakeholders indicated opportunities and enthusiasm for mutually productive collaborations under EDCTP2.

In January 2013, EDCTP and the European Federation of Pharmaceutical Industries and Associations (EFPIA) signed a memorandum of understanding on a clinical research fellowship scheme that will give sub-Saharan African researchers the possibility to be placed in European-based pharmaceutical companies. This scheme was merged with the WHO-TDR Career Development Programme which offers similar fellowships (but with a broader geographical scope). In 2014, EDCTP and TDR launched the first Clinical Research and Development Fellowship call for proposals on 31 October 2014. This call will be launched annually in order to build the necessary capacity in this area in sub-Saharan Africa.

Additionally, EDCTP actively sought to promote a wider European membership of EDCTP2 in order to integrate further the European clinical research effort regarding poverty-related and neglected infectious diseases. Part of this ongoing dialogue to expand the European membership of EDCTP was the one-day meeting of representatives of EDCTP member countries and prospective partner countries in Copenhagen in 2012. Finland joined the EDCTP Association as a new member.

In Africa, three high-level meetings were held in Africa to raise additional public and private engagement and support to EDCTP activities. The first 'High-Level Conference on the second EDCTP programme' was held in Cape Town in November 2012. This meeting marked an important step in the consultation of African and international stakeholders. The meeting provided a forum to discuss stakeholders' needs and expectations of EDCTP2. The second 'High-Level meeting on EDCTP2' took place in Dakar, Senegal in October 2013. The meeting galvanised the preparation of active and direct involvement of African countries in the EDCTP programme and governance. The strong willingness of African countries to be represented on the EDCTP General Assembly became abundantly clear. The third high-level meeting, again in Cape Town, South Africa on 2 December 2014 celebrated the actual launch of EDCTP2 with 11 African and 13 European countries having already joined the governing EDCTP Association as members.

Financial Management training workshops

Five financial management training workshops were held under EDCTP-Plus. The meetings took place in Dakar, Senegal (2012 and 2013) for finance staff of EDCTP grantees in West and Central Africa, and in Johannesburg, South Africa

Meetings

(2012, 2013 and 2014) for finance staff of EDCTP grantees in Eastern and Southern Africa grantee.

Preparation of the EDCTP organisation

EDCTP expanded its staff in view of the second programme. In 2012, in order to further research collaboration among the participating European countries, EDCTP appointed a North-North Networking Manager and a North-North Networking Officer. The development of the grants management and other systems required an Information Technology Officer (2012) while the EDCTP Africa Office appointed an additional Project Officer (2013).

The Executive Secretariat successfully underwent a comprehensive ex-ante assessment on its systems, policies, procedures for its readiness to implement and execute the second programme.

EDCTP implemented a new grants management system 'EDCTP grants', based on CC Grant Tracker®, a system developed by the company CC Technologies in Glasgow, United Kingdom. The system was implemented in order to substantially reduce the administrative complexity of grant application, review of proposals as well as reporting by grantees on EDCTP-funded projects. The new system went live on 31 October 2014.

As part of the advocacy and information efforts to enhance the visibility of the EDCTP programme, EDCTP produced an application (app) for tablets. This app allows quick access to most EDCTP publications regarding its activities and the projects it funds. The EDCTP website was restructured and restyled.

45ᵗʰ Union meeting

EDCTP staff – Project Officers Ms. Hager Bassyouni and Dr Monique Rijks-Surette – attended the 45th Union World Conference on Lung Health held in Barcelona, Spain on 28 October to 1 November 2014. The conference theme was "Community-driven solutions for the next generation". The 3000 attendees included clinicians and public health workers, health programme managers, researchers and advocates. An EDCTP booth was set-up to provide information about EDCTP's achievements and future calls under EDCTP2.

EVI 2014 Rendez-Vous

On 3 December 2014, the European Vaccine Initiative (EVI) annual "Rendez-Vous" meeting took place in Paris. EDCTP-funded malaria vaccine projects include the Malaria Vectored Vaccine Consortium (MVVC) and the P27A project. Presentations on progress and capacity development in the EDCTP-funded clinical trials were given by the investigators. Through MVVC, EDCTP has funded 6 clinical trials which enabled the ChAd64/MVA ME-TRAP malaria vaccine to move through the pipeline from phase I trials in adult volunteers to a large phase II in infants. Representing EDCTP, Mr Jean Marie Vianney Habarugira presented the EDCTP2 2014 Calls for proposals and those planned for 2015.

Project Office Hager Bassyouni in the EDCTP information booth

Caast-Net Plus

EDCTP was represented by Dr Ole Olesen, Director of North-North Cooperation, at the first CAAST-Net Plus stakeholder meeting in Entebbe, Uganda on 24-25 November 2014. The meeting focused on the role of science and knowledge transfer in addressing global challenges.

TB Transmission 2014

EDCTP Executive Director, Prof. Charles Mgone, chaired the session on possibilities of interrupting tuberculosis transmission in high-burden settings. It was part of the 'TB Transmission 2014' meeting' at the London School of Hygiene and Tropical Medicine on 11 November 2014.

FDAAA session on clinical research

The Food and Drug Administration Alumni Association (FDAAA, USA) organised a session on Clinical research enterprise in Africa, Asia, and South America at the 50th USA DIA Annual meeting, 16-19 June 2014. EDCTP South-South Networking and Capacity Development Manager, Dr Thomas Nyirenda, presented the new EDCTP programme.