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EDCTP

European & Developing Countries Clinical Trials Partnership



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EDCTP Strategic Business Plan for 2014-2024

The EDCTP Strategic Business Plan for 2014-2024 outlines the strategy for the second EDCTP programme (EDCTP2) covering the ten-year period 2014–2024. It summarises the scope, objectives and key features of EDCTP2, and its implementation by the EDCTP Association, the legal entity established to deliver the programme.

In its first 10 years, EDCTP established a reputation for supporting high-quality studies that influenced national and international health policy and practice. We aim to achieve yet more in the coming decade and – through this new programme and in partnership with like-minded organisations – ultimately to improve the health and wellbeing of the people living in sub-Saharan Africa.



The publication is available for download in PDF at www.edctp.org.

CONSOLIDATING THE PARTNERSHIP

Esteemed stakeholders,

In many ways, 2016 has been a year of consolidation for our Partnership. This is illustrated by the successfully concluded Eighth EDCTP Forum which took place in Lusaka, Zambia, from 6-9 November.

For the first time, an EDCTP Forum was opened by a Head of State, a clear signal of the growing interest among African governments to strengthen their collaboration with EDCTP. We are very grateful to the Republic of Zambia for its long-standing involvement in EDCTP and its support in hosting the Forum. I wish to reiterate our expression of gratitude to His Excellency Mr. Edgar Chagwa Lungu, the President of the Republic of Zambia, for gracing the opening session. In his address he stressed that his government pursued "a vigorous inclusive development agenda" which would leave nobody behind. He reminded us of the urgency of our common mission when he said: "Whilst I am delighted to officially open and host this Forum, I am equally heavily burdened by the reasons that create the need for us to meet: Africa's burden of poverty and neglected diseases".

The Forum ushered in our recently nominated High Representatives Dr Leonardo Simão and Professor Marcel Tanner into their important role as goodwill-ambassadors. It also saw the recognition of outstanding researchers and advocates of health research and research capacity through the EDCTP Awards, which are supported by the European Union.

The Forum programme featured a wide diversity of presentations on scientific issues and topics relevant to research ethics, research capacity development and health service implementation



policies. But let me single out here two aspects: first, the many scientific symposia organised by our stakeholders. This certainly was a show of our solid partnership. I also would like to thank our private and public sponsors most cordially. Secondly, the strong presence and contribution of Zambian researchers, including a symposium dedicated to Zambian research efforts towards effective malaria and HIV control programmes, organised by the Zambian Ministry of Health.

We consolidated the coherence of the EDCTP programme further through a focused Strategic Business Plan with funding priorities; a strategy and a team for monitoring and evaluating our progress; stakeholder meeting reports for new disease areas; and an annual strategic research agenda elaborated by the Scientific Advisory Board.

In concluding, I extend a warm welcome to our High Representatives and the new officers of the Executive Secretariat and I express our thanks to all partners who have contributed to making this a successful year of consolidation. We are ready to pursue our objectives with unity of purpose.

Dr Michael Makanga Executive Director

Open calls for proposals

EDCTP-WHO/TDR Clinical Research and Development Fellowships

Purpose: This call for proposals aims to support junior to midcareer 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 product development partnerships. The call is a joint initiative with WHO-TDR. EDCTP funding will support fellows from sub-Saharan Africa placed at pharmaceutical companies in Europe.

Call budget: EUR 3.5M

Funding level: 100% of eligible costs
Procedure: Two-stage application
Opening date: 20 October 2016
Deadline: 2 February 2017

Senior Fellowships

Purpose: This call for proposals aims to support the development of potential African research leaders (train-the-trainer model) and to mentor junior researchers with emphasis on hands-on research training linked to clinical trials activities conducted in sub-Saharan Africa. Moreover, it aims to support senior researchers to establish themselves as research leaders in product development through clinical trials and related activities.

Call budget: EUR 3M
Maximum funding: 500,000
Funding level: 100% of eligible costs
Procedure: One-stage application
Opening date: 3 October 2016
Deadline: 1 February 2017

Career Development Fellowships

Purpose: This call for proposals aims to support junior to midcareer researchers ("fellows") to train and develop their clinical research skills. The objectives are to promote career development and retention of postdoctoral researchers and postgraduate medical researchers in the research field and in sub-Saharan Africa, and to equip the fellows with the ability to establish themselves as independent researchers and with the skills to initiate and manage their own research and team at host organisations in sub-Saharan Africa.

