14 European countries
Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and United Kingdom

2 Aspirant members
Angola, Switzerland

16 African countries
**Vision**

Reduce the individual, social and economic burden of poverty-related infectious diseases in sub-Saharan Africa, by investing in **collaborative clinical research** to develop accessible, suitable and affordable medical interventions and investing in **research capacity development**

**Mission**

To enhance research capacity and accelerate the development of new or improved medical interventions for the identification, treatment and prevention of **poverty-related infectious diseases**, including emerging and re-emerging diseases in sub-Saharan Africa, through all phases of **clinical trials**, with emphasis on phase **II and III trials**.
EDCTP timeline

- Launch of EDCTP2
- Council of the European Union approval decision
- European Parliament approval decision for EDCTP2

2014
End of EDCTP1

2015
EDCTP Forum: Lusaka, Zambia

2016
First interim evaluation*

2017
EDCTP Forum

2018

2019
EDCTP Forum

2020
End of implementation phase
EDCTP Forum

2021
End of EDCTP2

2022
Second interim evaluation*

2023

2024

2025
Final evaluation* (Independent evaluations commissioned by the EC.)

2026
The EDCTP funding programme

EDCTP Participating States

≥ € 683 M
CASH/IN-KIND

Participating States’ Initiated Activities

• Administered by Participating States
• Selected and funded by Participating States
• Application of Participating States’ funding

European Union

≥ € 30 M
CASH/IN-KIND

EDCTP Calls for Proposals

• Administered by EDCTP
• Funded by the EU, Participating States and third parties
• Horizon 2020 rules for participation

Third parties

≤ € 683 M
CASH

Private sector
PDGs
Development organisations
Research institutions

≥ € 500 M
CASH/IN-KIND
EDCTP Programme objectives

**Medical interventions**
New or improved medical interventions against poverty-related infectious diseases

**Collaboration and capacity development**
Improve cooperation with sub-Saharan Africa through capacity building for conducting clinical trials according to ethical principles and regulatory standards

**European coordination**
Improve coordination, alignment and integration of European National Programmes

**External partnerships**
Increase international cooperation with public and private partners

**EU cooperation**
Increase interaction with other EU initiatives, including those linked to development assistance
Target diseases

- HIV, tuberculosis, malaria
- **Neglected infectious diseases***
  Dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); leishmaniasis; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen’s disease); trachoma; yaws
- **Diarrhoeal diseases**
- **Lower respiratory tract infections**
- **Emerging and re-emerging infectious diseases** of particular relevance for Africa, such as Ebola virus disease and yellow fever.

* Based on the WHO list of neglected tropical diseases (excluding Chagas disease)
Vulnerable populations

- Pregnant women
- Newborns and children
- Adolescents
- People living with co-infections and co-morbidities
European Union R&D funding under Horizon 2020

PRODUCT DEVELOPMENT PIPELINE

Discovery → Preclinical research → Clinical research → Implementation research

- H2020 collaborative translational research projects
- EDCTP2 programme
  - SME-Instrument
  - IMI2 programme
  - InnoFin ID – Infectious Diseases Financing Facility (IDFF)
## EDCTP supported activities

<table>
<thead>
<tr>
<th>Research &amp; Innovation Actions (RIA)</th>
<th>Coordination &amp; Support Actions (CSA)</th>
<th>Training &amp; Mobility Actions (TMA)</th>
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<tr>
<td>Multicentre clinical trials that are conducted by research consortia involving both European and African research teams, with integrated capacity development and networking elements.</td>
<td>Support of activities that strengthen the enabling environment for conducting clinical trials and clinical research, including ethical review and regulatory capacity.</td>
<td>Fellowships that focus on the career development of individual researchers or research team members.</td>
</tr>
<tr>
<td>Action</td>
<td>No. calls</td>
<td>No. grants funded</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-----------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Research and Innovation Actions (RIA)</td>
<td>7</td>
<td>34</td>
</tr>
<tr>
<td>Training &amp; Mobility Actions (TMA)</td>
<td>7</td>
<td>56</td>
</tr>
<tr>
<td>Coordination &amp; Support Actions (CSA)</td>
<td>6</td>
<td>32</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>20</strong></td>
<td><strong>122</strong></td>
</tr>
</tbody>
</table>

