

European and Developing Countries Clinical Trials Partnership



In a bid to reduce the burden of poverty-related disease in developing countries, EDCTP has been working to build partnerships between African and European researchers. Executive Director, **Professor Charles Mgone**, speaks to *International Innovation* about their progress to date

Could you first explain why EDCTP was formed and what the partnership's goals are?

EDCTP was established in 2003 in response to the overwhelming burden of poverty-related diseases (PRDs) in particular HIV/AIDS, malaria and tuberculosis. It was established as a partnership between European Union and sub-Saharan countries. The goal of the partnership is to reduce the burden of these diseases and contribute to improving the health of people living in developing countries, particularly in Africa, which is most affected. This is realised first by accelerating the development of intervention tools (drugs, vaccines, microbicides and diagnostics) to fight the three diseases through funding clinical trials, and also by strengthening research capacity and oversight (of regulations and ethics) to ensure the clinical trials are conducted according to best practice and international standards. The partnership also seeks to consolidate and build new links between European researchers working in this field to support innovative approaches to these challenges.

There are many organisations and charities that target Africa and PRDs like HIV/AIDS. How does your approach differ from existing strategies, and why do you think HIV/AIDS is still so prevalent despite past efforts?

Unlike many other organisations, EDCTP is a genuine partnership between Europe and Africa with the co-ownership of the African partners. This reaches to all levels, including policy making where African partners through African Union, Regional Economic Communities and Ministries of Health are represented at the EDCTP-EEIG General Assembly, to the Partnership Board, which is the scientific advisory body. Additionally, EDCTP has a body comprised entirely of Africa scientists and policy makers that is responsible for identifying capacity needs and priorities of the African partners.

Furthermore, and also unlike many other organisations, EDCTP specifically and proactively targets capacity development and

networking as one of its major undertakings. Capacity development and networking are embedded into clinical trial funding to ensure the developed capacity is utilised and retained to guarantee successful outcomes and facilitate sustainability. Networking between north-south aims to pool knowledge and support technology transfer among partners whereas south-south networking is to encourage proliferation of the developed capacity and enhance synergy.

What criteria do you use to partner up the European and African countries? How do you ensure that the relationship is mutual and beneficial to both parties?

In science, partners usually find themselves, but where scientists want to break new ground we also assist in getting them together to form new networks and collaborations. In the past many of these partnerships were based on traditional or colonial ties, but with EDCTP acting as a common platform, many new collaborations have been formed. This includes participation from European countries that previously had no tradition of working in Africa or of working in partnership with other European countries, especially where HIV/AIDS, malaria and tuberculosis was concerned. Our approach has contributed to more research collaboration in Europe as well as in Africa because we design our grant criteria to stimulate such research cooperation. Smart coordination of European and African research effort saves precious resources and can speed up innovation.

What progress have you made in developing capacity in Africa and training African scientists to undertake clinical trials?

This is progressing very well, and is reflected in the fact that in EDCTP, 70 per cent of the project leaders are Africans. Its success is based on the fact that research capacity development is embedded in the core business of supporting clinical trials whereby the identified capacity deficiencies for

conducting clinical trials are filled while the trials are ongoing.

Furthermore, many researchers funded by EDCTP have gone on to receive further competitive grants and awards, which have enabled them to develop their careers whilst remaining in Africa.

Could you explain the aim of the Pan-African Consortium for the Evaluation of Antituberculosis Antibiotics (PanACEA) which EDCTP funds? Who are some of the main contributors?

Under the auspices of EDCTP, PanACEA is an innovative brokered consortium of scientists from Europe, Africa and America funded by the European Union, African countries, international funding organisations and pharmaceutical companies. The initiative is jointly funded by Belgium, the European Commission, Germany, The Netherlands, Switzerland, The UK, South Africa, The Bill & Melinda Gates Foundation, TB Global Alliance and Sequella. The participating African countries, including Kenya, South Africa, Tanzania, Uganda and Zambia, also provide in-kind contribution by offering facilities and salaries to the participating research scientists. The goal of PanACEA is to develop treatment regimens that will shorten and simplify the current cumbersome and prolonged treatment of tuberculosis, which hampers adherence to treatment thus encouraging drug resistance. The consortium comprises 20 institutions, mainly from Europe and Africa as well as the U.S. It is undertaking several clinical trials centred on three main drugs or group of drugs called moxallin, rifapentines and a new drug SQ109 which is still under development.

How is EDCTP funded and how does it allocate funding to each of the projects it supports?

