



EDCTP

European & Developing Countries Clinical Trials Partnership

Funding prevention and treatment of HIV/AIDS, tuberculosis, malaria and neglected infectious diseases in places that need it most

The EDCTP programme is supported under Horizon 2020, the European Union's Framework Programme for Research and Innovation.



The power of sharing science

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between Europe and sub-Saharan Africa dedicated to combating poverty-related diseases (PRDs), including HIV/AIDS, tuberculosis (TB), malaria, a selection of neglected infectious diseases and emerging infectious diseases of particular relevance to Africa. This partnership is funded by the European Union and individual member countries of the EDCTP Association.

EDCTP supports collaborative clinical research to accelerate the clinical development of new or improved interventions against PRDs in sub-Saharan Africa. The EDCTP programme brings together the combined strengths of the European Participating States together with those of their sub-Saharan counterparts and interested third parties (like-minded funding and product development organisations and pharmaceutical companies) to fund collaborative clinical trials and related capacity.

The second EDCTP programme is implemented as part of the European Framework Programme for Research and Innovation, Horizon 2020, and governed by the African and European Participating States through the General Assembly of the EDCTP Association.



The development of EDCTP

EDCTP was established in 2003 as a research programme undertaken by 14 European countries with the support of the European Union (EU) in response to the global health crisis caused by HIV/AIDS, tuberculosis and malaria.

The first EDCTP programme will end in December 2015. The second programme (EDCTP2) was launched in December 2014 and will run up to 2024 as part of Horizon 2020.

Partnership model

With support of the EU, EDCTP brings together the research strengths of European and sub-Saharan African countries. EDCTP facilitates the internationalisation of research in Europe and sub-Saharan Africa and contributes to the development of the European Research Area.

EDCTP promotes African co-ownership of the programme by supporting development of scientific leadership and sustainable local capacity for conducting clinical trials under good practices. The programmes also fosters collaborative projects at all levels (south-south, north-north and north-south cooperation). Currently, over 70% of EDCTP-funded activities are led by researchers based in Africa.

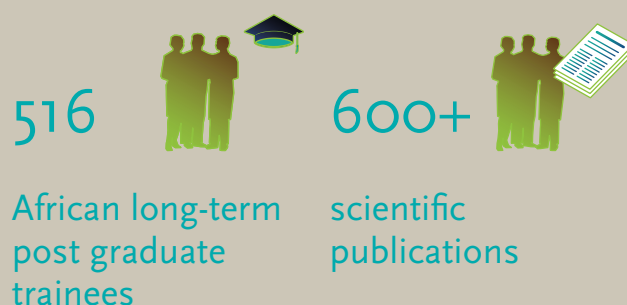
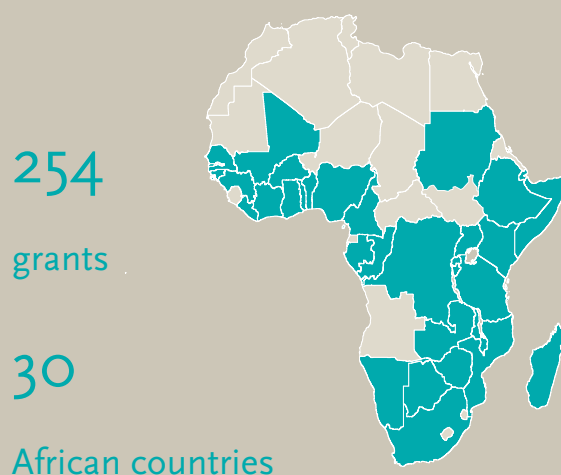
Moreover, EDCTP has maintained and developed collaborative relationships with third parties, including product development partnerships, multinational pharmaceutical companies, philanthropic organisations, and like-minded organisations contributing to the development of new clinical tools against poverty-related infectious diseases.

