

Editorial

EDCTP: a genuine north–south partnership

Charles S. Mgone and Waley Salami

European & Developing Countries Clinical Trials Partnership, The Hague, the Netherlands

keywords clinical trials, partnerships, capacity development, networking, co-funding

The European & Developing Countries Clinical Trials Partnership (EDCTP) was founded in 2003 in response to the overwhelming global burden caused by the three main diseases of poverty namely HIV/AIDS, tuberculosis and malaria. It is a partnership between European and sub-Saharan African states that work closely with third parties to accelerate research and development of new or improved interventions against these diseases and generally improve the quality of clinical research in Africa (Dentico & Ford 2005).

To achieve this, EDCTP coordinates national programmes of the participating 17 European member states to work effectively with their sub-Saharan counterparts in a mutual partnership whereby all partners are involved at all levels from conceptualisation to implementation of the programme (Binka 2005). This includes the defining of the health research agenda, policies and priorities; determination of the capacity needs; and ownership and delivery of the programme. To realise this, there is an African representation at various levels of the EDCTP governance and interactions between constituents. From the European perspective the ultimate goal is to achieve a joint programme whereby the participating member states will have an integrated research programme on poverty-related diseases with a common administration, peer-review and funding mechanism.

To encourage partnerships and strengthen collaborative research, EDCTP requires the participation of a minimum of two European and two African countries working together in each project. This also calls for the European partners to seek co-funding from a minimum of two European member states. This can be either in cash or in kind. Besides the co-funding from European member states, EDCTP encourages working together with third parties including like-minded organisations and the private sector, who are also encouraged to contribute funds to the projects. This approach has been very successful in fostering collaborative research, so that currently on average there are four African, and three European countries participating in each project. Moreover, by

bringing together and jointly funding the projects with other partners, the programme adds value to the projects it funds. To date EDCTP has funded 141 projects worth around 255 million Euros which involve 126 institutions from 28 sub-Saharan countries, 43 institutions from 17 European countries and 51 other partners – non-profit organisations and private sector partners mainly from the north. 21 clinical trials on HIV/AIDS are underway (nine on drugs, seven on vaccines and five on microbicides) with an investment of 89.12 million Euros; as well as 14 trials on tuberculosis (eight treatment, six vaccine) worth 73.91 Euros and 10 trials on malaria (eight treatment and two vaccines) worth 63.62 million Euros.

In accelerating the development of new interventions, EDCTP is focussing on supporting especially phase II and phase III clinical trials in Africa, mainly on vaccines, drugs, microbicides and diagnostics. To also ensure successful and sustainable outcomes, the partnership is paying great attention to capacity development and strengthening of an enabling environment for conducting clinical trials using best practices (Van de Wijgert & Jones 2006; Lang & Kokwaro 2008; Anonymous 2009; Coloma & Harris 2009). This is done in such a way that the grants for conducting clinical trials include elements of capacity development, project management and networking to support the required capacity for successful performance of clinical trials using internationally approved best practices. Besides ensuring successful outcomes, this allows the developed capacity to be utilised immediately and retained, thus ensuring sustainability. The networking component facilitates north-south technology transfer and south-south mentorship allowing proliferation of the developed capacity and enhancement of the critical mass. Additionally, the partnership supports the continent's capacity for health research ethics review, establishment of a regulatory framework and clinical trials registration. Such support includes grants to establish and strengthen institutional and national ethics committees to enable them to become functional and independent. Support is also provided for strengthening and harmonising National Regulatory

C. S. Mgone & W. Salami **Editorial**

Authorities and to improve registration of clinical trials in Africa through the recently established Pan-African Clinical Trials Registry. EDCTP also supports various types of training in ethics and regulation and maps ethics and regulatory capacity in Africa (Rennie & Mupenda 2008; Perrey *et al.* 2009).

