



EDCTP

*The power of sharing science*

# The added value of EDCTP to Europe



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## About EDCTP

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The European & Developing Countries Clinical Trials Partnership (EDCTP) was created in 2003 as a European response to the global health crisis caused by the three main poverty-related infectious diseases, HIV/AIDS, tuberculosis (TB) and malaria.

Part of the European Commission's Framework Programmes, EDCTP brings together European Union (EU) Member States plus Norway, sub-Saharan African countries, pharmaceutical companies, small and medium enterprises (SMEs), product development partners (PDPs) and international foundations to advance the development of vaccines, drugs, diagnostics and other interventions targeting poverty-related infectious diseases.

EDCTP is one of the EU's flagship programmes<sup>1</sup>, contributing towards the European Research Area in multiple ways.

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<sup>1</sup> European Commission. Next EDCTP programme to continue delivering life-saving solutions for sub-Saharan Africa. 2014. Available at <https://ec.europa.eu/programmes/horizon2020/en/news/next-edctp-programme-continue-delivering-life-saving-solutions-sub-saharan-africa>

## Delivering on EU commitments to tackle global challenges

Poverty-related infectious diseases have a profound economic impact on countries, in terms of healthcare costs and lost productivity. Tackling infectious diseases is therefore central to delivering the Sustainable Development Goals, a high priority for the EU<sup>1</sup>.

Europe is committed to addressing the chronic shortage of health workers in developing countries. EDCTP is making an important contribution to this priority through its capacity-building funding, supporting health researchers at different stages of their research careers and strengthening national health research systems<sup>2</sup>.

## Enabling greater scale and scope in the European Research Area

Between 2014 and 2019, EDCTP invested €526.04M in clinical research and €51.27M in capacity-building, benefiting 208 institutions in 37 sub-Saharan Africa countries and 150 institutions in 19 European countries.

EDCTP supports research that could not have been delivered by a single EU Member State alone. The EDCTP financing model combines funding from Participating States and the EU, accessible to European and African collaborations. Through a requirement for research consortia to have at least one sub-Saharan African and two European partners, EDCTP encourages European–African cooperation and cross-European collaborations that might not otherwise have been established.

Several EDCTP-funded consortia bring together large numbers of partners from Africa and Europe, including the Pan-African Network for Rapid Research, Response, Relief and Preparedness for Infectious Diseases Epidemics (PANDORA-ID-NET, 22 partners), the African Coalition for Epidemic Research, Response and Training (ALERRT, 21 partners) and the West African Network for TB AIDS and Malaria (WANETAM, 20 partners).

EDCTP has been identified as a prime example of the added value of European cooperation, and the greater impact that can be achieved by coordinated action, particularly in areas such as capacity-building<sup>3</sup>.

## Boosting scientific excellence and Europe's global competitiveness in research and innovation

As concluded by a Meta-Evaluation of Article 185 Initiatives, EDCTP has significantly increased the EU's global influence within the international research community<sup>4</sup>. Between 2003 and 2011, over 90% of publications from EDCTP-funded projects were published in high-impact journals<sup>5</sup>. Moreover, papers from Europe-wide or Europe–sub-Saharan Africa collaborations typically have higher citation rates and greater research impact<sup>2</sup>.

EDCTP has established a strong track record and platform for evaluating novel or improved medical interventions, many of them developed in Europe. Since 2013, EDCTP has invested €586M (83% of its clinical research funding) in projects investigating drug and vaccine candidates.

## Developing the evidence base for national and international policy-making

EDCTP has supported multiple studies that have influenced national and international policy and practice<sup>6</sup>.

