THE EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP

Professor Charles Mgone, Executive Director
A year after his last interview, Executive Director Professor Charles Mgone updates *International Innovation* on the latest developments at EDCTP. From a broadening scope in disease areas and the forming of valuable new alliances to the launch of a second EDCTP programme, the Partnership has had a busy year continuing its efforts to improve health in sub-Saharan Africa

**Can you outline the key goals of the European & Developing Countries Clinical Trials Partnership (EDCTP)?**

The goal of EDCTP is to help reduce the social and economic burden of poverty-related diseases in sub-Saharan Africa by accelerating the clinical development of effective, affordable and accessible medical interventions. This is achieved through the alignment, coordination and, where possible, integration of the European Participating States’ national programmes, working in partnership with sub-Saharan Africa, the private sector and other partners. This approach aims at maximising synergy and cost-effectiveness while ensuring co-ownership and strengthened cooperation with sub-Saharan African countries, in particular, in capacity development and promotion of sustainable programmes.

**How has the Partnership’s mission evolved since your previous interview with *International Innovation* in 2014?**

Although EDCTP’s goal has remained the same, the scope of the programme has broadened. In addition to HIV/AIDS, tuberculosis and malaria, the remit of EDCTP now includes the development of medical interventions for other neglected diseases, as well as emerging diseases of particular relevance to Africa (such as Ebola). Furthermore, although EDCTP’s mainstay continues to be phase II and III clinical trials, we now also support all phases of clinical trials from phase I to IV, including health services optimisation research.

**What motivated you to focus your work efforts on malaria, tuberculosis and HIV/AIDS?**

Having worked both in the developed and developing world, the stark contrast of the social and economic burden of these diseases is inescapable. The fact that the brunt of this burden is preventable galvanises many of us working in this field to look for solutions to address this imbalance. This is made more urgent by the knowledge that populations living in endemic areas for these diseases are trapped in a vicious cycle of poverty and disease in which one fuels the other, leading to perpetual misery. Moreover, the untoward effects of these diseases hit the most vulnerable groups, such as children, pregnant mothers and displaced or marginalised populations.

**Has the Partnership made any exciting developments over the past year?**

We have received approval for the expanded second EDCTP programme (EDCTP2) under a new legal structure. In spring 2014, the European Parliament and Council approved a 10-year continuation of the EDCTP programme and agreed to invest a maximum of €683 million to match the contribution of the European Participating States. Under the new legal framework, EDCTP is now an Association under Dutch law, which allows not only European Union (EU) Member States to become members of the Partnership, but also African states and all countries associated with Horizon 2020. Under this new format, African states can financially contribute and fully participate in its governance. EDCTP membership currently includes 26 Participating States – 13 European and 13 African – and we are still expanding. It must, however, be emphasised that to participate in the programme one does not have to be a member; membership has an added value of allowing countries to be part of the governance and hence involved in planning, decision making and shaping the policies and agenda of the programme.

On the operational side, several new calls have been launched or will be published soon. In keeping with our goal to enhance synergy, and to work more closely with the private sector and other international development partners, one of our first calls was jointly launched with the Special Programme for Research and Training in Tropical Diseases (TDR) and the European Federation of Pharmaceutical Industries and Associations (EFPIA). In this capacity, fellowships will be awarded to research scientists, regulators and relevant health services cadres to get day-to-day hands-on experience by working with pharmaceutical companies on project management, regulatory affairs, protocol writing and other clinical trials related practical trainings.

As the first EDCTP programme is drawing to an end, more projects are closing and their results are being published. To capitalise on this, and maximise the impact of these projects funded under the first programme, we have launched a call to support the translation of such results into policy and practice. Grants awarded from this call will enable researchers to package their results into reports suitable for policy makers and have meetings with them to facilitate their utilisation.

**Can you describe the key focus and strategy for EDCTP2?**

The new programme focuses on the delivery of new or improved medical interventions for poverty-related diseases, including neglected diseases. Our focus remains on collaborative phase II and III clinical trials, as well as capacity building and networking activities that promote best practice and enable an environment for conducting clinical research in sub-Saharan Africa.

A key strategic aim is to strengthen collaboration with other international development partners to ensure that resources are leveraged and that the most promising projects are supported. This also calls for closer
working relationships with other health product R&D partners, such as the pharmaceutical industry and product development partnerships.

What do you hope to achieve by the end of EDCTP2?

During its first programme, EDCTP has clearly shown its relevance and proved to be a very important player in the global health space. Its approach of aligning and coordinating research agenda and funding among European states and working in partnership with African counterparts is unique. This will be cemented further during the EDCTP2 era where more collaboration with other partners working in this area will be sought. It is hoped that by the end of EDCTP2 this will be very much engraved in the DNA of the programme.

Do you envision meeting any challenges along the way? How do you plan to overcome them?

There are, of course, challenges to be met, since all partners have different ways of working. These potential barriers can be gradually overcome through constant dialogue and continuous demonstration of the added value of collaboration.

