Cross-continent clinical trials

Professor Charles Mgone
Executive Director, European & Developing Countries Clinical Trials Partnership
EDCTP unites European and African countries to promote clinical trials for HIV/AIDS, TB and malaria. Professor Charles Mgone discusses the strengths and successes of the Partnership, its initiatives to encourage collaboration, and plans for Horizon 2020.

Can you provide a brief history of the European & Developing Countries Clinical Trials Partnership (EDCTP) and outline how its central mission has developed since its inception?

EDCTP was formed in 2003 through a co-decision of the European Parliament and European Council. It was founded by 15 European countries under the European Commission’s Sixth Framework Programme (FP6) to pool resources in response to the global health crisis caused by HIV/AIDS, TB and malaria.

EDCTP has remained focused on accelerating the development of clinical interventions against the three leading poverty-related diseases by supporting clinical trials, clinical research studies and capacity building and networking activities in Europe and sub-Saharan Africa. One of EDCTP’s main objectives is to ensure that the clinical trials we fund address the needs and priorities of developing countries by encouraging African co-ownership and leadership.

What is your background and how has it led you to take up the role of Executive Director?

I trained as a paediatrician and worked both as a clinician and research scientist in Africa before undertaking a PhD in Medical and Molecular Genetics in Glasgow, UK. Following this, I moved to Papua New Guinea where I worked as a research scientist and the Deputy Director of the Papua New Guinea Institute of Medical Research. At that time, I was working on malaria and sexually transmitted infections, with a focus on HIV/AIDS. I then moved back to Africa where I supported capacity development for malaria vaccine R&D.

Could you outline the ultimate goal of your work to combat infectious diseases in developing countries?

My strong desire is to contribute to an equitable world. My dream is to have a global community where no one is disadvantaged because of poor health from preventable diseases or malnutrition, which are intertwined.

What is EDCTP’s strategy with regards to the initiation of clinical trials?

The priorities for calls for proposals are developed by the Executive Secretariat in cooperation with EDCTP advisory bodies, following consultation with the relevant stakeholders. These priorities and their implementation plans are ultimately agreed and approved by the General Assembly – the governing body, comprised of European and African representatives, that ensures all activities are undertaken to achieve the statutory objectives of EDCTP, and that resources are properly and efficiently managed.

Under the current EDCTP programme, consortia comprising of collaborators from a minimum of two European Member States and one or more African institutions are formed in response to the competitive calls for proposals. Applications for clinical trial projects are then submitted for an independent scientific peer review and selection procedure. Once grants have been awarded to the successful consortia, the resources are distributed among the participating institutions and researchers.

Conducting Phase II and III clinical trials requires cooperation with local people. How does the Partnership form relationships with populations in sub-Saharan Africa?

Active involvement and co-ownership of the programme by African partner countries and communities is imperative. At the policy and scientific level, EDCTP research priority setting is a consultative process and is aligned to the host countries’ priorities. The implementation of clinical trials actively engages African scientists and policy makers in the consortia. EDCTP also requires a results dissemination plan for all funded projects, which includes policy briefs and the feedback of information to the communities that take part in the clinical trials.

At the community level, EDCTP requires that all clinical trials and research projects obtain local ethics approval. All good clinical practice (GCP) compliant ethics committees have a community representative. In addition, some of the clinical trials – especially those involving vaccines, microbicides and social science aspects – have a community advisory board.

Although our projects are highly collaborative, and invariably all clinical trials have sites in several African countries, we know that many researchers work in isolation, rarely sharing infrastructure and expertise. Clinical trials break barriers between researchers and local populations and lead to the identification of high-risk populations. An example worth mentioning is the ‘Fisher Folk Study’ involving fishermen communities based around the shores of Lake Victoria in Uganda and Lake Malawi – a joint collaboration led by the Uganda Virus Research Institute.

How do the regional networks of excellence (NoEs) for conducting clinical trials work to increase efficiency and avoid duplication of efforts in clinical trials? How do these NoEs overcome the vast social and political differences that exist across African nations?

Launched between 2009 and 2010, and based in Eastern, Western, Central and Southern Africa, the NoEs promote interaction between individual African research teams and their European collaborators. They facilitate regional networking by uniting diverse institutions and combining their individual strengths and infrastructures for conducting clinical trials. These strengths include good clinical and laboratory practice, data management and epidemiology, among others. By collaborating, scientists within NoEs learn and develop, thereby raising the quality of clinical research and practice in sub-Saharan Africa.

Given the heterogeneity of the underlying sociopolitical climate across African nations, it is often difficult to match political priorities with the health needs of communities. Nevertheless, the NoEs endeavour to operate at a Pan-African level. As such, they are a prime example of science overcoming social and political obstacles in the pursuit of common international objectives, such as the Millennium Development Goals.

