



EDCTP

The power of sharing science

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Register for our ninth Forum

**Ninth
EDCTP
Forum**

Clinical research and sustainable development in sub-Saharan Africa: the impact of North-South partnerships.

EDCTP organises its ninth Forum in partnership with the Portuguese national Foundation for Science and Technology (FCT) and the Gulbenkian Foundation. We invite all our stakeholders to attend the Ninth EDCTP Forum at the Gulbenkian Foundation, in Lisbon, Portugal from 17-21 September 2018.

The EDCTP Forum brings together a diverse audience, including representatives from research institutions and universities, the larger scientific community, health care providers, governments, regional bodies, regulators, civil society and public and private research and development partners.

Register at the Forum website (www.edctpforum2018.org) which has the complete programme and opportunities for sponsorships.

Assessing research systems

Esteemed stakeholders,

As EDCTP scales up its clinical research funding, we are also developing capacity to ensure adherence to ethical principles and regulatory standards. This newsletter offers an overview of the EDCTP2 portfolio of projects on ethics review and regulatory oversight of clinical studies and several examples related to this effort. The TRUST project, funded by the European Union and led by Professor Doris Schroeder, concluded its main activities with a successful event in the European Parliament on 29 June 2018. The project's Global Code of Conduct for Research in Resource-Poor Settings was adopted by the European Commission as guidance material for relevant research projects funded under Horizon 2020.

Moreover, I wish to draw your attention to the update on the meeting in Accra, Ghana from 09-10 July 2018. In collaboration with the WHO Regional Office for Africa (WHO AFRO), EDCTP organised a first meeting on assessing African national health research systems. The delegates were from the 17 African EDCTP member countries and included also strategic partners in the African Union and regional economic communities. A main objective was to prepare for a survey of the national health research capacities in African countries using the NHRS barometer, an assessment tool developed by WHO AFRO.



Dr Michael Makanga
Executive Director

The results of the survey will be presented at a high-level side event during the 68th session of the WHO-AFRO Regional Committee meeting in Dakar, Senegal on 31 August 2018. This high-level meeting will bring together African ministers and their technical team representatives, regional bodies that deal with health and research, regulators, and strategic partners committed to strengthening national health research systems in Africa.

A second high-level meeting to deliberate how best to maximise European-African partnerships on clinical research and innovation will take place on 17 September, prior to the Ninth EDCTP Forum in Lisbon, Portugal, from 17-21 September 2018. The invited African and European policy-makers, along with other key international stakeholders, will discuss how to advance the EDCTP agenda and consolidate the gains of EDCTP2 for a successor programme under the next European Union Framework Programme for Research and Innovation, Horizon Europe (2021-2027).

I warmly encourage all our stakeholders to participate actively in shaping the future of our programme and fully expect to welcome you in a short while to the Ninth Forum in Lisbon.

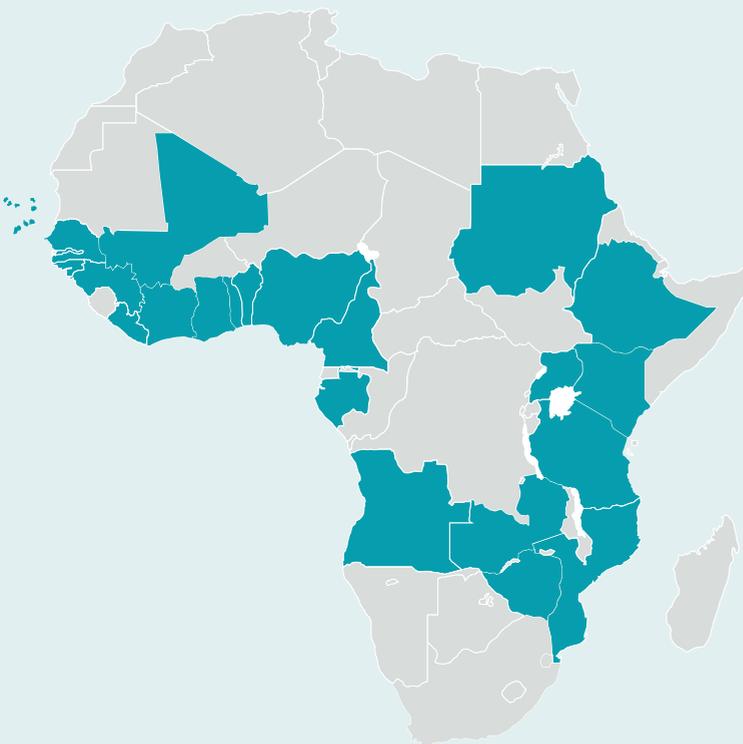
Dr Michael Makanga
Executive Director



EDCTP portfolio: Ethics and regulatory capacities



By end of 2017, EDCTP-supported ethics and regulatory projects were being conducted in 17 sub-Saharan African countries.