Call budget: EUR 2.1M

Maximum funding: EUR 150,000 Funding level: 100% of eligible costs Procedure: One-stage application Opening date: 3 October 2016 Deadline: 28 February 2017

More information about calls for proposals is available at www.edctp.org.



Partners' and advisors of the TRUST Consortium at the TRUST European Partner meeting in Paris, France

TRUST European Partner Meeting

The European partners and advisors of the TRUST consortium convened at the ANRS Headquarters in Paris, France. The European partner meeting was hosted by Inserm and took place from 19-20 October 2016. The attending partners were ACF (Action contre la faim), COHRED, EDCTP, FGVA (Foundation Gobal Values Alliance), Inserm, UNESCO, Signosis Sprl, and UCLan (Centre for Professional Ethics, University of Central Lancaster). European TRUST advisors included Dr Francois Bompart (Sanofi/EFPIA), Dr Mihalis Kritikos (European Parliament advisor) and Paul Woodgate (Wellcome Trust). The main aim of the meeting was to coordinate European activities, engagement and dissemination for the TRUST ethics project.

The meeting was opened by Dr Hervé Chneiweiss, President of the Inserm ethics committee. Inserm then gave a background talk on CRISPR/CAS9 gene-editing technology in Africa. All partners' provided activity updates and discussed policy briefs. COHRED presented the online version of the Fair Research Contracting webtool (www.cohred.org/frc). Dr Michelle Singh, EDCTP Project Officer, delivered an update on her contribution to the analysis of ethical principles contained in local, national and international research ethics codes. This analysis will support the working group responsible for one of the main deliverables of TRUST, a Global Code of Conduct.

The TRUST African Partner meeting will be hosted in South Africa (28 Feb-2 March 2017). For more about TRUST, its partners and their global collaborative efforts to improve adherence to high ethical standards, equitable research partnerships and fair research, please visit: http://trust-project.eu.

Experts' views on new EDCTP diseases areas

New reports – on **diarrhoeal diseases** and **lower respiratory tract infections** – detail product development, gaps and priorities for two disease areas that were added to the scope of the second EDCTP programme. The stakeholder meetings were held in July 2016 to consult experts in these fields in order to inform EDCTP funding strategy and annual work plan priorities.

The reports are available for download in PDF at www.edctp.org.

EDCTP High Representatives: a first interview

In October 2016, EDCTP appointed two High Representatives to act as its goodwill ambassadors. Dr Leonardo Santos Simão, a former Minister of Health and Minister of Foreign Affairs and Cooperation of Mozambique, has been appointed High Representative South, i.e. with special focus on sub-Saharan Africa. Professor Marcel Tanner, former Director of the Swiss Tropical and Public Health Institute, has been appointed as the High Representative North, i.e. with special focus on Europe. Their main task is to increase the high-level visibility of the programme and promote partnerships with both private and public stakeholders in the fight against poverty-related and neglected diseases in Africa, Europe and globally. On 12 October we had a first interview with them at the EDCTP offices in The Haque, Netherlands.

Asked what appealed to them in the role of High Representative, they both explained that it was the continuation of life-long interests in health and development; particularly in Africa. Prof. Tanner: "The aims of EDCTP that encompass the whole value chain from lab to field and communities, have been my daily business. Now, with so many unfinished agendas in global health, to be able to serve in retirement, that was no major decision but a harmonious continuation." Dr Simão pointed out two important elements of the EDCTP approach. "I have seen and dealt with poverty-related and neglected disease all my life. There have been not enough results. In my view, EDCTP offers two essential elements to achieve results for the health of African populations. It invests in real African research capacity and it takes a long-term view of getting sustainable results."

Dr Leonardo Santos Simão has been active in public health, development and diplomacy throughout his career. He became Minister of Health of Mozambique in 1988. From 1994 to 2005 he was Minister of Foreign Affairs and Cooperation of Mozambique. He is a strong advocate for cross-border and international cooperation and driven by the goal of healthcare advancement and socio-economic development in Africa.

