EDCTP2 - Opportunities for clinical research on poverty-related diseases in sub-Saharan Africa.

Info Day, Horizon 2020
Societal Challenge 1: ‘Health, demographic change and wellbeing’
8 July 2016, Brussels
Our mission

To reduce poverty and improve health in sub-Saharan Africa by funding **collaborative research** to accelerate the development of new or improved medical interventions against **poverty-related and neglected infectious diseases**.
The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between countries in Europe and sub-Saharan Africa, and the European Union.

**Background**

- Established in 2003 by a co-decision of the European Parliament and Council: Article 185 Initiative (Ex 169)
  - Pool research activities to achieve greater impact PRDs
  - Promote integrated approach to clinical health research in Europe
- In response to MDGs and global health crises caused by PRDs
  - No economic incentive for private investments in PRDs
  - Public investments sparse and know-how fragmented
- First EDCTP programme: completed in December 2015
- Second EDCTP programme: will run from 2014-2024
What we do

• Fund research in SSA to accelerate the clinical development of effective, safe, accessible, suitable, and affordable medical interventions for PRDs

• Support international alignment, coordination and integration of national research agendas and programmes for PRDs.

• Seek the advice, support and collaboration of many stakeholders including research institutions, development organisations, private charities and funders, pharmaceutical companies, and PDPs.

• Offer a single European-African platform for research cooperation and funding.

• Promote African co-ownership of the EDCTP programme and the development of clinical research capacity and scientific leadership in sub-Saharan Africa.

• Support SSA countries to develop their capacity for conducting clinical trials in compliance with fundamental ethical principles and relevant (inter)national standards and regulations.
EDCTP partnership

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

1 Aspirant Member
Switzerland

14 African Countries
**Public-public partnership**

**EDCTP operates as an independent legal entity**
- Association under Dutch private law as a non-profit organisation

**28 PSs members Association**

**PSs minimum annual contribution of €200,000 (cash and/or in-kind)**

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**General Assembly**
Reps. from each PS EC, AU and WHO as Observers

**Board**
5 Members
SAC Chair & EC as Observer

**EDCTP Secretariat**
The Hague, Netherlands
Cape Town, South Africa

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**Scientific Advisory Committee (SAC)**
16 Members

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**Governance**

- General Assembly
- Board
- EDCTP Secretariat
- Scientific Advisory Committee (SAC)

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**Advice**

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The EDCTP 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 rules

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
PDPs
Development organisations
Research institutions

≥ € 500 M

CASH/IN-KIND
DEROGATIONS FROM H2020 RULES FOR PARTICIPATION (ART.6 DECISION No 556/2014/EU)

• Participation and funding of African entities:
  – 2 legal entities established in 2 different European PSs and a third legal entity in a sub-Saharan African country
  – Any legal entity established in a sub-Saharan country shall be eligible for funding

• Cooperation with other legal entities:
  – EDCTP may launch joint calls with third countries or their scientific and technological organisations and agencies, with international organisations or with other third parties, in particular NGOs
Diseases covered by EDCTP

• HIV, tuberculosis, malaria
• **Neglected infectious diseases (NIDs)**
  Buruli ulcer; cysticercosis/taeniasis; dengue; dracunculiasis; echinococcosis; foodborne trematodiasis; Hansen disease; human African trypanosomiasis; leishmaniasis; lymphatic filariasis; mycetoma; onchocerciasis; rabies; schistosomiasis; soil-transmitted helminthiases; trachoma; yaws

• **Diarrhoeal diseases**

• **Lower respiratory tract infections**

• **Emerging infectious diseases** of particular relevance for Africa, such as Ebola virus disease and yellow fever.
Conducting interventional clinical studies on medicinal products (*) in compliance with fundamental ethical principles and relevant regulation.

(*) Community code relating to medicinal products for human use.
## Clinical research in scope EDCTP

<table>
<thead>
<tr>
<th>Interventional studies</th>
<th>Clinical research activities</th>
<th>Output</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicinal products</td>
<td>Clinical studies phase I to III</td>
<td>Registration of medicinal product, new indication of an existing product or new therapeutic regimen</td>
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<tr>
<td>Preventive or curative pharmacological intervention (drug, vaccine, microbicide)</td>
<td>• Clinical pharmacology • Therapeutic exploratory and confirmatory</td>
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<tr>
<td>Diagnostics</td>
<td>Development, evaluation or demonstration studies</td>
<td>Development of new diagnostic medical devices for PRDs</td>
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|                        | • Collection of biological samples  
|                        |   • Biomarkers 
|                        |   • Pharmacogenomics 
|                        | • Implementation research for test validation | |
| Pragmatic or community trials on medicinal products | Operational research to determine the effectiveness of a proposed intervention through comparison methods in an interventional study | Disease management policies, guidelines on benefit and harms of intervention in health care |
| Postmarketing surveillance | Clinical trial phase IV  
|                          | • Pharmacovigilance (PV)  
|                          | • Therapeutic use | Development of PV platforms to facilitate collection of safety data on medicinal products |
## Type of grants

