WHO WE ARE

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public–public partnership funding collaborative clinical research on medicinal products to fight poverty-related infectious diseases (PRDs) affecting sub-Saharan Africa.

EDCTP’s vision is to reduce the individual, social and economic burden of these diseases by supporting the clinical development of accessible, suitable and affordable medical interventions.

EDCTP’s mission is to accelerate—while enhancing African clinical research capacity—the development of new or improved medicinal products for the identification, treatment and prevention of infectious diseases, including emerging and re-emerging diseases, through pre and post registration clinical studies, with emphasis on phase II and III clinical trials.
What we do

We fund collaborative clinical research on medicinal products and support the capacity of sub-Saharan African countries to conduct high quality clinical studies by developing laboratory and clinical facilities, and investing in the development of the next generation of African researchers. EDCTP also strengthens ethical review capacity and the regulatory framework for clinical research in sub-Saharan Africa.

The EDCTP programme encompasses pre- and post-registration clinical studies with populations often excluded from clinical studies and with major unmet medical needs—including pregnant women, newborns, children, other vulnerable populations, and people with co-infections and co-morbidities.

EDCTP also funds product-focused implementation research on the delivery and uptake of medical interventions. This makes our work directly relevant to health services in sub-Saharan African countries. This research provides new opportunities for partnerships with development organisations and other partners working on health systems, optimisation of health services and access to safe and effective medical interventions for the populations that need them most.

How we work

EDCTP operates as a true partnership of equals between North and South. European and African partners are involved at all levels, including priority setting, strategy development, implementation of plans, and overall decision making. This contributes to co-ownership and political commitment which increases the likelihood that research results influence policy and practice.

We have a strong practical focus on clinical challenges and policy-relevant questions, with the aim that results of funded research feed directly into national and international policy-making and practice.

We are committed to working with like-minded partners to promote wider use of the opportunities established for collaborative research. We have set up multiple highly effective partnerships with global public and private sector organisations and are looking for new collaborations.

We are committed to promoting transparency of our funding and open access to the results and data of the clinical research we fund.

Our objectives

- Clinical Research: Accelerate the development of new or improved medical interventions against poverty-related infectious diseases.
- Capacity development: Increase cooperation with sub-Saharan Africa through capacity development for conducting clinical studies according to the highest ethical principles and regulatory standards.
- European coordination: Improve coordination, alignment and integration of European national programmes.
- Cooperation with public and private partners: Increase international cooperation with public and private partners and interactions with other EU initiatives, including those linked to development aid.

Working in partnership

With the support of the European Union, EDCTP has established itself as a key contributor to the Africa–EU Strategic Partnership. EDCTP is an important player in global health and now the focal point for European research activities, promoting coordinated action to maximise impact on poverty-related infectious diseases.

EDCTP funded activities are underpinned by a strong commitment to networking within the research community. North–South collaboration promotes the exchange of knowledge and expertise between researchers and institutions in Europe and in Africa. North–North coordinated activities in Europe would maximise the impact of investments in health research. South–South collaboration, for example through regional Networks of Excellence, supports sharing local expertise and enables multicentre international studies. We engage with African governments to promote a better alignment of research and development agendas within the scope of the EDCTP programme.

We work with a wide range of partners beyond the European and African Participating States. Other countries in Europe and Africa can work with the programme, while researchers outside Europe and Africa can join EDCTP-funded collaborations. We engage with national and international development agencies for collaboration and alignment in view of common goals. We also work with international organisations, industry, private non-profit organisations and public–private product development partnerships, which can take advantage of the funding offered by EDCTP.
What we fund

The EDCTP programme supports clinical research, research capacity development and international networking to address the infectious diseases affecting Africa.

Target diseases
EDCTP supports clinical research on HIV, tuberculosis (TB), malaria, neglected infectious diseases, diarrhoeal diseases, lower respiratory tract infections, and emerging and re-emerging infections relevant to sub-Saharan Africa, including Ebola and yellow fever.

