EDCTP

*The power of sharing science*

# The added value of EDCTP to Africa

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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 partnerships (PDPs) and international foundations to advance the development of vaccines, drugs, diagnostics and other interventions targeting poverty-related infectious diseases affecting sub-Saharan Africa.**

**The added value of EDCTP in Africa is evident in multiple ways and at different levels.**

## Contributing to the achievement of the African Union

African countries have committed to implement the African Union Agenda 2063 – a vision and plan to build a more prosperous and healthier Africa within 50 years. As poverty-related infectious diseases have a profound economic impact on African countries, in terms of healthcare costs and lost productivity, tackling infectious diseases is central to delivering the Sustainable Development Goals (SDGs) and Aspiration 1 of Agenda 2063 – a prosperous Africa based on inclusive growth and sustainable development[1].

Furthermore, the African Union's Science, Technology and Innovation Strategy 2024 (STISA-2024) recognises that research and international cooperation are key to tackling the greatest challenges facing the continent, including prevention and control of disease, one of STISA-2024's six priorities[2].

## Creating and retaining a new generation of African scientists

Africa's potential in science and innovation is handicapped by a shortage of trained scientists – Africa has less than 200 researchers per million people, far fewer than many middle-income countries.

EDCTP is driving change to correct this deficit and make progress towards creating a critical mass of scientists with a view to longer term self-sustainability and peer level integration into the international network of research against PRDs.

EDCTP research consortia must have a minimum of one sub-Saharan African partner, and the number of African principal investigators has been steadily increasing.

In addition, since its inception the EDCTP capacity-developing programme has supported more than 500 African researchers, including 146 fellows and 400 MSc/PhD students, with at least 90% continuing their research career in Africa.

The EDCTP senior fellowship scheme promotes scientific excellence and supports emerging scientific leaders in Africa, who mentor and develop the next generation of researchers. The scheme also enables research leaders working outside Africa to return and reintegrate into the African science base.

## Strengthening and harmonising enablers of high-quality and ethical clinical research

Regulatory systems and ethical review capabilities are also a key aspect of national health research capacity. EDCTP has supported projects developing these capabilities in 24 sub-Saharan African countries, helping to create enabling environments for high-quality research.

EDCTP is a member of the newly established African Medicines Regulatory Harmonisation Partnership Platform, which aims to improve coordination of regulatory systems strengthening and harmonisation activities in Africa. EDCTP also has a long-term working relationship with WHO-AFRO, which hosts the African Vaccine Regulatory Forum (AVAREF). EDCTP funding contributed to the establishment of AVAREF and most members of the AVAREF Technical Advisory Committee were trained through the EDCTP ethics fellowship scheme.

## Contributing to the provision of safe medical interventions

A key purpose of clinical trials is to assess the safety of new medical interventions under controlled conditions. However, the safety of new interventions needs to be monitored when they are introduced into routine care and are used by much larger numbers of people.

This requires effective national pharmacovigilance systems. EDCTP has supported several projects building national and international networks and engaging expertise from the WHO international drug monitoring programme and the Uppsala monitoring centre to strengthen pharmacovigilance systems, to build national capacities to detect and respond to possible adverse events and to maintain public confidence in interventions.

## Promoting demand-driven research

EDCTP-supported scientists from sub-Saharan Africa have been involved in more than 150 clinical trials, studies addressing key issues in infectious disease treatment and control in Africa[3]:

- The **PredART trial** provided the first evidence of an effective strategy to reduce the risk of a potentially fatal complication seen when HIV-infected patients being treated for TB begin antiretroviral therapy[4] .
- The **TB-NEAT consortium** has generated key evidence on methods of TB diagnosis – including the first evidence that use of a new diagnostic saves lives.
- The **WANECAM trial** in West Africa has shown that two newly developed antimalarials remain safe and efficacious even when used repeatedly and provided a new option for national malaria control programmes.

## Bridging the gap between science and policy for health

EDCTP has supported multiple studies that have influenced national and international policy and practice[4]:

- 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 revision of WHO guidelines, which recommended more extensive use of antiretrovirals in pregnant and breastfeeding women.
- The **WANETAM network** has built capacities in TB microscopy and culture across partnering laboratories to generate the first comprehensive West African drug-resistance data for TB.
- 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.

Importantly, EDCTP engages with national health policymakers to strengthen the focus on priority research questions and to encourage the uptake of research evidence, including through implementation studies.

## Promoting cross-border engagements across Africa

EDCTP membership includes 30 Participating States – 14 European and 16 in Africa. Each Participating State contributes to EDCTP governance, including planning, decision-making and shaping the agenda of the programme. Through the networks and consortia, EDCTP engages a further 31 countries in project activities. EDCTP's work in Africa cuts across language barriers, with collaborations uniting Anglophone, Francophone, Lusophone and Arabic-speaking countries.

EDCTP works closely with regional bodies, including regional economic communities, the Africa Centres for Disease Control and Prevention, WHO-AFRO, and the New Partnership for African Development (NEPAD) now renamed African Union Development Agency (AUDA).

## Ensuring transparency in clinical trials to inform health research

Registration of clinical trials provides policymakers, health researchers and funding agencies with a comprehensive overview of clinical trials being conducted in specific countries and disease areas.

EDCTP adheres to the WHO recommendation that all clinical trials should be registered, and in 2006 it established the Pan-African Clinical Trials Registry (PACTR; www.pactr.org) as a repository tailored to the needs of researchers working on trials in Africa.