The Ebola outbreak remains a major public health issue in Sub-Saharan Africa. How is EDCTP contributing to the fight against this widespread epidemic?

Prior to the current Ebola outbreak, there had been approximately 20 other outbreaks since 1976 – the year when the disease was first described. The current outbreak has been a rude awakening, reminding us of the weak healthcare delivery and poor research and surveillance systems in most of the affected areas. There is an urgent need for better preparation for similar situations that may involve Ebola – or indeed any other emerging or re-emerging diseases – both during an outbreak and in long-term management. With this in mind, EDCTP and TDR are putting together a call for proposals to develop capacities (individual to regional) for conducting high-quality clinical trials during health emergencies, including epidemics. This will address issues such as the development of policies and ethical guidelines for using experimental therapies, training of health carers in the safe handling of infectious material, and community engagement and communication skills.

Can you elucidate the recent offering of the EDCTP-TDR first joint Clinical R&D Fellowships?

This initiative, which was launched at the end of last year, is a result of discussions with EFPIA and TDR. As part of EDCTP’s capacity building efforts, EDCTP and EFPIA signed a Memorandum of Understanding in 2013 to allow scientists and clinical staff from sub-Saharan Africa with an interest in clinical trials to be hosted at European-based pharmaceutical companies. Given the similarities between this and TDR’s Career Development Fellowships programme, we decided to join forces by harmonising and streamlining the activities of both organisations.

In particular, this initiative will promote R&D in low- and middle-income countries, with EDCTP focusing on bringing sub-Saharan African researchers to European companies, and TDR supporting researchers from any LMIC to be placed in organisations around the world. Both the European Commission and Bill & Melinda Gates Foundation provide financial support, while EFPIA and the International Federation of Pharmaceutical Manufacturers & Associations facilitate contacts with potential host organisations. So far, we are pleased to have received interest for placements from 20 host organisations and over 150 applications from members of clinical research teams.

How do you envision EDCTP’s work advancing in the next five years?

Dynamics are changing in the field of poverty-related and neglected diseases; the malaria elimination and eradication agenda, for instance, is gaining considerable momentum. There are calls for the development of drugs and vaccines that block the transmission of malaria, as well as a shift in focus of capacities to ensure better detection of clinical cases, good surveillance, improved mathematical modelling and enhanced outbreak forecasting and detection. EDCTP will, of course, have a major role to play in these activities. Similarly, following the London Declaration of 2012, there has been impetus to eradicate tropical neglected diseases – and EDCTP will contribute towards this goal.

Although there have been recent gains in the prevention of HIV – mainly through early detection and treatment, as well through various forms of prophylactic therapies – vaccine development has remained elusive. EDCTP will continue to support vaccine R&D for HIV and other diseases, including malaria and tuberculosis.

Supporting studies and clinical trials leading to the simplification and shortening of current tuberculosis treatment will remain to be one of EDCTP’s top priorities. Along with R&D of new or improved interventions, EDCTP will also support (in partnership with others) capacities to establish a pharmacovigilance platform and ensure all new products are safe and continue to be effective when deployed.
A GROUP EFFORT

Currently, the EDCTP portfolio includes 100 clinical trials of new or improved products, which are all at different stages of development. Examples of projects that are driving forward the improved prevention, diagnosis and treatment of infectious diseases in the developing world include:

**PanACEA consortium**

EDCTP is funding the PanACEA consortium, which brings together researchers in 14 European and African countries to develop tuberculosis (TB) treatment regimens that are shorter and simpler than the standard six-month treatment. The group is using an innovative multi-arm-multi-stage (MAMS) trial design to test different treatment regimens in a single trial. The trial design uses smaller patient numbers and fewer resources, and it should accelerate the development of promising regimens that combine existing and new drugs. Results from PanACEA’s first MAMS trial are expected in 2015.

**GeneXpert**

EDCTP has played an important role in the evaluation of GeneXpert, an automated assay for diagnosing TB. Currently, the platform is rolled out across countries in Africa, Asia and Europe and is used to diagnose TB and detect rifampcin resistance simultaneously and in a matter of a few hours.

**Malaria Vectored Vaccine Consortium**

The Consortium is conducting trials of malaria vaccines in Burkina Faso, The Gambia, Kenya, Senegal and Tanzania. Its standardised approach, shared expertise and resources enable it to evaluate new candidates rapidly. Several promising candidate vaccines are progressing through the clinical development pipeline.

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**TACKLING TARGETS**

EDCTP has a set of target outputs for increasing the number of new or improved medical interventions for poverty-related and neglected infectious diseases. These include:

- Registering at least one new medical intervention (vaccine, drug or diagnostic)
- Developing approximately 30 guidelines for improved or extended use of existing medical interventions
- Facilitating progress of clinical development of approximately 20 health products
- Increasing capacity development activities including training of personnel
- Improving coordination, alignment and, where possible, integration of European national programmes aiming for at least 50 per cent of the public investment of activities within the scope of EDCTP to be channelled through the programme
- Enhancing international cooperation with other public and private partners
- Supporting at least 150 clinical trials