Discussing the role of a High Representative in relation to the various objectives of the EDCTP2 programme, Dr Simão stressed the importance strengthening the African contribution. "We need more African countries in the programme; we need all the African countries in the programme. If you look at the minimum required contribution, it is clear that this is no real issue. They can do it. It is about increasing the political will." This requires a change of mind-set at various levels. In his view African medical schools should carefully explain the spirit of research, the logic of science that lies behind the medicinal products and intervention. Ministers of economic planning and finance should see evidence of effectiveness, hear success stories and be convinced of the multiplying effects of better national health. Dr Simão: "However, the main thing is that the programme is shown to be relevant to national priorities. Its relevance to the country is decisive for increasing political will." Prof. Tanner passionately concurred: "International, global and other multilateral initiatives cannot work without roots in the countries themselves. No roots, no fruits."



Professor Marcel Tanner

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Dr Leonardo Santos Simão

Prof. Marcel Tanner has a broad academic and policy experience comprising communicable disease control, health systems research, public and global health policy and strategy including diplomacy at national and international levels. He has strong connections with both the private sector and many government agencies for development cooperation. Currently, he is President of the Swiss Academy of Sciences, Chair and member of the Board of Drugs for Neglected Diseases (DNDi) and chair of the INDEPTH network, to name just a few functions. He is also a member of the Advisory Group for Horizon 2020's Societal Challenge 1 (on Health, Demographic Change and Wellbeing) which contributes to setting programme priorities for 2018-2020.

Reflecting on the various EDCTP2 programme objectives, he stressed that the High representatives have to contribute to all of them, i.e. new interventions, capacity development, alignment of research programmes, joint action with third parties, advocacy and communication. Prof. Tanner: "All objectives contribute to this central concept of the whole value chain that connects lab research with innovation and delivery of medical and social interventions." He strongly supported Dr Simão regarding the importance of research

'Health is wealth' - the Eighth EDCTP Forum

The Eighth EDCTP Forum took place in Lusaka, Zambia, from 6 to 9 November 2016. The Eighth Forum was the first to be opened by a head of state. It was both an indication of the commitment of the Zambian Government to health research and a sign of the increasing recognition of the value of EDCTP's contribution to health research in Africa.

His Excellency the President of the Republic of Zambia, Mr Edgar Chagwa Lungu said that his Government would continue to 'pursue a vigorous agenda' on health research. Speakers from EDCTP and the European Community congratulated Zambia on its commitment to health and health research and thanked it for the support it has given to EDCTP since the programme was first launched.

Speakers at the Forum's opening session stressed that Africa and Europe are equal partners in EDCTP and called upon African countries to engage fully with the programme and make their voices heard in deciding on the priorities for health research. EDCTP aims not simply to discover new treatments but to support the entire 'pipeline' in which a new product is tested and finally brought to the point where it can be used in routine health care.

A high-level meeting took place as part of the Forum on 7 November 2016. It brought together invited representatives and policy makers from existing and aspiring EDCTP member countries in Africa and Europe, African regional bodies, health and research councils, and funding agencies. The first part of the meeting focused on EDCTP's value to African countries through the facilitation of research uptake and the rapid translation of results into policy on poverty-related infectious diseases. The second part was dedicated to the Ebola virus disease outbreak in West Africa.

The Forum presented a comprehensive scientific programme with a total of 39 sessions for more than 400 participants. The programme consisted of 123 oral presentations in plenary, parallel and collaborative sessions, panel discussions and educational workshops, as well as 133 poster presentations. Moreover, research groups and other organisations contributed a total of 9 scientific symposia. Alongside the main programme were 4 satellite meetings.

A report on the Eighth EDCTP Forum will be published in December 2016. For more information about the Eighth EDCTP Forum, please visit www.edctpforum.org.













1. His Excellency the President of the Republic of Zambia, Mr Edgar Chagwa Lungu at the opening ceremony. 2. Forum participant presenting a poster. 3. Dr Catherine Hankins (Netherlands) at her keynote speech on Monday 7 November 2016. 4. Participants at the workshop 'Applying for an EDCTP2 grant'. 5. Prof. Jimmy Volmink (South Africa) gives a presentation at the scientific symposia 'Using systematic reviews to inform policy and research direction on neglected diseases.' 6. Participants at the exhibition area.

capacity in sub-Saharan Africa: "African countries need their own scientists, capable of doing research that supports the whole value chain, from basic discovery to implementation research and surveillance."