The **BERC-Luso** project engages four sub-Saharan African countries – Angola, Cape Verde, Guinea Bissau and Mozambique. It aims to develop and strengthen national medicines regulatory systems and capacities for ethical review of clinical research, in order to preserve public health interest, allowing pharmaceutical industry to pursue their activity while respecting ethical and cultural values.

The **IGORCARDIA** project was designed to further strengthen the Liberia Medicines and Health Products Regulatory Authority (LMHRA), especially its mandate and capacity to regulate research on diagnostics for infectious diseases. The objectives are to strengthen LMHRA's capacity to: regulate the use of diagnostics in research; supervise diagnostics research; and establish inter-agency collaboration.

The **Enhancing ethics in Sudan** project will build and strengthen the capacity of the National Health Research Ethics Committee (NHREC) and the National Medicine and Poisons Board (NMPB). Both bodies have the legal authority and the responsibility to develop guidelines, and to regulate and oversee the ethical review process and the conduct of research in Sudan.

EDCTP's contribution to bioethics capacity in Africa

2017 marked the 70th anniversary of the Nuremberg Code, a set of medical research ethics principles which dates to post-Second World War trials of Nazi scientists. The Nuremberg code was formulated by the judges and is considered and accepted as the start of modern biomedical ethics. Since then, various stakeholders, national and international institutions and organisations, academia and industry, authorities and professional associations as well as parliaments have continued to develop frameworks for ethical review and medical research.

In June 2018, the *Central European Journal of Medicine* published a series of articles on 'Medical Ethics in the 70 Years after the Nuremberg Code, 1947 to the Present'. The publication results from an international conference held at the Medical University of Vienna on 2-3 March 2017. It aimed to give an overview of the developments since the formulation of the Nuremberg Code and its impact on today's medical research. A central topic was the role played by international organisations in endeavouring to establish normative standards with a global validity. The article 'The development of bioethics in Africa: the role of the European and Developing Countries Clinical Trials Partnership' highlights EDCTP's activities to strengthen bioethics capacity in Africa.

Under the first EDCTP programme (2003-2015) a grant scheme was launched in 2005 to support the development of ethics review and regulatory capacities in sub-Saharan Africa at both the institutional and national level. Grants were awarded to develop the appropriate human resources and infrastructure. Seventy-five grants were made during the first programme, with total funding of over € 4M. Through this scheme, EDCTP funded the establishment and strengthening of ethics review frameworks for health research in countries with little or no existing ethics review capacity such as Benin, Democratic Republic of Congo, Gabon, Liberia, Mozambique, Rwanda and Togo. Of the 75 grants awarded, 38 were intended to support an Institutional Review Board (IRB), 13 supported National Ethics Committees (NEC), 8 supported both an IRB and NEC, 11 provided support for courses on ethics, and 5 supported coordination activities.

During the second EDCTP programme (2014–2024) support for ethics and regulatory capacity activities has been scaled up. Its focus shifted to a national and sub-regional strategic approach with more engagement with national governments. EDCTP encourages national RECs and regulatory bodies to collaborate on their submissions to its calls for proposals, to increase communication and harmonisation of approaches between these organisations. A requirement to register all clinical trials as part of the ethical review process promotes and facilitates oversight of the national research landscape. Therefore EDCTP supported the establishment and development of the Pan African Clinical Trials Registry. By the end of 2017, 13 ethics and regulatory capacities grants had been awarded in the second EDCTP programme, with a total value of € 3.83M.

REECAO project: ethics review network in West Africa

West Africa has seen a strong increase of clinical trials in the last ten years. The need to conduct more clinical trials on malaria, TB, HIV and neglected infectious diseases and the recent epidemic of Ebola virus disease posed new challenges for ethical oversight and protection of clinical trial volunteers.

As in other regions of sub-Saharan Africa, many volunteers in clinical trials belong to poor rural populations, are often illiterate, have urgent health care needs, and sometimes have very different sociocultural views. These are all important factors that limit their understanding of complex aspects of clinical research. To better protect these populations, it is crucial to strengthen the governance, operation, effectiveness and sustainability of ethics committees. Additionally, language barriers to multicentre clinical trials and the need to prepare for emergency research during epidemics indicated a need for a regional ethics network.

The REECAO project is a research ethics network for West Africa based on North-South collaboration. The project was funded in 2017 with an EDCTP grant under its 2015 Ethics and regulatory capacities call. Until recently, the activities of REECAO (Renforcement de l'Ethique des Essais Cliniques en Afrique de l'Ouest) are supported by the Ministries of Health of Mali, Ghana and Guinea, the Institutional Review Boards, and the Catholic University of Lyon, France, which contributes its experience in ethics training.