Whilst utilising European research and expertise is undoubtedly useful, a big focus of your work is enhancing regional research capacity in Africa. How do you achieve this?

One of EDCTP’s primary mechanisms for enhancing regional research capacity in Africa has been through the establishment of the four regional NoEs. Whilst the networks naturally utilise the research expertise of their European collaborators, the onus has been placed on more experienced African research partners to take the lead in the establishment and coordination of the networks and to nurture the development of their less-established partners.

The NoEs have developed through collaboration with both European and African experts, thereby raising the quality of clinical research and practice in sub-Saharan Africa.

In recognising that the lack of suitably qualified researchers presents a barrier to capacity development, our senior fellowship scheme represents another channel through which regional research capacity is strengthened. EDCTP’s strategy is to support researchers at different
Contributions to research

The Partnership places great importance on measuring the progress of all operational activities and reporting on these in a concise and transparent manner. This includes:

- Supported grants and projects
- Levels of integration and co-founding
- African and European countries participating in the partnership

stages of their career who are capable of building and leading research groups at sub-Saharan African institutions.

How does EDCTP ensure that ethical considerations are taken into account when carrying out clinical trials?

The strengthening of ethics and regulatory frameworks is a major focus for EDCTP, given that they are inadequate in many sub-Saharan African countries, primarily due to a lack of human and financial resources. To rectify this, EDCTP is providing grants to establish oversight committees and ensuring that such committees are operational, as well as supporting the training of their staff and mapping their capacity.

EDCTP requires that all clinical trials and research on human subjects have ethical and applicable regulatory clearances. The release of EDCTP funds is normally tied to the provision of evidence of all necessary ethics and regulatory approvals from all countries participating in the project. To ensure transparency and avoid duplication in clinical trials, all must be registered with the Pan-African Clinical Trials Registry – the first World Health Organization (WHO) endorsed trials registry in Africa.

EDCTP was also instrumental in the establishment of the African Vaccines Regulatory Forum, to facilitate capacity strengthening and harmonisation, including joint reviews and inspection among African national regulatory bodies.

Partnership between European nations and sub-Saharan African countries forms the basis of EDCTP’s work. Could you outline the benefits of this partnership?

As a partnership between countries, EDCTP ensures synergy and optimal use of resources and creates a win-win situation for all parties. The Partnership has shown the importance of opening up research to worldwide collaboration by combining the strengths of its European participating states with their sub-Saharan counterparts. EDCTP’s governance includes both European and African policy makers and researchers responsible for decision-making and priority-setting. The Partnership has become a good example of a modern north-south collaboration on the basis of equal partnership, while contributing to the European research area by facilitating cross-border research. Through EDCTP, European and African countries have a coherent and coordinated international voice and a common strategy in the fight against poverty related diseases.

Local strains of pathogens and genetic differences in populations mean that treatments might have variable efficacies in different parts of the world. Are there any plans to extend your remit to other developing nations afflicted with the ‘big three’ infectious diseases?

Although expansion beyond sub-Saharan Africa is not excluded, such an extension would require the development of a separate strategy and additional funding. Collaborative research will be supported outside sub-Saharan Africa but initially this is likely to be through global research collaborations with other funders, rather than directly from EDCTP. The PanACEA-REMoxTB project is an example of this type of collaboration. The project aims to develop collaboration for the conduct of regulatory standard clinical trials for three TB drugs. The consortium includes six European research organisations, 12 sub-Saharan clinical trial sites and three pharmaceutical companies. While EDCTP funds the sub-Saharan component of the project, other donors support activities in India, China, Thailand and Latin America. Collaboration with other funders to support research outside sub-Saharan Africa will be necessary for EDCTP to achieve its objectives.

What are your plans for the future, with particular reference to the second EDCTP programme (EDCTP2)?

The current EDCTP programme will end in May 2015 and EDCTP2 is expected to start in 2014 under Horizon 2020. EDCTP2 will consolidate and expand upon the foundations established under the first programme, particularly in relation to research facilities and trained personnel, as well as integrating national research programmes and supporting committees on drug regulatory affairs and ethics.

Building on the progress made so far, EDCTP2 will see an expansion of its remit and activities to include all clinical trial phases; neglected infectious diseases; and implementation research. The new programme will also see a stronger partnership with more European and African countries and increased collaboration with the pharmaceutical industry, product development partners, philanthropic organisations and development agencies. It will also provide opportunities for sub-Saharan African countries, and all Horizon2020 associated countries, to fully participate in the governance and funding of the programme.

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