<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 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>
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2016 CALLS FOR PROPOSALS

Research & Innovation Actions (RIAs)

1. Clinical trials aiming to accelerate the clinical development of new vaccines (preventive or therapeutic) against PRDs
   - Call budget: €70M – max funding / project €15M
   - 2-stage call
   - 1st Open date: 7 July 2016 / Close date: 13 October 2016
   - 2nd: Open date: 22 December 2016 / Close date: 16 March 2017

2. Clinical trials and operational research studies to optimise the use, delivery and access to products for PRDs in SSA for mothers, newborns, children and/or adolescents
   - Call budget: €10M – max funding / project €3M
   - 2-stage call
   - 1st Open date: 7 July 2016 / Close date: 29 September 2016
   - 2nd: Open date: 12 December 2016 / Close date: 2 March 2017
2016 CALLS FOR PROPOSALS

Research & Innovation Actions (RIAs)

3. The establishment of a consortium for research and clinical management of patients in PRD epidemics in sub-Saharan Africa
   • Call budget: €10M – max funding / project €10M
   • 2-stage call
   • 1\textsuperscript{st} Open date: 7 July 2016 / Close date: 29 September 2016
   • 2\textsuperscript{nd}: Open date: 22 December 2016 / Close date: 2 March 2017

3. Strategic actions supporting large-scale clinical trials that have the potential to achieve rapid advances in the clinical development of new or improved medical interventions against PRDs
   • Focus on phase 3 clinical trials and $\geq$50\% costs of trial should be supported by other funders
   • Foreseen total costs of the entire trial $\geq$ €3.0 million
   • Call budget: €28M – max funding / project €15M
   • 2-stage call
   • 1\textsuperscript{st} Open date: 14 July 2016 / Close date: 13 October 2016
   • 2\textsuperscript{nd}: Open date: 22 December 2016 / Close date: 16 March 2017
2016 CALLS FOR PROPOSALS

Coordination & Support Actions (CSAs)

- Strategic actions supporting health systems/services optimisation research capacities in cooperation with development assistance initiatives, including development of PV capacities in SSA and the translation of research into policy and practice
  - Call budget: €10M – max funding / project €3M
  - 2-stage call
  - 1st Open date: 14 July 2016 / Close date: 29 September 2016
  - 2nd: Open date: 8 December 2016 / Close date: 2 March 2017

- Ethics and regulatory capacities to strengthen the functionality, recognition and performance of NECs and NRAs in SSA
  - Call budget: €2M – max funding / project €300k
  - 1-stage call
  - Open date: 4 August 2016 / Close date: 22 November 2016
2016 CALLS FOR PROPOSALS

Training & Mobility Actions (TMAs)

• **EDCTP-TDR Clinical Research and Development Fellowships** for junior to mid-career researchers or clinical staff from low- and middle-income countries to provide targeted training in clinical research and development within pharmaceutical companies and PDPs

• **Career Development Fellowships** to support junior to mid-career researchers to train and develop their clinical research skills

• **Senior Fellowships** to support the capacity development of potential African research leaders
HOW TO ACCESS INFORMATION

http://www.edctp.org/funding-opportunities/calls/
BENEFITS AND OPPORTUNITIES FROM PARTICIPATION IN EDCTP

EDCTP offers researchers:

• Opportunities to participate in large international clinical research consortia across Europe and Africa
• Increased networking opportunities, including with major pharmaceutical companies, public and private funders
• Collaborative research = higher citation impact

Other opportunities to engage include:

• EDCTP organises a biennial Forum (next on 6-9 November 2016 in Lusaka, Zambia) – gathers ~600 scientists, stakeholders, policy-makers
• Thematic stakeholder meetings (on average 1-2 per year)
  – In 2016: Diarrhoeal disease and lower respiratory tract infections, 5-6 July 2016
• Register as an EDCTP expert reviewer
THANK YOU

WWW.EDCTP.ORG

For more information, please contact:

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Calls and grants procedure

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
- 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