- Data from the **CHAPAS trials** contributed to the approval of fixed-dose antiretroviral drug formulations for children by the US Food and Drug Administration, paving the way for their distribution through global philanthropic programmes and greatly enhancing African children's access to life-saving antiretroviral drugs.
- The **Kesho Bora study** provided some of the earliest and strongest evidence that triple antiretroviral therapy could dramatically reduce mother-to-child transmission of HIV during breastfeeding. It informed the development of revised WHO guidelines, which recommended more extensive use of antiretrovirals in pregnant and breastfeeding women.
- The **WANECAM study** demonstrated the safety and efficacy of an antimalarial formulation specifically developed for children, paving the way for its approval by the European Medicines Agency and recommendation by WHO.
- The **MiPPAD study** provided high-quality evidence on mefloquine for prevention of malaria in pregnancy. Although safe and effective, mefloquine was not well tolerated. The results provided valuable input to WHO policymakers and are ensuring that resources are now devoted to investigating more promising alternatives.
- Several projects under the EDCTP umbrella managed by individual countries have led to changes in guidelines of European countries. For example, UK studies have contributed to Paediatric European Network for Treatment of AIDS (PENTA) guidelines.

1 European Commission. A Global Partnership for Poverty Eradication and Sustainable Development after 2015. 2015. Available at [https://ec.europa.eu/europeaid/sites/devco/files/com-2015-44-final-5-2-2015\\_en.pdf](https://ec.europa.eu/europeaid/sites/devco/files/com-2015-44-final-5-2-2015_en.pdf)

2 European Commission. European programme for action to tackle the critical shortage of health workers in developing countries (2007 – 2013): Progress report on implementation. 2008; p. 15. Available at [https://ec.europa.eu/europeaid/sites/devco/files/working-paper-critical-shortage-of-health-workers-developing-countries-sec20082476\\_en.pdf](https://ec.europa.eu/europeaid/sites/devco/files/working-paper-critical-shortage-of-health-workers-developing-countries-sec20082476_en.pdf)

3 European Commission. European Added Value of EU Science, Technology and Innovation actions and EU-Member State Partnership in international cooperation: Main Report. 2014; p. 35. Available at [https://ec.europa.eu/research/jscp/pdf/publications/Final\\_European\\_Added\\_Value\\_inco\\_MainReport.pdf](https://ec.europa.eu/research/jscp/pdf/publications/Final_European_Added_Value_inco_MainReport.pdf)

4 European Commission. Meta-Evaluation of Article 185 Initiatives; p.16. 2017. Available at [http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail\\_groupDetailDoc&id=36281&no=1](http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail_groupDetailDoc&id=36281&no=1)

5 Breugelmans JG, Roberge G, Tippet C, Durning M, Struck DB, Makanga MM. Scientific impact increases when researchers publish in open access and international collaboration: A bibliometric analysis on poverty-related disease papers. PLoS One. 2018;13(9):e0203156.

6 European Commission. Meta-Evaluation of Article 185 Initiatives. 2017; p. 18. Available at [http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail\\_groupDetailDoc&id=36281&no=1](http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail_groupDetailDoc&id=36281&no=1)



## The impact we anticipate

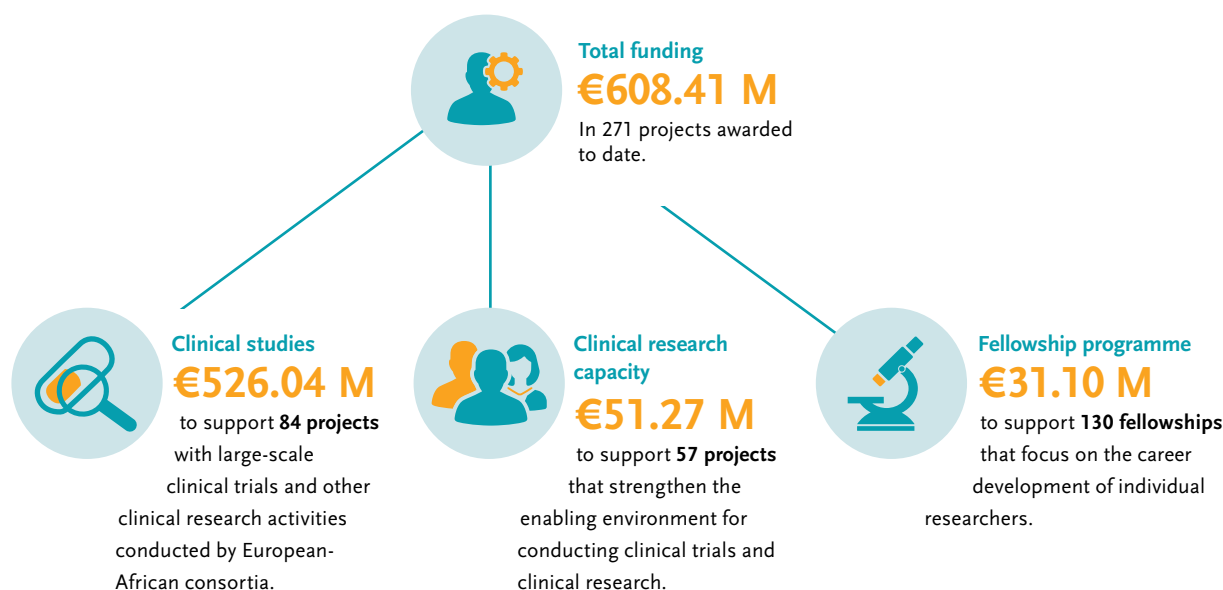
EDCTP is supporting large-scale initiatives that could have a major impact on poverty-related infectious diseases responsible for a huge global burden. Examples include:

- **TB vaccines:** Building on previous **TB vaccine trial partnerships**, EDCTP recently committed approximately €32M to support three large clinical trials on candidate TB vaccines – the largest European investment in clinical development of TB vaccines to date.
- **Schistosomiasis control in young children:** The **PZQ4PSAC trial** is evaluating a new more palatable formulation of praziquantel to treat schistosomiasis in pre-school-age children. The new formulation will enable younger children to benefit from a highly effective drug for treatment and mass prevention. (Trial co-funded by the Global Health Innovative Technology Fund and sponsored by Merck KGaA.)
- **Better tools for control of parasitic worm infections:** The **STOP study** is developing a convenient fixed-dose pill that combines ivermectin and albendazole to improve control of parasitic worm infections in Africa.
- **Better detection of sleeping sickness:** The **DiTECT-HAT study** is evaluating a range of tools that will make it easier to detect, treat and ultimately eradicate sleeping sickness. By evaluating different tools and pathways of analysis, DiTECT-HAT will identify how diagnostic tools could be deployed most effectively to treat infection in routine care, to support eradication campaigns, and to facilitate the development of new drugs.
- **Better treatment of fungal infections:** The **AMBITION-cm project** is evaluating a novel liposome-based formulation of amphotericin B, which could transform treatment of cryptococcal meningitis, responsible for up to one in five HIV-related deaths in Africa.
- **Treatment of pneumonia in children:** The **PediCAP project** is aiming to identify an optimal treatment for severe pneumonia in children, including an earlier switch from injected to oral antibiotics.
- **Novel vaccines:** The **THECA study** will provide additional data on Typbar-TCV, a typhoid conjugate vaccine that has been recommended for use despite limited data on its efficacy. The **PREVAC-UP project** will enable an additional four years' data to be collected on the safety and efficacy of the two leading Ebola vaccines, rVSV-ZEBOV-GP and Ad26.ZEBOV, including data on vaccine use in children.
- **Prevention of river blindness:** The **MoxiMultiDoseMod project** is evaluating repeat administration in children of moxidectin, the first new treatment for river blindness (onchocerciasis) approved in 20 years. This is necessary in view of its use in mass drug administration campaigns. Groups
- **Cryptococcal diagnosis:** The **DREAMM project** aims to demonstrate the benefit of introducing early screening for cryptococcal fungal infections, responsible for approximately a quarter of HIV-related deaths.
- **TB diagnosis:** The **CAP-TB project** is evaluating new TB diagnostic technologies in realistic field settings to determine health impacts and implementation enablers/barriers.
- **A four-strike vaccine against malaria:** The **Multi-Stage Malaria Vaccine Consortium (MMVC)** will test a novel vaccine combination targeting four stages of the malaria parasite life cycle. Such a vaccine could help to reduce the incidence of an infection that still kills more than 1000 children every day.
- **Combining drugs and vaccines to prevent HIV infection:** The **PrEPVacc trial** is the first to test whether a combination of pre-exposure prophylaxis and an experimental vaccine can prevent HIV infection. PrEPVacc is one of the first 'adaptive' HIV vaccine trial – testing of combinations can be halted mid-trial if they prove ineffective.
- **Improving TB diagnosis in children:** The **RaPaed TB study** is exploring a range of new and innovative tools for diagnosing TB in children – one of the biggest obstacles to control of TB disease.



