

EDCTP Fact Sheet

EDCTP commemorates World TB Day and launches € 8,000,000 call for proposals

EDCTP recognises that this World TB Day, 24 March 2009, is about celebrating the lives and stories of people affected by TB: women, men and children who are affected by tuberculosis, nurses and doctors, researchers, community workers and all those who are contributing towards the global fight against TB. EDCTP joins them in the fight against this preventable disease by accelerating the development of tools for preventing, diagnosing and treating TB. EDCTP has funded several large-scale projects that prepare clinical research sites to conduct TB vaccine research, and that simplify and shorten first-line treatment of TB. A specific action that EDCTP is taking on this World TB Day is the launch of a call for proposals for TB diagnostics worth EUR 8,000,000.

TB diagnosis

Current TB diagnosis based on sputum examination is cheap but not very sensitive (i.e. some patients with TB are missed by the test). This is because of the nature of the test: it requires a specific number of bacteria to be present before the examiner in the laboratory can see them. In addition, HIV infection makes the number of bacteria in sputum scanty due to reduced immune response.

One project in the field of TB diagnostics has been funded, which investigates surrogate markers to predict the outcome of anti-tuberculosis therapy. In October 2008 EDCTP organised a stakeholder meeting in Paris to get a consensus on how TB diagnosis clinical studies should be funded. As a result an 8 million euros grant for call for proposals in this area has been published on World TB Day.

Call for proposals

Clinical trials, capacity building and networking in new and improved diagnostics for tuberculosis (TB)

The purpose of this call is to develop simpler, cheaper and more accurate TB diagnostic tool(s). The investigational product(s) should be manufactured under Good Manufacturing Practice (GMP). Priority will be given but not limited to products that can be deployed at the Point of Care (POC).

Available funds: € 8,000,000*
 Number of projects to fund: 2-4
 Deadline of application: 24 July 2009

* We expect the EDCTP contribution of € 8,000,000 to be matched by at least an equivalent amount of cofunding from the European Member States and possibly further contributions from third parties.

Who can apply?

Participants in a proposal must be drawn from at least two publicly funded institutions from the EDCTP EEIG Member States and at least two sub-Saharan African institutions. Preference will

be given to proposals where the project coordinator is a sub-Saharan African national based in Africa. Please note that clinical trials and activities outside of sub-Saharan Africa are outside the scope of EDCTP.

For more details on this call and how to apply, please consult the EDCTP website: www.edctp.org.



TB Vaccines

Currently the most effective vaccine is BCG (Bacille Calmette-Guérin). The downside of BCG is that it does not prevent children from developing TB or protect adults already infected with TB and its protection is not lifelong. Therefore development of more effective vaccines is required.

There is however a lack of capacity and sites to conduct TB vaccine trials. EDCTP has since 2007 funded site preparation projects for the conduct of TB vaccine trials in Kenya, Uganda, Ethiopia, Guinea-Bissau, Tanzania and Madagascar. If contract negotiations are successful two more TB vaccine projects will soon be starting expanding capacity and performing TB vaccine trials in Senegal, The Gambia, South Africa, Uganda, Kenya and Mozambique.

TB Drugs

The current TB drugs require patients to take a large number of tablets per day and to continue taking them for at least 6 months. The problem with this regimen is that it reduces patient adherence. In addition, some of the drugs in the current combination interact with anti-retroviral treatment (ART) that is used to treat HIV/AIDS, preventing patients to start both treatments together.

In 2009 EDCTP in collaboration with other partners will start with a EUR 24,000,000 project to fund a Pan African Consortium for Evaluating Anti-tuberculosis agents (PanACEA). The consortium developed a group plan for simplifying and shortening first-line treatment. As a result, EDCTP will fund studies to:

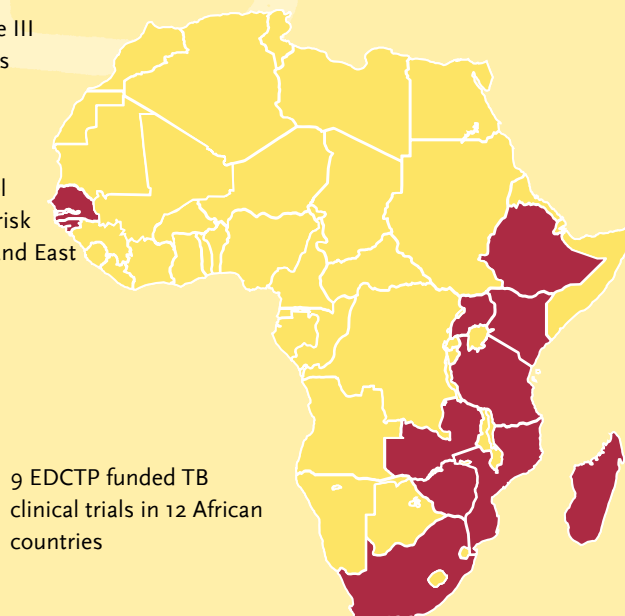
- Reduce duration of treatment while maintaining the same cure rates or preferably lower recurrent rates
- Determine safer combinations with antiretroviral treatment.

The studies will be phase III trials of moxifloxacin and phase I/II trials of high dose rifampicin, and SQ109 respectively. The studies will be conducted in South Africa, Tanzania, Kenya, Uganda, Zambia and Gabon.

EDCTP funded TB Clinical Research and capacity building

To date EDCTP has committed around EUR 21,000,000 to fund TB clinical trials and capacity building in the following areas:

- Surrogate markers to predict the outcome of anti-tuberculosis therapy (South Africa)
- Rapid evaluation of moxifloxacin in the treatment of sputum smear-positive tuberculosis (Tanzania, Zambia and South Africa)
- A controlled clinical trial to evaluate high dose rifampentine and moxifloxacin in the treatment of pulmonary tuberculosis (South Africa, Mozambique, Zambia and Zimbabwe)
- Determining the optimal doses of antiretroviral and anti-tuberculosis medications when used in combination for the treatment of HIV/TB in co infected patients (South Africa)
- Optimisation of tuberculosis and HIV co-treatment in Africa looking at pharmacokinetic and pharmacogenetic aspects on drug-drug interactions between rifampicin and efavirenz (Ethiopia and Tanzania)
- Conduct of ICH-GCP level Phase II TB vaccine trials in high risk populations in Africa
- Prospective epidemiological studies of TB in neonates and adolescents in preparation for future vaccine trials in Karemo Division of Siaya district in Western Kenya
- Toward conducting phase III trials of novel TB vaccines in Ugandan infants and adolescents
- Capacity building for the conduct of ICH-GCP level TB vaccine trials in high risk populations in Ethiopia and East Africa.



Future TB plans

Between 2009 and 2010 EDCTP will commit more funds on projects conducting phase II and phase III TB vaccine trials in TB/HIV co-infection and TB vaccines. In addition to the commitments mentioned above EDCTP will continue to fund infrastructure development at African research sites, training of African researchers and supporting research enabling environment of regulatory and ethical procedures.

More information on TB and World TB Day:

- World TB Day website
http://www.stoptb.org/events/world_tb_day/2008/default.html
- Stop TB Partnership
<http://www.stoptb.org>
- WHO Report 2008 Global tuberculosis control - surveillance, planning, financing
http://www.who.int/tb/publications/global_report/2008/summary/en/index.html
- International Union against TB and Lung Disease
<http://www.ariatd.org>



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