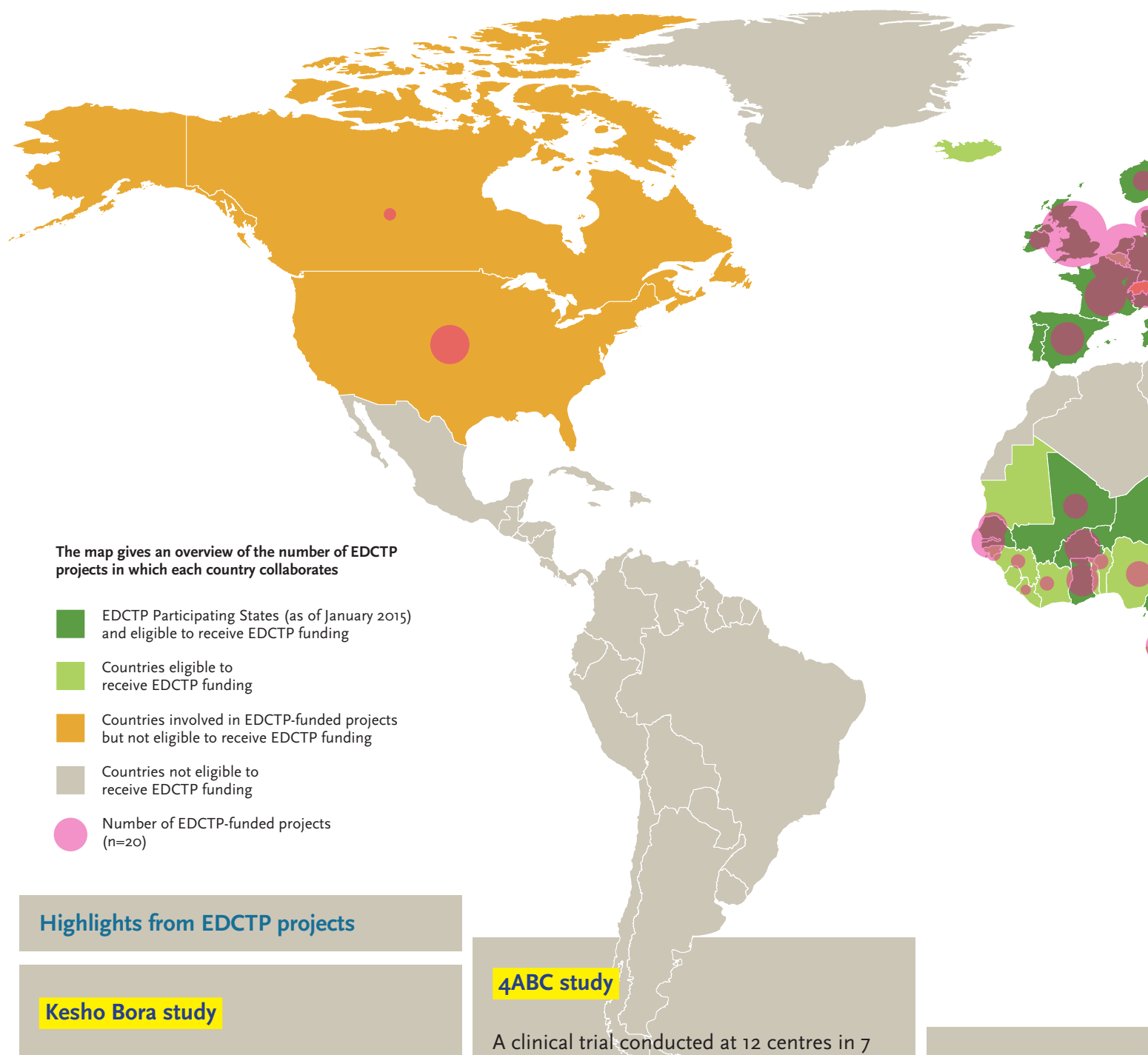
Governance

The EDCTP2 programme is implemented and governed by the General Assembly of the EDCTP Association (established in April 2014), in which states from Europe and sub-Saharan Africa participate as members. Currently, 13 European countries and 13 African countries have joined the Association in order to participate in the programme and the governance of EDCTP2.

The General Assembly is advised by the Strategic Advisory Committee, an advisory board of independent scientific experts mainly from Europe and Africa.

EDCTP (2003–2014)