## EDCTP's investment in research & development

2014-2019



### Developing European capacities in clinical research against poverty-related infectious diseases

EDCTP is developing the skills of European researchers. In multi-country EDCTP consortia, European researchers have the opportunity to work with each other, build international networks, and expand their range of interests. They also build their skills in managing global collaborative projects.

EDCTP is also strengthening European research institutions. EDCTP encourages interdisciplinary and cross-disease approaches, enabling institutions to build and diversify their expertise. For example, some institutions involved in HIV vaccine trials are now working on vaccines for emerging infections. In addition, centres from some European countries have further developed their research on poverty-related infectious diseases, including Luxembourg (neglected infectious diseases), Finland (HIV, Ebola) and Poland (emerging infections).

Thanks to the involvement of industry and PDPs in EDCTP consortia, European academic institutions are developing their capacity to undertake trials compliant with the rigorous standards demanded of regulatory studies. Moreover, EDCTP plays a critical role in developing ethical and regulatory environment for clinical research in Africa which facilitates the conduct of clinical studies from European based academic institutions, PDPs and Private sector in resource constrained and epidemic settings.

### Providing mechanisms to prepare for and respond to public health emergencies

Globalisation and broad access to international travel coupled with the (re)emergence of new communicable diseases highlight the importance of doing local field research to address public health risks. EDCTP's Emergency Funding Mechanism allows funding to be rapidly mobilised in case of public health emergencies. In September 2018, EDCTP launched a €2.25M emergency funding initiative in response to Ebola outbreaks in the Democratic Republic of the Congo, supporting 24 institutions in Africa and Europe.

Furthermore, two large EDCTP-funded consortia – ALERRT and PANDORA-ID-NET – are working to enhance the capacity of African regions to detect, prepare for and respond to infectious disease outbreaks, and to carry out clinical research in emergency situations. These consortia are actively involved in the Ebola and novel coronavirus (2019-nCov) preparedness.

### Promoting open science in Europe and beyond

All EDCTP-associated scientific papers must be published in open access journals. This not only improves citation rates and research impact<sup>2</sup> but also promotes the use of research evidence in policymaking and enhances the efficiency and quality of research<sup>1</sup>.

1 OECD. Open Science. Available at <http://www.oecd.org/sti/inno/open-science.htm>

## Fostering partnerships for effective solutions to concerns shared by citizens in Europe and elsewhere

EDCTP membership currently includes 30 Participating States – 14 European and 16 African countries. Each Participating State contributes to EDCTP governance and hence can be equally involved in planning, decision-making and shaping the policies and agenda of the programme.

In a world that is increasingly complex and overloaded with information the efficient exchange and sharing of expertise between European and African researchers and policy makers is critical. EDCTP forges symbiotic collaborations among researchers from academia, industry and PDPs that might not otherwise have been created. This links the creativity of academic scientists with the results-based R&D management approach of pharmaceutical companies and PDPs.

EDCTP has forged new partnerships that transcend established historical links and overcome language barriers, including collaborations uniting Anglophone, Francophone and Lusophone countries in sub-Saharan Africa (Figure 1).