Box: Neglected infectious diseases in the scope of EDCTP*

- Buruli ulcer
- Dengue
- Dracunculiasis (guinea-worm disease)
- Echinococcosis
- Foodborne trematodiases
- Human African trypanosomiasis (sleeping sickness)
- Leishmaniasis
- Leprosy (Hansen’s disease)
- Lymphatic filariasis
- Mycetoma
- Onchocerciasis (river blindness)
- Rabies
- Schistosomiasis
- Soil-transmitted helminthiases
- Taeniasis/cysticercosis
- Trachoma
- Yaws (endemic treponematoses)

* Based on the WHO list of neglected tropical diseases 2017; Chagas disease, chikungunya, chromoblastomycosis and other deep mycoses, scabies and other ectoparasites, and snakebite envenoming are currently not in the EDCTP scope.

Medical interventions
EDCTP supports clinical studies on medicinal products designed to detect, prevent or treat target diseases. These include novel drug treatments and formulations, new therapeutic regimens, microbicides, vaccines and diagnostics.

Type of research
Interventional clinical studies make up the bulk of the EDCTP portfolio. We support phase I–III safety/efficacy studies, with a particular emphasis on phase II and III trials. We also support phase IV, pharmacovigilance and post-licensing effectiveness studies (pragmatic trials, utility/impact studies), product-focused implementation research and field trials (diagnostic tests).

Collaboration and partnerships
EDCTP seeks to build relationships and broker sustainable partnerships – promoting North-South, South-South and North-North collaborations, and developing relationships with multiple private- and public-sector organisations.

Transparency
EDCTP promotes transparency by publishing funding information in its public grants portal and contributing funding data to international initiatives such as G-finder and World Report. For the clinical research it funds, EDCTP actively demands and supports public registration, ethics review, the creation and depositing of open access research data sets, and open access publishing of clinical research results.

Capacity development
EDCTP makes an important contribution to the development of clinical research capacity of sub-Saharan Africa. EDCTP supports researchers at various career stages, from master’s and PhD training through to senior fellowships. The EDCTP Alumni Network facilitates reflection on experiences, and fosters collaboration and networking among past and current fellows. EDCTP also supports activities strengthening the ethical, regulatory and legal framework for conducting trials.
Calls for proposals

The topics for most EDCTP calls for proposals are broad and non-disease specific to maintain flexibility in financing. This allows for timely funding of clinical trials of promising candidate drugs or vaccines, accommodating unexpected approaches and novel ideas, and leaves flexibility to support a response to emerging infectious diseases.

EDCTP calls for proposals are open to participation of researchers globally provided they team up with European and sub-Saharan African partners. Only 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 directly.

More information on calls is available at www.edctp.org. Subscribe to our newsletter on the EDCTP website to be notified about open calls for proposals.
### Organisational structure

The EDCTP Association, the legal structure for the second EDCTP programme, is governed by the General Assembly. The Association Board is entrusted by the General Assembly with the management of the Association and the oversight of the Secretariat. The Scientific Advisory Committee is the principal advisory body to EDCTP. The Executive Secretariat implements the programme.

### States participating in the EDCTP Association

By the end of 2017, the EDCTP Association had 16 African and 14 European member countries – the so-called Participating States – and also one African and one European Aspirant members.

EDCTP member countries contribute directly and indirectly to EDCTP. National research activities within the scope of EDCTP that are independently funded and administered by EDCTP participating states are an integral part of the EDCTP programme. These so-called Participating States’ Initiated Activities (PSIAs) help achieving our strategic objectives.

The General Assembly of the EDCTP Association is composed of the institutions mandated by national governments representing respective participating states. The European Commission, the African Union and the World Health Organization are observers.

### Funding of the programme

The current EDCTP programme will run for ten years from 2014 to 2024. The partnership aims for a €2 billion budget, having already secured €1.36 billion in pledges. This includes a commitment of up to €683 million from the European Union (EU) to match the contribution from the European countries that are members of the EDCTP Association. Additional funding will be sought from public and private third parties. The programme is implemented as part of the European Union’s Framework Programme for Research and Innovation, Horizon 2020.

#### EDCTP Participating States

- Selected and administered by Participating States
- Funded by Participating States
- Application of Participating States’ funding rules

#### EDCTP Calls for Proposals

- Selected and administered by EDCTP
- Funded by the European Union, Participating States and third parties
- Application of Horizon 2020 rules for participation

#### Participating States’ Initiated Activities

- Selected and administered by Participating States
- Funded by Participating States
- Application of Participating States’ funding rules

### Funding

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<th>Third parties</th>
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<td>Cash/In-Kind (≥ €683 M)</td>
<td>Cash (≥ €30 M)</td>
<td>Cash (≥ €500 M)</td>
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</table>

- Private sector
- PDPs
- Development organisations
- Research institutions
The route to impact

Through its funding, EDCTP is expected to generate valuable new evidence on medical interventions and how they can best be implemented in practice, and enhance the capacity of countries in sub-Saharan Africa to undertake clinical research.