REECAO is to reinforce ethics oversight of clinical trials in Mali, Ghana, and Guinea. The project aims to achieve this by establishing a joint 'ethical watch' through North-South and South-South collaboration; creating and implementing standardised procedures for protocol submission and evaluation; training a critical mass of trainers for ethics review; and reinforcing the governance of ethics committees.

After its first year, REECAO already delivered first results. It has set up the network, organised two case studies and two training sessions for trainers (one in English and one in French). Six training modules were developed: ethical principles and methods; National Ethics Committees and Institutional Review Boards governance; ethics of biotechnology in humans; ethics in emergency cases; clinical research and related ethical issues; and community authorisation and individual consent. Additionally, the hotline to assist research and ethics committee members and the database for ethics professionals were set up.

For more information on REECAO, please visit www.reecaoafrica.org.

Tribute to Prof. Ogobara Doumbo (1956-2018)

Professor Ogobara Doumbo, Director of the Malaria Research and Training Center (MRTC) in Bamako, Mali, passed away on 9 June 2018. He was recognised as a global leader in malaria research. Among many other activities, he coordinated the EDCTP-funded REECAO ethics project.



“We are extremely sad by the passing away of Professor Ogobara Doumbo, an outstanding research leader and true mentor of the next generation. May he rest in peace.”

*Dr Michael Makanga,
EDCTP Executive Director*

“Professor Ogobara Doumbo will be sadly missed by the global malaria community. I trained at the Malaria Research and Training Center in Mali in the early 1990s; he was a great mentor.”

*Prof. Moses Bockarie,
EDCTP Director of International Cooperation (Africa) and Head of Africa Office*

TRUST project: final event in European Parliament

The final event of the TRUST project took place in the European Parliament, Brussels, on 29 June 2018. The EU-funded project addresses double standards, the export of non-ethical research practices to low- and middle-income countries ('ethics dumping') and equity in international research.

The event in the European Parliament 'Ethics Dumping - Looking for Justice' was co-hosted by TRUST and the European parliamentary group GUE/NGL. Among the speakers were Prof. Jeffrey Sachs (keynote), Prof. Doris Schroeder (TRUST coordinator, University of Central Lancaster), Dr François Bompard (formerly Sanofi/EFPIA, currently DNDi) and from EDCTP, Dr Michael Makanga and Dr Leonardo Simão (EDCTP High Representative for Africa). Final speaker was Wolfgang Burtscher (Deputy Director General) who represented Jean-Eric Paquet, Director-General of the DG Research and Innovation, European Commission. He announced the adoption of the Code as guidance material by the European Commission.

The main deliverable of the TRUST project was the development of the Global Code of Conduct for Research in Resource-Poor Settings. Universal values of fairness, respect, care and honesty form its fresh ethical framework. It aims to counter ethics dumping by providing guidance across all research disciplines. It is presented in short clear statements in simple language to achieve the highest possible accessibility, focuses on research collaborations that entail considerable imbalances of power, resources and knowledge. Along with the code, the project offers a wide range of learning materials and affiliated information. The code was developed in a process of extensive consultation and engagement with ethics committee chairs, research councils, policy makers, vulnerable research populations (South African San community and sex workers), funders and industry representatives.

The global code is available at www.globalcodeofconduct.org and on the Horizon 2020 participants portal (<https://ec.europa.eu/research/participants/portal/desktop/en/home.html>). For more information about the TRUST project, visit <http://trust-project.eu>.



Photo: TRUST consortium in European parliament

Photo credit: Amy Ezra Dean



Uganda: 10th Annual National Research Ethics Conference

The Uganda National Council for Science and Technology (UNCST) organised the tenth Annual National Research Ethics Conference (ANREC) on 10-11 July 2018. Its theme was 'Evolution of Research Ethics in Uganda and the Region: past, present and future'. A total number of 594 participants, including from research and regulatory organisations in Burundi, Kenya, Malawi, Rwanda, South Sudan, Tanzania, attended the conference.

ANREC is a platform for engagement and interaction among the various actors involved in the protection of human subjects in Uganda. It brings together researchers, regulators, policy makers, members of research ethics committees, civil society groups and research communities.

The first ANREC was organized in 2009 by UNCST with support from EDCTP. Since then, ANREC was organised by UNCST in collaboration with partners, notably the National Drug Authority and the Uganda

National Health Research Organisation. This year UNCST received again support for the conference from EDCTP through its funding of CREDU (Consortium for clinical research regulation and ethics capacity development in Uganda) under its Call for proposals for strengthening Ethics and regulatory capacities (2015).