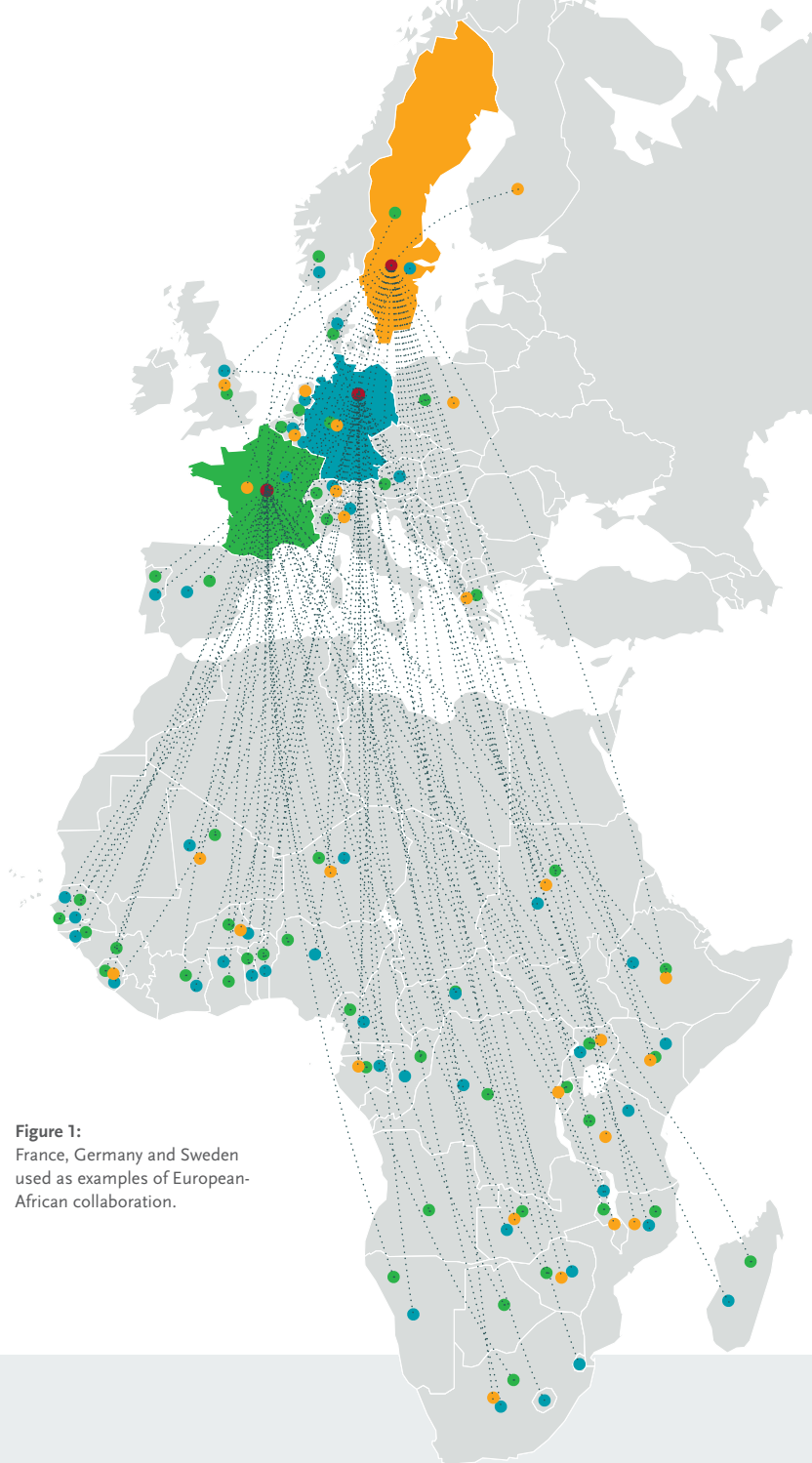


Figure 1:  
France, Germany and Sweden  
used as examples of European-  
African collaboration.

EDCTP is also working in partnership with product development partnerships and drug developers to advance individual therapeutics and collections of compounds:

- **A portfolio of novel antimalarial drugs:** The **WANECAM II study** is accelerating development of a new class of antimalarial drug developed by Medicines for Malaria Venture (MMV) and Novartis that may have significant advantages over existing treatments. The **PAMAFRICA portfolio grant** is advancing a suite of novel drugs developed by MMV to address unmet needs in malaria treatment, including single-dose treatments and formulations for young children.
- **New options for TB:** The **PanACEA consortium** is bringing a hopefully promising novel anti-TB drug, BTZ-043, into phase II clinical trial. As part of a wider global trial coordinated by the TB Alliance, the **SIMPLICI-TB study** is evaluating a novel and potentially shorter treatment for drug-sensitive and drug-resistant TB. In the **CLICK-TB study**, an innovative trial design is being used to compare a suite of anti-TB compounds developed by GSK.