The expected long-term result of EDCTP’s second programme (2014-2024) is the uptake of research results on poverty-related infectious diseases in health policy and practice and ultimately wider societal benefits such as the reduction of health disparities associated with these diseases.

Output and outcomes

**Clinical research**
Generate high-quality research data relating to the safety and efficacy of new and improved medicinal products.

**Capacity development**
Enhance the ability of sub-Saharan African countries to conduct high-quality clinical research relevant to poverty-related diseases.

**Coordination and partnership**
Promote coordination and alignment of national research efforts to maximise the impact of European investments in global health research. Ensure that clinical research capacity established in sub-Saharan Africa allows timely evaluation and registration of new or improved medical interventions. Partnerships with development agencies and related organisations will contribute to sustainable delivery of validated medical interventions through strengthened healthcare systems.
Our achievements 2014-2017

50 projects include a clinical trial to conduct research on treatment, vaccines and diagnostics.

58 researchers from sub-Saharan Africa supported through EDCTP fellowship schemes.

13 grants funded to strengthen the regulatory framework and increase capacity for research ethics review in sub-Saharan Africa.

6 peer-reviewed scientific publications resulting from EDCTP-funded research.

34.4% grants led by a female project coordinator.

19 grants prioritise treatment for vulnerable populations such as children and pregnant women.

35 sub-Saharan countries participate in EDCTP projects.

16 European countries participate in EDCTP projects.

69.6% grants coordinated by a sub-Saharan African institution, including fellowship grants to sub-Saharan African researchers.

206 sub-Saharan institutions participate in EDCTP projects.

95 European institutions participate in EDCTP projects.

€255.38 million is the total funding towards projects awarded by end of 2017.

3% of European Participating States’ contributions are aligned or coordinated through EDCTP.

€6.67 million contribution from third-parties to EDCTP programme. These include contributions from charitable foundations, industry, and product development partnerships.
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<td><strong>Career Development of researchers</strong></td>
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<td><strong>Clinical Research and Development Fellowships</strong></td>
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<tr>
<td>Dr Isodore Traore <em>Burkina Faso</em></td>
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<td>Dr Solomon Mequanent Ayab <em>Ethiopia</em></td>
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<td>Dr Stephen Ian Walimbwa <em>Uganda</em></td>
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<td>Dr Suzanne Staples <em>South Africa</em></td>
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<td>Dr Armel Martin Zemsi Kala <em>Cameroon</em></td>
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<td>Dr Mwaka Kakolwa <em>Tanzania</em></td>
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<td>Asst Professor Ahmed Zeynudin Kasim <em>Ethiopia</em></td>
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<td>Dr Alphonce Liyoyo <em>Tanzania</em></td>
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<td>Dr Workineh Shibeshi Alemayehu <em>Ethiopia</em></td>
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<td>Dr Tecla Temu <em>Kenya</em></td>
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<td>Dr Deogratius Ssemwanga <em>Uganda</em></td>
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<td>Assistant Professor Yaya Kassogué <em>Mali</em></td>
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<td>Dr Yunia Mayanja <em>Uganda</em></td>
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<td>Dr Kingsley Badu <em>Ghana</em></td>
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<td>Dr Jean-Bertin Bukasa Kabuya <em>Zambia</em></td>
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<td>Dr Dan Kajungu <em>Uganda</em></td>
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<td>Dr Moustapha Mbow <em>Senegal</em></td>
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*Note: Countries listed refer to the country of Project Coordinator.*
### Collaborative clinical trials and clinical studies

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<td>POI-TB South Africa</td>
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### Intervention
- Drugs
- Diagnostics
- Vaccines

### Other
- Product-focused implementation research
- Behavioral and social sciences
- Capacity building/training

### Disease
- HIV and HIV-associated infections
- Tuberculosis
- Malaria
- Neglected infectious diseases
- Emerging diseases
- Lower respiratory tract infections
- Diarrhoeal diseases

* Project funded through the UK Joint Global Health Trials scheme.

Note: This overview includes both signed and approved grants. Countries listed refer to country of Project Coordinator.