Highlights from EDCTP projects

Kesho Bora study

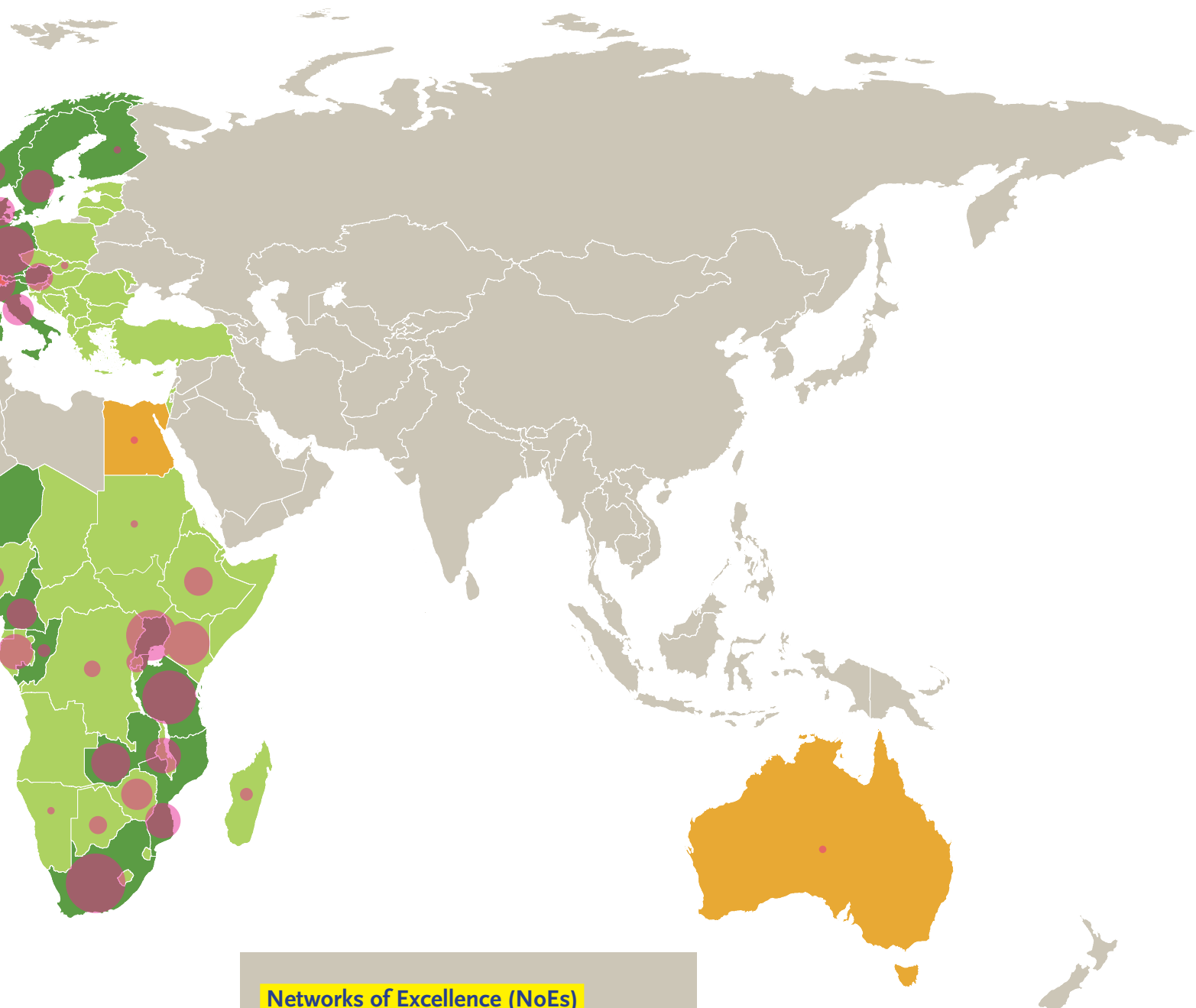
This World Health Organization (WHO)-sponsored study of highly active anti-retroviral therapy during pregnancy and breastfeeding demonstrated a 43% decrease in HIV infections in infants and 54% reduction of mother-to-child transmission during breastfeeding. The trial had many large funders. EDCTP provided the funding to allow centres in South Africa to participate in this global trial which was essential for achieving the full required recruitment of volunteers. It also provided the necessary laboratory support to the centre in Mombasa, Kenya. Findings were influential in updating the 2010 WHO guidelines on prevention of mother-to-child transmission of HIV.

4ABC study

A clinical trial conducted at 12 centres in 7 countries: Burkina Faso, Gabon, Mozambique, Nigeria, Rwanda, Uganda, and Zambia. A total of 4,116 children out of more than 10,000 children between 6 and 59 months old screened, were included in the study and treated. Three novel artemisinin-based combination drugs were found to be safe and efficacious in treating children with uncomplicated malaria. The study informed African Ministries of Health on relative safety and efficacy of available artemisinin-based combination therapies, and its results supported the WHO recommendation of dihydroartemisinin-piperaquine (DHAPQ) as a treatment option for uncomplicated malaria.

PanACEA

The Pan African Consortium for the Evaluation of Antitubercular Agents (PanACEA) conducts phase IIb, and phase III clinical trials of new drugs or drug regimens for tuberculosis. The consortium has a shared governance structure and capacity development. The consortium introduced MAMS (multi-arm multi-stage) in its final ongoing trial. The consortium also collaborates with other organizations such as the Global TB Alliance, the Bill & Melinda Gates Foundation, Sequella, and the Medical Research Council.