The tenth ANREC focused on advancing research ethics in Uganda and the East Africa Region with the overall objective of understanding the evolution of research ethics. The main topics of discussion were ethical issues associated with advanced science and research. The conference showed achievements, persistent challenges and a consistent effort in the region to align with global developments in the field of research ethics. Among the recommendations of the meeting are: addressing duplication of effort and long review times for large clinical trials through joint review platforms; further review capacity development; and developing national legal frameworks.

African countries to assess their health research systems

The kick-off meeting of a project to develop and strengthen national health research systems (NHRS) in sub-Saharan Africa took place in Accra, Ghana, on 9-10 July 2018. The main objective of the meeting is to prepare for a survey of national health research capacities in the 17 African EDCTP member countries. It was jointly organised by EDCTP and WHO Regional Office for Africa (WHO-AFRO).

The meeting was hosted by Ghana, an EDCTP member country, through the Ghana Health Service of the Ministry of Health. The meeting was the largest gathering to date of EDCTP General Assembly and government representatives of the African member countries of the EDCTP Association. It brought together over 50 delegates from the 17 African member countries of EDCTP to initiate development of a strategic plan to strengthen NHRS.

The delegates included senior government officials responsible for research oversight in their respective countries, officials of the African Union and Regional Economic Communities, national representatives to the EDCTP General Assembly, as well as EDCTP and WHO-AFRO representatives. The purpose of the strategic plan is to provide guidance and support to governments for strengthening their NHRS. This will optimise national health research production and utilisation, and ultimately, contribute to achieving the sustainable development goals (SDGs) and Universal Health Coverage.

Specific objectives of the meeting

- Development of a conceptual framework for assessment of NHRS in Africa.
- Documentation of tools and guidelines for use of the NHRS barometer developed by WHO-AFRO.
- Implementation of the NHRS barometer by government institutions to conduct surveys to assess African NHRS capacities.
- Development of a strategic policy plan to provide guidance to assess and strengthen health research systems capacity in Africa to generate and utilise research that will inform national policies on health.

Expected outputs of the meeting

- A conceptual framework for the assessment of the NHRS in Africa developed.
- 14 health professionals from the African EDCTP Participating States to be trained in the utilisation of the NHRS assessment tool, the NHRS barometer.
- 34 health professionals to be prepared to complete NHRS assessment surveys in the 17 African member countries of the EDCTP.
- Results from NHRS surveys to be presented at a high-level side event during the next meeting of the African Ministers of Health in Dakar, Senegal, 30 August 2018.

A report of the meeting is available at www.edctp.org.

Open 2018 calls for proposals

The EDCTP calls for proposals are supported through three distinct types of Horizon 2020 'actions':

- **Research & Innovation Actions (RIA)** are multicentre clinical trials conducted by research consortia involving both European and African research teams, with integrated capacity development and networking elements.
- **Coordination & Support Actions (CSA)** support activities that strengthen the enabling environment for conducting clinical trials and clinical research, including ethical review and regulatory capacity.
- **Training & Mobility Actions (TMA)** are fellowships that focus on the career development of individual researchers or research team members.

In 2018, EDCTP will launch 11 calls for proposals to support clinical research and related activities on poverty-related diseases (PRDs). Eight calls are already open to applications:

Diagnostic tools for poverty-related diseases

Type:	Research & Innovation Action (RIA)
Procedure:	Two-stage application
Open to applications:	6 June 2018
Deadline for applications:	11 October 2018

Strategic action for the comparison, selection and development of malaria vaccine candidates

Type:	Research & Innovation Action (RIA)
Procedure:	Single-stage application
Open to applications:	12 June 2018
Deadline for applications:	1 November 2018

Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities

Type:	Research & Innovation Action (RIA)
Procedure:	Two-stage application
Open to applications:	6 June 2018
Deadline for applications:	18 October 2018

Capacity development to facilitate delivery and uptake of new or improved medical interventions in African health systems

Type:	Coordination & Support Actions (CSA)
Procedure:	Two-stage application
Open to applications:	12 June 2018
Deadline for applications:	18 October 2018

Strategic action for overcoming drug resistance in malaria

Type:	Research & Innovation Action (RIA)
Procedure:	Single-stage application
Open to applications:	12 June 2018
Deadline for applications:	30 October 2018

Ethics and regulatory capacities

Type:	Coordination & Support Actions (CSA)
Procedure:	Single-stage application
Open to applications:	2 August 2018
Deadline for applications:	22 November 2018

Vaccines for diarrhoeal diseases or lower respiratory tract infections

Type:	Research & Innovation Action (RIA)
Procedure:	Single-stage application
Open to applications:	12 June 2018
Deadline for applications:	30 October 2018

Career Development Fellowships

Type:	Training & Mobility Actions (TMA)
Procedure:	Single-stage application
Open to applications:	6 August 2018
Deadline for applications:	27 November 2018

More information about calls for proposals is available at www.edctp.org. To apply, visit www.edctpgrants.org.

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