*as of November 2017
Research and Innovation Actions (2014-2016)

Amount in millions (EURO) of funded/awarded projects

- HIV
- TB
- Malaria
- NID
- DD & LRTI
- Emerging diseases
- Co-morbidities

- Other (epidemiology and disease management)
- Vaccines
- Drugs (treatment and prevention)
- Diagnostics
EDCTP2 programme so far (2014-2016)

www.EDCTP.org
EDCTP involvement in broader trends

• Open access
  – Publications & data (European open science cloud)

• Transparency
  – clinical trial registration (PACTR)
  – Reports & databases: World RePort (NIH/World Bank, TAG, G-Finder, etc.

• Alignment
  – Sustainable Development Goals
  – national, regional and global priorities

• Emergency preparedness against infectious diseases
  – “Research capacity development in support of the EVD response” (2014)
  – “Research and clinical management of patients in PRD epidemics in sub-Saharan Africa” (2016)

• Antimicrobial resistance (AMR)
Thank you!
surette@edctp.org
## EDCTP2 calls for proposals

### RIA Numbers of proposals (2014-2016 Calls)

<table>
<thead>
<tr>
<th>Call</th>
<th>LoIs</th>
<th>Full proposals invited (%)</th>
<th>Full proposals submitted</th>
<th>Funded (%) over FP submitted</th>
<th>Funded (%) over LoI submitted</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIA – 2014 - Diagnostics</td>
<td>88</td>
<td>22 (25.0%)</td>
<td>21</td>
<td>6 (28.6%)</td>
<td>6 (6.8%)</td>
</tr>
<tr>
<td>RIA – 2015 - Treatment</td>
<td>125</td>
<td>42 (33.6%)</td>
<td>40</td>
<td>4 (10.0%)</td>
<td>4 (3.2%)</td>
</tr>
<tr>
<td>RIA – 2015 - Strategic</td>
<td>45</td>
<td>10 (22.2%)</td>
<td>10</td>
<td>3 (30.0%)</td>
<td>3 (6.7%)</td>
</tr>
<tr>
<td>RIA – 2016 - Vaccines</td>
<td>46</td>
<td>17 (37.0%)</td>
<td>15</td>
<td>6 (40.0)</td>
<td>6 (13.0)</td>
</tr>
<tr>
<td>RIA – 2016 - Maternal and child health</td>
<td>42</td>
<td>10 (23.8%)</td>
<td>10</td>
<td>4 (40.0)</td>
<td>4 (9.5)</td>
</tr>
<tr>
<td>RIA – 2016 – PRD Epidemics</td>
<td>10</td>
<td>3 (30.0%)</td>
<td>3</td>
<td>2 (66.7)</td>
<td>2 (20.0)</td>
</tr>
<tr>
<td>RIA – 2016 – Strategic</td>
<td>23</td>
<td>9 (39.1%)</td>
<td>8</td>
<td>5 (62.5)</td>
<td>5 (21.7)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>379</strong></td>
<td><strong>113 (29.8%)</strong></td>
<td><strong>107</strong></td>
<td><strong>30 (39.7%)</strong></td>
<td><strong>30 (11.6%)</strong></td>
</tr>
</tbody>
</table>
### EDCTP2 calls for proposals