One of the challenges to achieve is to close the gap between development aid and research capacity development. Prof. Tanner: "It is a very precise balancing act but the two approaches should become a collaboration. If we in Europe can bring about this shift of mind-set, not only would we have a stronger long-term approach and better results, but it would also make involvement of the private sector easier. A mind-set shift is necessary also in the private sector. Shareholder value was not always everything; we could use again some of the old 'Tropical Medicine' and "Medicine in the tropics" spirit when there was a drive to address a disease because it was there and a burden for particulary the poor and neglected people."

Talking on developments in sub-Saharan Africa, Dr Simão painted with a broad brush the changing African attitudes (including to science and research) pointing to the demographic transition with a large younger generation that is much better educated than ever before and much better connected and informed. Further development of the African research base will also help to address the 'brain drain'. He said that the challenge is to create a leading role for Africans. Development and also research regarding African problems should become more and more an initiative led by African countries and based on their national priorities. "Look, Africans have their own plans rooted in national realities. This means that there will be legitimate differences in agendas within international initiatives. But convergence can be achieved through dialogue. EDCTP's General Assembly certainly has become a common platform for dialogue. As African academic infrastructure develops further, a more balanced, more evidence-informed dialogue will develop also. But you can never relinquish your nation's priorities."

Dr Leonardo Santos Simão is a medical doctor by training. After his graduation from the Eduardo Mondlane University, Mozambique in 1980, he worked in rural areas of Mozambique as medical officer at district and provincial levels. He holds a Master's degree in Public Health (Community Health in Developing Countries) from the London School of Hygiene & Tropical Medicine (United Kingdom). He also taught in the Faculty of Medicine of the Eduardo Mondlane University, Mozambique. Dr Simão was the Executive Director of the Joaquim Chissano Foundation. He is also the Chairman of the SADC Mediation Reference Group, and Chairman of the steering committee of the Business Environment Support Fund in Mozambique, a development initiative funded under Denmark's development cooperation activities.

Professor Marcel Tanner was Director of the Swiss Tropical and Public Health Institute from 1997 to 2015 and is now President of the Swiss Academy of Sciences. He holds a PhD in medical biology from the University of Basel and a MPH from the University of London. For his expertise in the field of infectious diseases research and control he received global recognition. He lived and worked in Africa and Asia, trained more than 200 African PhD and master's students, and has published extensively in many fields of health research (>650 original papers). He was co-investigator and coordinator of the first African malaria vaccine trial in 1992 and participated as co-principal investigator in several major intervention trials on malaria and schistosomiasis. He developed a Swiss field laboratory to what is now the Ifakara Health Institute in Tanzania from 1981-1985 and when back in Europe as programme director 1987-1997.

Secretariat: new staff

Dominika Jajkowicz took up the new position of Monitoring & Evaluation Officer at EDCTP in October 2016.

Prior to joining EDCTP, she worked for nearly five years at DSW (Deutsche Stiftung Weltbevölkerung) in Brussels, Belgium and Nairobi, Kenya. She supported, conducted and managed monitoring & evaluation and research exercises for DSW's

advocacy and service delivery programmes on Global Health R&D, HIV/ AIDS and Maternal, Newborn & Child Health across Africa, Asia and at EU-level.

Dominika was born in Poland and has a Master's in Sociology from Jagiellonian University in Krakow with a focus on quantitative and qualitative research methods.

Dr Magda Moutaftsi joined EDCTP in October 2016 as North-North Networking Officer. She has a background in research (vaccine immunology) and global health.

From 2012-2016, Dr Moutaftsi worked at the Bill & Melinda Gates Foundation (USA) for the HIV Vaccine Initiative. As a Program Officer she managed grants ranging from upstream research to clinical development.

Of Greek descent, Magda was born and raised in Germany. She obtained a Master's in Biology from the University of Hanover (Germany) and a PhD in Viral Immunology from the University of Wales College of Medicine (United Kingdom). Her postdoctoral training at the La Jolla Institute for Allergy and Immunology (USA) focused on large-scale epitope identification and analysis for protection efficacy to advance vaccine discovery. She then joined the Infectious Disease Research Institute (USA) in the Preclinical Biology Department, evaluating adjuvant technologies for vaccines relevant to global health diseases such as malaria, HIV, and TB.