Networks of Excellence (NoEs)

These EDCTP-funded networks facilitate regional collaboration by uniting diverse institutions that each contributes its individual strengths to the network. All four regions of sub-Saharan Africa have their own NoE: the East Africa Consortium for Clinical Research (EACCR, www.eaccr.org); the Central African Network on TB, HIV/AIDS and malaria (CANTAM, www.cantam.org); the Trials of Excellence for Southern Africa (TESA, www.tesafrica.org); and West African NoE for TB, AIDS and Malaria (WANETAM, www.wanetam.org). These networks conduct on-going training, infrastructure development, epidemiological studies as well as laboratory and clinical research activities aimed at developing regional clinical trial capacity.

Research ethics and regulatory environment

A collaborative project with the WHO involved capacity strengthening of the national regulatory environment of various African countries. EDCTP funding significantly contributed to the establishment of the African Vaccine Regulators Forum (AVAREF) which has provided a framework for harmonisation among national regulatory authorities and joint reviews of multinational clinical trials (such as RTSS phase III). Additionally, EDCTP funded the Pan African Clinical Trials Registry (PACTR), the only primary registry linked to the WHO international clinical trials portal in Africa.

ortium for the
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several phase IIa,
cal trials for new TB
s. The consortium
ce, administration
ment strategy. In 2014,
uced the innovative
ulti-stage) approach to
The consortium col-
er funders including
Bill & Melinda Gates
and the South African
ncil.

EDCTP (2014–2024)

The second EDCTP programme (EDCTP2) will run over a ten-year period from 2014 to 2024 with a budget of €1.36 billion in commitments. The European Union will provide a contribution of up to €683 million, on the condition this is equally matched by contributions from the European Participating States. Additional funding will be sought from third parties and African Participating States.

Scope of EDCTP2

EDCTP2 will support all stages of clinical trials, from phase I to IV, on HIV/AIDS, tuberculosis, malaria and neglected infectious diseases for new or improved medical interventions, as well as advanced testing and field validation of new diagnostic tools.

Activities supported by EDCTP2

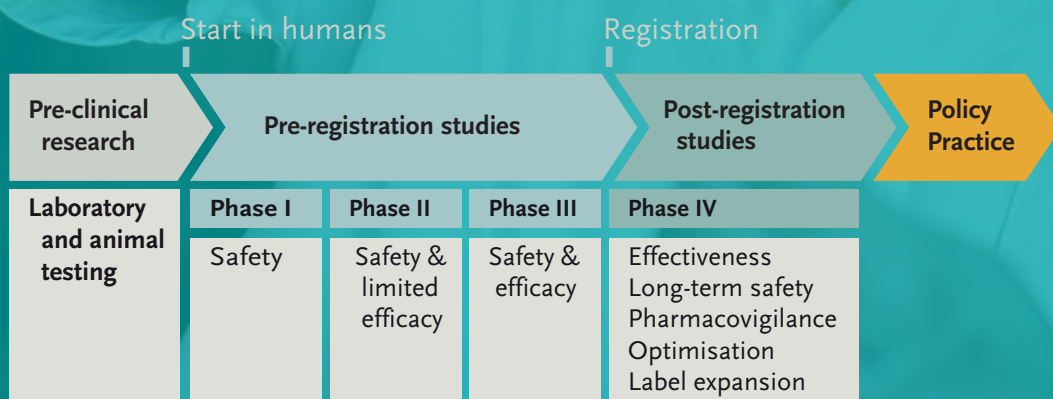
- Multicentre clinical trials that are conducted by research consortia involving both European and African research teams, with integrated capacity development and networking elements
- Capacity support activities that strengthen the enabling environment for conducting clinical trials and clinical research
- Fellowships that focus on the career development of individual researchers or clinical staff.

PRDs covered by EDCTP2

In EDCTP2 PRDs include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue; rabies; human African trypanosomiasis (sleeping sickness); Leishmaniasis; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola.

Funding opportunities

EDCTP Calls for Proposals are open to participation from across the world. Researchers from all countries anywhere in the world can team up with European and sub-Saharan African partners to jointly develop knowledge, research data and leading scientific teams and networks. However, only participants (i.e. researchers and/or institutions) from sub-Saharan Africa, the European Union or one of the Countries Associated to Horizon 2020 are eligible to receive and administer EDCTP funding.



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