**Portfolio by disease/topic**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Number of RIAs (% of total)</th>
<th>Number of TMAs (% of total)</th>
<th>Number of CSAs (% of total)</th>
<th>Number overall (% of total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria</td>
<td>3 (10.0)</td>
<td>6 (12.8)</td>
<td>2 (6.3)</td>
<td>11 (10.1)</td>
</tr>
<tr>
<td>HIV and HIV-associated infections</td>
<td>6 (20.0)</td>
<td>12 (25.5)</td>
<td>2 (6.3)</td>
<td>20 (18.3)</td>
</tr>
<tr>
<td>TB</td>
<td>9 (30.0)</td>
<td>9 (19.1)</td>
<td>2 (6.3)</td>
<td>19 (18.3)</td>
</tr>
<tr>
<td>HIV/TB</td>
<td>3 (10.0)</td>
<td>1 (2.1)</td>
<td>0</td>
<td>4 (3.7)</td>
</tr>
<tr>
<td>NIDs</td>
<td>5 (16.7)</td>
<td>7 (14.9)</td>
<td>0</td>
<td>12 (11.0)</td>
</tr>
<tr>
<td>Emerging diseases</td>
<td>3 (10.0)</td>
<td>1 (2.1)</td>
<td>6 (18.8)</td>
<td>10 (9.2)</td>
</tr>
<tr>
<td>Lower respiratory tract infections (LRTI)</td>
<td>1 (3.3)</td>
<td>1 (2.1)</td>
<td>0</td>
<td>2 (1.8)</td>
</tr>
<tr>
<td>Diarrhoeal diseases (DD)</td>
<td>0</td>
<td>2 (4.3)</td>
<td>0</td>
<td>2 (1.8)</td>
</tr>
<tr>
<td>Ethics and Regulatory</td>
<td>0</td>
<td>0</td>
<td>14 (43.8)</td>
<td>14 (12.8)</td>
</tr>
<tr>
<td>Networks</td>
<td>0</td>
<td>0</td>
<td>4 (12.5)</td>
<td>4 (3.7)</td>
</tr>
<tr>
<td>Capacity building and training</td>
<td>0</td>
<td>7 (14.9)</td>
<td>2 (6.3)</td>
<td>10 (8.3)</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>1 (2.1)</td>
<td>0</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30 (100.0)</strong></td>
<td><strong>47 (100.0)</strong></td>
<td><strong>32 (100.0)</strong></td>
<td><strong>109 (100.0)</strong></td>
</tr>
</tbody>
</table>
EDCTP programme implementation: integrated approach
EDCTP priority-setting mechanisms

THREE-YEAR PLAN
- Short and medium term priorities
- Estimated budgets

ANNUAL STRATEGIC RESEARCH AGENDA
- Annually adjusted priorities taking into account EDCTP criteria for prioritisation

ANNUAL WORKPLAN
- Planned calls for proposals
- Participating States’ Initiated Activities (PSIAs)
- Detailed targets

STRATEGIC BUSINESS PLAN
- Overall programme strategy
- Scope of programme
- Funding mechanisms
- High-level priorities

• Performance evaluation
• Monitoring and evaluation activities
Clinical studies supported by EDCTP

- **Human pharmacology**
  - Phase I: Discovery & Pre-clinical research
  - Phase II: Therapeutic exploratory
  - Phase III: Therapeutic confirmatory
  - Phase IV: Therapeutic use

**Clinical trials**

- Safety and/or efficacy of investigational medicinal product
- Product formulation
- Dosing recommendations
- Biomarkers
- Pharmacogenomics
- Clinical trial on specific populations
- Low interventional clinical trials
- Pragmatic trials
- Effectiveness
- Comparing medical intervention strategies
- Optimizing the use of existing intervention
- Diagnostics test validation
- Product-focused implementation research
EDCTP clinical research

**Medical Interventions**

Drug

Vaccine

Microbicide

Diagnostics

Preventive or curative

**Clinical research activities supported**

- Human Pharmacology
- Therapeutic exploratory
- Therapeutic confirmatory
- Therapeutic use (Phase I to IV studies)

- Safety and efficacy
- Optimisation of interventions for special population groups
- Active surveillance to gather product’s safety data
- Biomarkers
- Pharmacogenomics
- Implementation research for test validation
- Pragmatic studies on effectiveness
- Implementation research with a product focus

**Outcome**

- Clinical development progress leading to registration of new medicinal product, therapeutic regimen, indication, formulation
- Optimised product formulations for special populations
- Development of pharmacovigilance platforms and product registries
- New methodologies and appropriate medical devices for PRDs diagnosis
- Optimising the delivery of existing interventions
- Guidelines on benefit of medical intervention in health care
- Influencing disease management policies
Outcome from EDCTP research activities

• Clinical development progress leading to registration of new medicinal products, therapeutic regimens, indications
• Optimised product formulations for special populations
• Development of pharmacovigilance platforms and product registries
• New methodologies and appropriate medical devices for diagnosis of PRDs
• Optimising the delivery of existing interventions to contribute to a high level of public health
• Guidelines on benefit of medical interventions in health care
• Changing disease management policies
EDCTP strategy for capacity development