Dr Claire Whitaker started as a Project Officer at EDCTP in October 2016. Claire Whitaker is based at the EDCTP office in Cape Town, South Africa.

Before joining EDCTP, she worked six years at the South African Medical Research Council (SAMRC), first in the HIV Prevention Research Unit as a Science Writer. She then joined

the Cancer Research Initiative of South Africa (SAMRC/CANSA), where she managed the grant application, review and assessment process, as well as producing and managing social media and website content. Finally, she joined the SAMRC Grants and Scholarships Administration Division as Scientific Review Officer and Science Communicator.

Claire was born in Durban (South Africa). She was trained as a researcher in the field of seed and molecular biology, and conducted research in Cape Town, Pietermaritzburg and in the Namib-Naukluft Park (Namibia). She holds a PhD in Biology from the University of KwaZulu-Natal, specialising in the seed biology and pathology of *Welwitschia mirabilis*.

EDCTP 2016 Awards

The EDCTP awards aim to recognise outstanding individual researchers and research teams, as well as further the research programmes research-related activities of the winners. The ceremonies of the EDCTP 2016 Awards took place at the Eighth EDCTP Forum in Lusaka, Zambia.

The EDCTP 2016 Award for Outstanding Research Team 2016 was given to the **University of Zambia – University College London Medical School (UNZA-UCLMS) Research & Training Program** on 6 November 2016. The award consisted of a trophy and 50,000 euro. At the opening session of the Eighth EDCTP Forum, Dr Peter Mwaba, on behalf of his team, received the award from His Excellency, the President of the Republic of Zambia, Mr Edgar Chagwa Lungu. The award is given to an outstanding research team in Africa or Europe working on poverty-related infectious diseases within the scope of the second EDCTP programme.



His Excellency the President of the Republic of Zambia, Mr Edgar Chagwa Lungu, and the representatives of UNZA-UCLMS Research & Training Program at the award ceremony

On 7 November 2016, **Professor Shabir A. Mahdi** received the EDCTP 2016 Award for Scientific Leadership. The award consisted of a trophy and 10,000 euro and was presented by Dr Michael Makanga, EDCTP Executive Director. This award recognises an excellent world-class scientist up to 50 years of age residing in Africa and working in research activities within the scope of the second EDCTP programme.



Prof. Shabir Mahdi speaks at the ceremony of the EDCTP 2016 award for Scientific Leadership

Professor Marleen Temmerman received the EDCTP 2016 Award for Outstanding Female Scientist on 8 November 2016. The award consisted of a trophy and 20,000 euro. The award was presented by Professor Nkando Luo, the Honourable Minister of Higher Education, Research, Vocational Training, Science and Technology of Zambia. The award recognises an excellent world-class female scientist residing in sub-Saharan Africa and working in research activities within the scope of the second EDCTP programme.



Prof. Marleen Temmerman (left) receives the award for Outstanding Female Scientist from Prof. Nkandu Luo

The EDCTP Dr Pascoal Mocumbi Prize was given to **Professor Fred Binka** in recognition of his outstanding achievements in advancing health research and capacity development in Africa. The ceremony took place at the closing session of the Eighth EDCTP Forum on 9 November 2016. The award consisted of a trophy and 50,000 euro. Professor Charles Mgone, former Executive Director of EDCTP, presented the award to Prof. Fred Binka. The Dr Pascoal Mocumbi Prize rewards an individual in recognition of his or her outstanding achievements in advancing health research and capacity development in Africa with significant impact on the wellbeing of the African population.



Prof. Fred Newton Binka (right), winner of the Dr Pascoal Mocumbi Prize with EDCTP Executive Director Dr Michael Makanga

More information about the EDCTP 2016 Awards is available at www.edctp.org.



EDCTPNEWSLETTER is a quarterly newsletter from the European & Developing Countries Clinical Trials Partnership secretariat. Digital copies of this newsletter are available in English, French, and Portugese on our website <u>www.edctp.org</u>.

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