However, from common knowledge and input of African stakeholders, it is known that there is generally a wide disparity in research capacity, and in regulatory and ethics oversight to conduct clinical trials in Africa. This divide is likely to be widened by keeping the traditional ways of awarding grants in which excellence is rewarded at the expense of underdeveloped capacity seen in less-endowed centres. This problem is also compounded by channelling of support through traditional ties between northern and southern institutions that usually favour advanced centres. To mitigate this, EDCTP has established regional networks of excellence for conducting clinical trials (Kitua *et al.* 2008; Matee *et al.* 2009).

These networks, divided into Central, Eastern, Southern and Western African regions, comprise institutions of varying and complementary capacities that work in synergy to conduct clinical trials, training, south-south mentorship and capacity development in the continent. It is realised that for the networks to be effective and sustainable they must not only work closely with each other, but also with other networks that have been established by other initiatives. Moreover, there is a strong need for garnering the support and commitment of African leadership and funding. This calls for the various global initiatives to work closely together and with the African constituencies to ensure effective and synergistic programmes (Whitworth *et al.* 2009).

The fight against poverty-related diseases is a long-term undertaking requiring equally long-term commitment and investment. The current remit of EDCTP is to support mainly phase II and phase III clinical trials of the three main poverty-related diseases, and capacity development in Africa. It is becoming clear that although this should remain the main focus, there is a need to broaden its base to include related activities that would add value to the programme. Therefore, it is natural for EDCTP to extend its scope to include phase I clinical trials in Africa and phase IV post registration studies to answer health services questions such as determining the most effective ways of

delivering new products (Gryseels *et al.* 2009). The phase I studies would also bridge the gap between pre-clinical and clinical development and encourage the growth of the fledgling African pharmaceutical industry (Mboya-Okeyo *et al.* 2009).

References

- Anonymous (2009) Strengthening research capacity in Africa. *Lancet* **374**, 1.
- Binka F (2005) Editorial: North-South research collaboration: a move towards a true partnership? *Tropical Medicine and International Health* **10**, 207–209.
- Coloma J & Harris E (2009) From construction workers to architects: developing research capacity in low-income countries. *PLoS Biology* **7**, 1–3.
- Dentico N & Ford N (2005) The courage to change the rules: a proposal for an essential health R&D treaty. *PLoS Medicine* **2**, 0096–0099.
- Gryseels B, Zumala A, Troye-Blomberg M *et al.* (2009) European Union on poverty-related diseases research. *Lancet* **9**, 334–337.
- Kitua AY, Corrah T, Herbst K *et al.* (2008) Strengthening capacity, collaboration and quality of clinical research in Africa: EDCTP networks of excellence. *Tanzania Journal of Health Research* **11**, 51–54.
- Lang TA & Kokwaro GO (2008) Malaria and drug vaccine trials in Africa: obstacles and opportunities. *Transactions of the Royal Society of Tropical Medicine and Hygiene* **102**, 7–10.
- Matee IM, Manyando C, Ndumbe PM *et al.* (2009) European and Developing Countries Clinical Trials Partnership (EDCTP): the path towards a true partnership. *BMC Public Health* **9**, 249. doi:10.1186/1471-2458-9-249.
- Mboya-Okeyo T, Ridley RG & Nwaka S (2009) The African Network for Drugs and Diagnostic Innovation. *Lancet* **373**, 1507–1508.
- Perrey C, Wassenaar D, Gilchrist S & Ivanoff B (2009) Ethical issues in medical research in developing world: a report on meeting organised by Fondation Mériex. *Developing World Bioethics* **9**, 88–96.
- Rennie S & Mupenda B (2008) Living apart: together on bioethics, global inequity and social justice. *Philosophy, Ethics and Humanities in Medicine* **3**, 25. doi:10.1186/1747-5341-3-25.
- Van de Wijgert J & Jones H (2006) Challenges in microbicide trial design and implementation. *Studies in Family Planning* **37**, 123–129.
- Whitworth JAG, Kokwaro G, Kinyanjui S *et al.* (2009) Strengthening capacity for health research in Africa. *Lancet* **372**, 1590–1593.

Corresponding Author Charles S. Mgone, European & Developing Countries Clinical Trials Partnership, The Hague, the Netherlands. E-mail: mgone@edctp.org