In 2009, PACTR was officially recognised as a WHO primary registry, and is the only WHO-endorsed primary registry in Africa. It is open access and trials can be registered free of charge.

## Boosting preparedness for infectious disease outbreaks in Africa

Africa is at risk of multiple emerging and re-emerging infections, including Ebola and other viral haemorrhagic fevers, yellow fever and plague. If not controlled effectively, outbreaks can have a catastrophic human and economic impact. The 2014–16 Ebola epidemic claimed 11,000 lives and cost the three countries affected an estimated US$2.2bn in lost GDP in 2015 alone.

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.

EDCTP's Emergency Funding Mechanism allows resources 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 9 institutions from 6 countries in Africa.

Global demand for yellow fever vaccine significantly exceeds supply. Fractional dosing could enable more individuals to receive a potentially life-saving vaccine, but it will be important to ensure that this does not compromise vaccine effectiveness. The EDCTP-funded NIFTY trial will determine whether lower doses of yellow fever vaccine stimulate protective immune responses – which could enable more people to benefit from a vaccine in limited supply.

## Supporting integrated capacity building for health research in Africa

As well as a trained scientific workforce and leadership, EDCTP is contributing to other key aspects of health research capacity.

- EDCTP-funded Networks of Excellence in four African regions have created platforms for high-quality clinical studies spanning multiple sites and enabled the sharing of research experience, expertise and knowledge, developing sustainable capabilities across 63 institutions in 21 African countries to date.
- 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).
- Joint calls with WHO have developed capacity in responding to Ebola outbreaks, clinical research and implementation research.
- Participation of industry and PDPs in EDCTP consortia have enabled African academic institutions to further develop their capacity to undertake trials compliant with the rigorous standards demanded of regulatory studies.

At a national level, health research generates new evidence to facilitate better planning of health services, the development of new and innovative public health strategies, and enhances the capacity and knowledge of health care workers and institutions.

EDCTP is contributing to the strengthening of national health research systems in sub-Saharan Africa. It recently organised a meeting to discuss a new tool for systematic assessment of national health research systems, as well as a high-level meeting of African Union policymakers, strategic partners and African EDCTP Participating States during the WHO African Regional Committee in Dakar, Senegal, to discuss strengthening of national health research systems[5].

**Map:**
Country involvement in EDCTP activities:

- Collaborative clinical trials and clinical studies
- Capacity development (excluding fellowships)
- Fellowship programme

### Endnotes


1 African Union. Agenda 2063: The Africa We Want. 2013. Available at https://au.int/sites/default/files/pages/3657-file-agenda2063_popular_version_en.pdf

2 African Union. Science, Technology and Innovation Strategy For Africa 2024. 2014. Available at https://au.int/sites/default/files/newsevents/workingdocuments/33178-wd-stisa-english_-_final.pdf

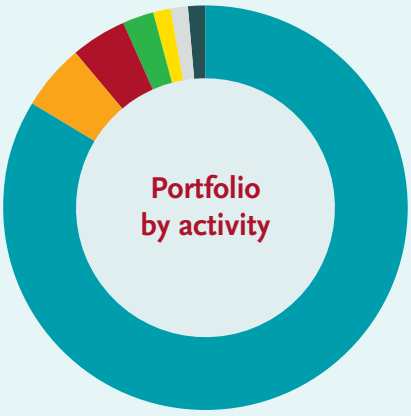
3 EDCTP. Tackling infectious disease in sub-Saharan Africa. EDCTP-funded clinical studies for medical interventions 2003-2018. 2018. Available at http://www.edctp.org/web/app/uploads/2018/09/Tackling-infectious-disease-in-sub-Saharan-Africa_EDCTP-funded-clinical-studies-for-medical-interventions-2003-2018-4.pdf

4 Meintjes G et al. Prednisone for the prevention of paradoxical tuberculosis-associated IRIS. *N Engl J Med*. 2018;379:1915–25

5 EDCTP. Development and Strengthening of the National Health Research Systems in sub-Saharan Africa. 2018. Available at http://www.edctp.org/publication/development-and-strengthening-of-the-national-health-research-systems-in-sub-saharan-africa/

## African participation in EDCTP grants (2014-2018)

**514** African researchers collaborate in **193** EDCTP grants.




- Collaborative clinical trials and clinical studies, *57 grants*
  **€374.32 M**
- Health system preparedness, *13 grants*
  **€23.42 M**
- Fellowships, *90 grants*
  **€19.57 M**
- Networks of Excellence, *4 grants*
  **€11.98 M**
- Pharmacovigillance, *3 grants*
  **€6.30 M**
- Ethics and regulatory framework, *20 grants*
  **€5.83 M**
- Evidence-informed policy, *6 grants*
  **€5.35 M**


- Tuberculosis, *38 grants*
  **€126.50 M**
- HIV & HIV-associated infections, *40 grants*
  **€91.76 M**
- Malaria, *23 grants*
  **€67.86 M**
- Neglected infectious diseases, *20 grants*
  **€47.98 M**
- Emerging diseases, *17 grants*
  **€42.85 M**
- Diarrhoeal diseases, *4 grants*
  **€21.97 M**
- Lower respiratory tract infections, *4 grants*
  **€18.25 M**

Note:
*A further €29.60M for 47 grants was awarded for projects on non-disease-specific topics.*

## EDCTP grant value allocation

- Africa, *226 institutions*
  **62%**
- Europe, *139 institutions*
  **38%**

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