EDCTP is primarily co-financed by the European Commission and the EDCTP-EEIG Member States, but also through additional



Participants of the EDCTP-funded project on severe malaria, led by Professor Peter Kremsner.

contributions in cash and in-kind from third parties participating in EDCTP funded projects. EDCTP allocates funds to the various activities that contribute to meeting the goal of accelerating the development of drugs, vaccines, microbicides and diagnostics to fight HIV/AIDS, malaria and tuberculosis. This is done in consultation with another advisory body called Developing Countries Coordinating Committee (DDCC), which solely comprises African scientists and policy makers that help in identifying research priorities and capacity needs to ensure research is conducted using best practice and is in alignment with African national programmes.

Could you provide an example of how you are working to decrease the number of mother-to-baby transmissions of HIV/AIDS?

EDCTP is funding several clinical trials to establish the optimal way of preventing transmission of HIV from mother to child including during breast feeding. Among these studies include the recently ended Kesho Bora project (meaning 'a better future' in Kiswahili) that contributed to the current World Health Organization (WHO) recommendations on drug treatment to pregnant and breastfeeding mothers to prevent passing the virus to their unborn children and during breastfeeding.

Moreover, improving maternal health is also key to improving the health of newborns and children in general. EDCTP is supporting clinical trials for the prevention of malaria during pregnancy and several other studies that directly target childhood HIV/AIDS, malaria and tuberculosis.

It is often said that poverty causes disease, and disease causes poverty. How do you view this and to what degree is EDCTP engaging in this debate through its activities?

This adage is very true as typified by the three diseases that EDCTP focuses on. Disease leads to absenteeism at school and work, underperformance in production and is costly at individual and societal level. Sick persons have to travel to healthcare facilities, often accompanied by relatives who have in turn to be away from their productive work whilst required to pay for the services including transport and medicines. Some of this cost has to be met by communities and governments that have limited resources, diverting funds from development activities thus fuelling the vicious cycle; disease leading to poverty and poverty to disease. In working to reduce the burden of PRDs, the work of EDCTP is part of a broader contribution to alleviating poverty by addressing the UN's Millennium Development Goals.

How would you rate the level of collaboration and open dialogue between pharmaceutical companies and organisations such as EDCTP?

EDCTP has stepped up its dialogue and engagement with pharmaceutical companies through the appointment of a Private Sector Relations Officer and a Working Group to enhance engagement with the private sector. The task of the Private Sector Relations Officer and the Working Group is to develop a strategy that will increase the engagement of EDCTP with industry. Currently, there is a growing momentum by pharmaceutical companies and Product Development Partnerships to participate in EDCTP-funded clinical trials.

What were some of the priorities discussed at the 'Innovation in Antiretrovirals to Meet Developing Country Needs' held in London this Summer? Were any concrete resolutions drawn up?

Antiretroviral therapy (ART) has not been developed with resource constrained settings in mind. This involves administering and monitoring of treatment in environments where laboratory setups

are limited; health systems are weak; adherence to treatment and follow-up is inadequate; and the burden of disease among special groups such as children and individuals with HIV/TB co-infection is overwhelming. It was agreed that there is a great need to simplify treatment regimens and to come up with innovative formulations that would encourage adherence to treatment. This includes the development of special formulations for children, fixed dose combinations that will reduce the number of pills to be taken, determining of safe regimens for second- or even third-line therapy in the case of failure of first-line therapy, and development of safe regimens for HIV/TB co-infected individuals.

This requires various organisations working together and in synergy. This is where EDCTP could play a major role in supporting the necessary clinical trials to evaluate such regimens. EDCTP has already invested a lot on these lines, in terms of establishing a true partnership between Europe and Africa; building and strengthening of clinical trials research capacity and networks; enhancing enabling environment by establishing and strengthening of ethics review and regulatory oversight; and fostering of partnerships and synergy with other like-minded organisations.

Are there any other aspects of EDCTP you would like to highlight?

Out of necessity the EDCTP membership will grow both in Europe and in disease endemic countries. Several of the newer European Union Members States have shown interest in joining or working cooperatively with EDCTP through their existing relevant programmes. Similarly, for one reason or another, including lack of capacities, there are some sub-Saharan African countries that are currently not fully participating in the EDCTP programme. EDCTP is currently developing a strategy to encourage the participation of these new European Member States and the African countries.

EDCTP has also established Regional Networks of Excellence for conducting clinical trials. These networks act as foci of development and proliferation of clinical research capacity in Africa. Their task is to establish regional and pan-African cooperation in conducting clinical trials in a sustainable manner. For this to be successful, besides EDCTP they will require support from other organisations including African countries. The Regional Networks of Excellence for conducting clinical trials could be strengthened to a point where they may become regional focus for supporting and coordinating African countries informing national policies of treatment and prevention regimens, drug resistance, research agenda, ethics and regulatory issues and related clinical research matters.

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