TDR believes the best approach is to squeeze the most out of each source, both public and private, says Rob Ridley, Coordinator for Product Research and Development at TDR. "Our experience is that if you have a very specific proposal that may do some good, that's professionally thought through, then very often companies are more than willing to participate. In fact most of TDR's successes have resulted from major input from industrial partners."

TDR is already working with industry on two scientifically related neglected diseases – leishmaniasis and trypanosomiasis, both caused by "kinetoplastid" organisms. "We received a fairly substantial sum from Aventis for work related to African trypanosomiasis (sleeping sickness); and we've had some seed funding from industry to push forward and try to identify products for kinetoplastids as a whole" said Ridley.

David Heymann, Executive Director for Communicable Diseases at WHO, adds "We need better tools for neglected diseases, but we shouldn't forget that we've also had some great donations of existing drugs. We need to use every tool we've got. To see an end to diseases that have been around for centuries is an opportunity we just can't miss." ■

Robert Walgate, *Bulletin*

Europe finds US$ 200 million to support African clinical trials

At long last the European and Developing Countries Clinical Trials Partnership (EDCTP) is set to begin its work next year, with a focus on Africa. The European Commissioners — the top bureaucrats of the European Union — approved what should be a US$ 200 million four-year programme, with more to come if nations and donors, including industry, are prepared to support it.

Professor Antoni Trilla of the University of Barcelona is the Coordinator of the EDCTP. He and his colleagues describe its five main objectives as: first, supporting the networking and pooling of trials within the EU (largely Phase I trials); second, supporting the networking and pooling of trials in Africa; third, supporting the development of infrastructures for trials in Africa, especially through capacity-building and training; fourth, actually sponsoring new clinical trials, attracting external sources of co-financing, particularly with the European biopharmaceutical industry; and fifth, developing a European, rather than national, presence in international initiatives for research and development to combat HIV/AIDS, tuberculosis and malaria.

But despite three years of gestation — and a final positive meeting with the Director-General of WHO, Gro Harlem Brundtland, this June — the EDCTP is still not completely approved: the next hurdles will be acceptance by the European Parliament in October, and then by the final political governing body of the 14-state European Union, the Council of Ministers, plus one outside partner — Norway. Approval is scheduled for "early next year", and Commission staff are expecting no difficulties.

Marie-Paule Kieny, director of the WHO Initiative for Vaccine Research, says: "We've had several meetings with the EDCTP but programmes of this size at the EU usually take months to materialize!" Nevertheless the programme will be welcome. "There are clinical trial sites in Africa for testing for each of the three diseases, but they are scattered, the resources are not enough and the networking is poor" says Kieny. "And the EDCTP has impressive funding".

The EDCTP has in fact billed itself as a US$ 600 million programme, but only US$ 200 million of this will come from the Commission itself, and data on the source of the other US$ 400 million are somewhat hazy. US$ 200 million is to be added by member states, but there is no guarantee they will cough up — and, if they do, whether it will be new money. The remaining US$ 200 is hoped for from industry or other partners.

José Esparza, who has been responsible for HIV/AIDS vaccinology at WHO but now deals with all viral vaccines, has also been involved in the partnership. "At the beginning the idea was very European" — coordinating European trials programmes — and WHO and African partners had to press harder for "a meaningful participation" of developing countries in the programme. "But I think they are going in that direction".

Antoni Trilla confirms that while the governance structure will involve a Steering Committee with two representatives from each European Union country, there will also be a Working Group with fifteen Europeans and fifteen Africans, a Management Group with five Europeans and five Africans, and a Coordination Team consisting of one African and one European.

But, no doubt making the task of EU officials look even harder and more time-consuming, Esparza believes that yet more coordination is required: "The EDCTP can only succeed if they coordinate with other efforts. The last thing we want to see is Americans and Europeans and others fighting for sites in Africa .... But it's a good initiative and we are strongly supporting it."

What's really needed, according to WHO experts, is to develop and coordinate African trial sites. "What is a trial site? It is a population with the appropriate epidemiology of the disease you want to work on. You can't study leishmaniasis in Switzerland!" said Esparza. "Then you need the scientific infrastructure, political support, and community support in the region. Those four things will make a working trial site."

But, he said, you need to consider ethics, which entails community involvement. This is becoming essential. The concept of a "site" is "something that is evolving" says Esparza. "In the past a site was where foreign investigators could come to a country and do research to take their samples back home and publish a paper. That concept has gone. The sites we're talking about, and that EDCTP wants to develop, are ones with *ownership* in the country, as that's the only way to ensure continuity, and the appropriate investment of time and resources."

Marie-Paule Kieny also argues that Africa needs to build the capability to do some of the immunological testing on-site, "which is still often done in Europe or the US". Kieny would like to see the EDCTP support networking of existing and new facilities. "For example the International AIDS Vaccine Initiative is investing in Kenya and Uganda to do very complex immunological analysis. This kind of capacity could be used for more than one disease. So I'd like to investigate networking these. EDCTP should be helping us with that." ■

Robert Walgate, *Bulletin*