Strengthening product-focused health systems research
- Phase IV studies
  - Pragmatic studies
  - Implementation research with a product focus
  - Pharmacovigilance

Site preparation for conducting clinical research

Comprehensive fellowship programme
- Preparatory Fellowship
- R&D Fellowship
- Career Development Fellowship
- Senior Fellowship

Regional Networks of Excellence

Strengthening ethics capacity and regulatory framework
EDCTP Fellowship schemes

CLINICAL RESEARCH AND DEVELOPMENT FELLOWSHIP

Objective: to support researchers and key members of clinical trial research teams from low- and middle-income countries to acquire specific skills in clinical trials research through placements in pharmaceutical companies, CROs, clinical or academic affiliated research organisations and PDPs.

Target individuals:
• Post-graduate (MSc or PhD) or medical graduate with clinical and/or research experience in infectious diseases
• Post-graduate or medical graduate degree within 15 years of submission of the application
• Researcher or clinical staff member employed for the last 12 months in an organisation with a registered legal entity in sub-Saharan Africa.

Funding level: 100% of eligible costs
Max. funding: €100,000

EDCTP-AREF PREPARATORY FELLOWSHIP

Objective: to enhance the competitiveness of up-and-coming post-doctoral African scientists and clinicians aspiring to win international/regional/national fellowships or grant support through short-term placements at a host organisation in EU Member States, in countries associated to Horizon 2020 or in sub-Saharan Africa which will be contracted by the home organisation to host the fellow.

Target individuals:
• Post-doctoral scientists
• Individuals who have been awarded their doctorate within three years before submission deadline
• PhD students or MDs who have been active researchers for up to three years following award of their doctorate
• Resident of, or willing to relocate to, a sub-Saharan African country

Funding level: 100% of eligible costs
Max. funding: €70,000

* Joint call by EDCTP and the Africa Research Excellence Fund (AREF).

CAREER DEVELOPMENT FELLOWSHIP

Objective: to support junior to mid-career researchers to train and develop their clinical research skills. The objectives are to promote career development and retention of postdoctoral researchers and postgraduate medical researchers in the research field and in sub-Saharan Africa; and to equip the fellows with the ability to establish themselves as independent researchers and with the skills to initiate and manage their own research at host organisations in sub-Saharan Africa.

Target individuals:
• Resident of, or willing to relocate to, a sub-Saharan African country
• A graduate in a subject relevant to the EDCTP2 programme, with a PhD and a minimum of five years’ relevant research experience after the doctorate, or a medical doctor with a post-graduate qualification in a subject relevant to the EDCTP2 programme, and a minimum of five years’ research experience after the post-graduate qualification
• A minimum of 5 first-author publications in international peer-reviewer journals

Funding level: 100% of eligible costs
Max. funding: €150,000

SENIOR FELLOWSHIPS

Objective: to support capacity development of potential African research leaders using the train-the-trainer model and to mentor junior researchers with hands-on training linked to clinical trials activities in sub-Saharan Africa.

Target individuals:
• Resident of, or willing to relocate to, a sub-Saharan African country
• A graduate in a subject relevant to the EDCTP2 programme, with a PhD and a minimum of five years’ relevant research experience after the doctorate, or a medical doctor with a post-graduate qualification in a subject relevant to the EDCTP2 programme, and a minimum of five years’ research experience after the post-graduate qualification

Funding level: 100% of eligible costs
Max. funding: €500,000.

* Joint call by EDCTP and the Africa Research Excellence Fund (AREF).
Building international collaboration

- Wellcome
- World Health Organization
- UNAIDS
- SMEs
- European Investment Bank
- Pharma
- Mundo Sano
- PDPs
- Bill & Melinda Gates Foundation
- The Global Fund
- World Bank Group
Criteria for setting priorities

1. **State of the product development landscape**
   For each disease area, these analyses identify the current state of clinical development of interventions for treatment, prevention and diagnosis.

2. **Priority infections**
   Analyses of disease burdens and changing patterns of disease feed into priority setting for the poverty-related infectious diseases targeted by EDCTP.