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## European participation in EDCTP projects

2014-2019



14

European countries are members of the EDCTP Association.



19

European countries participate in EDCTP projects.



150

European organisations are involved in EDCTP projects.



€224 M

is the total grant value allocated to 106 projects involving European organisations (2014-2019).



136

European organisations are involved in 73 collaborative clinical trials and clinical studies conducted by European-African consortia.

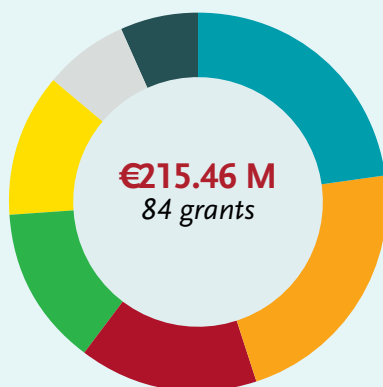


39

European organisations are involved in 33 projects that aim to strengthen clinical research capacity for conducting clinical trials and clinical studies in sub-Saharan Africa.

## Portfolio by disease

2014-2019



- Tuberculosis, 23 grants  
€49.66 M
- Malaria, 12 grants  
€47.27 M
- HIV & HIV-associated infections, 16 grants  
€32.93 M
- Neglected infectious diseases, 13 grants  
€29.72 M
- Emerging diseases, 13 grants  
€26 M
- Lower respiratory tract infections, 4 grants  
€15.78 M
- Diarrhoeal diseases, 3 grants  
€14.10 M

**Note:**

A further €8.54 million for 22 grants is allocated to projects on non-disease-specific topics.

# European country involvement in EDCTP projects

2014-2019

## Netherlands

- €21.96 M
- 15 institutions
- 41 grants
- 14 European countries
- 34 African countries

## United Kingdom

- €91 M
- 30 institutions
- 74 grants
- 14 European countries
- 34 African countries

## Ireland

- €0.01 M
- 1 institution
- 1 grant
- 2 European countries
- 1 African country

## Portugal

- €0.78 M
- 6 institutions
- 5 grants
- 4 European countries
- 15 African countries

## Spain

- €12.76 M
- 12 institutions
- 21 grants
- 8 European countries
- 25 African countries

## Luxembourg

- €0.04 M
- 1 institution
- 3 grants
- 5 European countries
- 13 African countries

## Belgium

- €5.61 M
- 5 institutions
- 12 grants
- 11 European countries
- 23 African countries

## France

- €19.39 M
- 28 institutions
- 33 grants
- 14 European countries
- 33 African countries

## Switzerland

- €28.38 M
- 16 institution
- 29 grants
- 11 European countries
- 30 African countries

## Denmark

- €11.96 M
- 4 institutions
- 7 grants
- 10 European countries
- 15 African countries

## Sweden

- €7.82 M
- 6 institutions
- 13 grants
- 10 European countries
- 16 African countries

## Norway

- €1.50 M
- 2 institutions
- 7 grants
- 8 European countries
- 11 African countries

## Finland

- €0.50 M
- 3 institutions
- 4 grants
- 5 European countries
- 5 African countries

## Germany

- €17.58 M
- 18 institutions
- 39 grants
- 13 European countries
- 31 African countries

## Moldova

- €0.13 M
- 1 institution
- 1 grant
- 2 European countries
- 2 African countries

## Greece

- €0.50 M
- 1 institution
- 1 grant
- 3 European countries
- 2 African countries

## Poland

- €0.07 M
- 1 institution
- 1 grant
- 3 European countries
- 2 African countries

## Austria

- €0.24 M
- 2 institutions
- 2 grants
- 5 European countries
- 5 African countries

## Italy

- €4.46 M
- 11 institutions
- 13 grants
- 9 European countries
- 16 African countries



Value of EDCTP grants



Number of institutions involved in projects



Number of grants



Number European collaboration in EDCTP grants



Number African collaboration in EDCTP grants