3. **Disease burden and treatment/prevention priorities**
   These analyses identify key knowledge gaps and need for new evidence.

4. **Emerging opportunities**
   Our expansion into new disease areas and into post-licensing studies, including effectiveness studies, pharmacovigilance and product-focused implementation research, provides new opportunities for EDCTP to achieve impact.

5. **Balanced portfolio**
   We aim to develop and sustain a balanced portfolio, across disease areas, types of intervention and type of study, balancing short-term and long-term priorities; this will help to ensure steady flows through product development pipelines.
Key features of EDCTP

We were established as a flagship European–African partnership and are recognised as an international funder of clinical research for poverty-related infectious diseases.

We are enhancing the research capacity of sub-Saharan African countries to conduct clinical studies in compliance with ethical and regulatory standards.

We operate as a true 'partnership of equals' between North and South, with input from African countries at all levels.
Key features of EDCTP

We support studies encompassing populations often excluded from clinical studies but with major unmet medical needs.

Our expansion to cover product-focused implementation research on delivery and uptake of medical research outputs makes our work more relevant to health services in sub-Saharan Africa. It also provides new opportunities for partnership with development assistance initiatives.
Key features of EDCTP

We focus on clinical challenges and policy-relevant questions, ensuring results of funded research feed directly into national and international policy-making.

We are committed to working with like-minded partners to promote wider use of the opportunities established for collaborative research.
EDCTP supported activities

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<td>Multicentre clinical trials that are conducted by research consortia involving both European and African research teams, with integrated capacity development and networking elements.</td>
<td>Support of activities that strengthen the enabling environment for conducting clinical trials and clinical research, including ethical review and regulatory capacity.</td>
<td>Fellowships that focus on the career development of individual researchers or research team members.</td>
</tr>
</tbody>
</table>
## Eligibility criteria for EDCTP calls for proposals

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</tr>
</thead>
<tbody>
<tr>
<td>Consortia of ≥ 2 European countries and ≥ 1 sub-Saharan African country</td>
<td>Individual institutions or consortia for ethics, training, networking and regulatory activities</td>
<td>Grants to individuals: Career development, Senior, other</td>
</tr>
<tr>
<td>Either full funding (RIA) (100% of costs) or cofunding (SRIA) (≤50%) with other funders (PSs and/or third parties)</td>
<td>100% funding</td>
<td>100% funding</td>
</tr>
<tr>
<td>Broad non-prescriptive topics, bottom-up</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Broad non-prescriptive topics, bottom-up
Competitive process for grants

**Annual work plan with call topics**
- Thematic stakeholder meetings
- Consultation with SAC/GA members
- Approval by EC
- Adoption by GA

**Proposal preparation and submission**
- Launch of call for proposal
- Proposal/LoI submitted by applicant
- Full proposal (2nd stage)

**Proposal review and approval**
- Eligibility check by EDCTP
- Peer review by independent experts
- Ethics review by independent experts
- GA decision

**Project award**
- Contract negotiations
- Grant agreement & start of project

**Monitoring and grant closure**
- Periodic project reporting and monitoring
- External audits and site visits
- Peer-reviewed publication & end of project
Types of co-funding by EDCTP Participating States

- **In-kind contribution to EDCTP through PSIA:s**: support networking, clinical trials or capacity building

- **Cash** (unrestricted or restricted)
  - Direct to EDCTP2-funded projects
  - Common pot of EDCTP2

- **Non-grant related**
What are the Participating States’ Initiated Activities (PSIAs)

Activities funded and managed by a single or several Participating States (independently or jointly) that fall within the scope of the EDCTP programme, based on common principles.

- Equal treatment
- Transparency
- Independent peer review evaluation
- Ethics and scientific integrity
- Functional appeal system
- Exploitation and dissemination of results
What are eligible PSIAs?

Activities within the EDCTP scope

- Clinical development of new or improved medicinal products for treatment and prevention of diseases covered by EDCTP
- Networking, coordination, alignment, cooperation and integration activities on EDCTP disease areas
- Capacity development for clinical research
- Implementation research with a product focus
- Product focused: diagnostics, drugs, vaccines and microbicides
- All phases of clinical trials from human pharmacology to therapeutic use