Overview of EDCTP2

H2020 - Open Info Day
Brussels, 18th Sept 2015
Dr Ole Olesen
EDCTP, The Hague, Netherlands
EDCTP aims to support collaborative research that accelerates the clinical development of new or improved interventions to prevent or treat HIV/AIDS, tuberculosis, malaria and neglected infectious diseases in sub-Saharan Africa

Objectives:
1. Increase the number of medical interventions for poverty-related diseases
2. Strengthen capacity for clinical trials in sub-Saharan Africa
3. Coordinate and align European national programmes
4. Cooperate with other public and private partners
5. Cooperation with EU initiatives, incl. development assistance
Background & Mission

Background

- Established in 2003 by a co-decision of the European Parliament and Council: Article 185 Initiative (Ex 169)
  - Pool clinical research activities to achieve greater impact against PRDs
  - Promote integrated approach to 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
- EDCTP-1: 2003-2015
The EDCTP2 Programme

Capacity for Clinical Trials in Africa

Synergy

Clinical Trials in Africa on PRDs

≥ € 683 M

≤ € 683 M

≥ € 500 M

IN-KIND/CASH

CASH

IN-KIND/CASH

PARTICIPATING STATES’ INITIATED ACTIVITIES

- Administered by Participating States
- Selected and funded by Participating States
- Application of Participating States’ funding rules

EDCTP2 CALLS FOR PROPOSALS

- Administered by EDCTP
- Funded by the EU, Participating States and third parties
- Horizon 2020 rules for participation
Who we are:
EDCTP Association

EDCTP2 Participating States (PSs)

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

14 African Countries
Cameroon, Burkina Faso, Rep of Congo, Gabon, Ghana, Mali, Mozambique, Niger, Senegal, South Africa, Tanzania, Gambia, Uganda, Zambia

Countries that can receive funding
• All sub-Saharan African countries
• All EU MSs and Associated Countries
gmz2: edctp-funded malaria vaccine candidate in phase 2

vaccine candidate (gmz2):
- hybrid of glutamate-rich protein and msp3+alum
- targeting blood stage of the parasite

4 clinical trial sites in africa:
- cnrfp (burkina faso), makerere university (uganda), albert schweitzer hospital (gabon) and nhrc-navrongo (ghana)

2 european partners:
- ssi (denmark – project coordinator), tubingen university (germany)

1747 children:
- 3 vaccinations at day 0, 28 and 56
- followed up for 24 months after 1st vaccination
- close-out: feb 2014

total budget: **eur 6.6 m** (from edctp)
## Comparison of H2020 and EDCTP2

<table>
<thead>
<tr>
<th></th>
<th>SC1, H2020</th>
<th>EDCTP2</th>
</tr>
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<tbody>
<tr>
<td><strong>Programme planning and publication of calls</strong></td>
<td>Work programme + participant portal</td>
<td>Work plan + EDCTP website</td>
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<tr>
<td><strong>Rules for participation</strong></td>
<td>H2020</td>
<td>H2020 with derogation</td>
</tr>
<tr>
<td><strong>Funding instruments (project types)</strong></td>
<td>RIA, CSA, TMA</td>
<td>RIA, CSA, TMA</td>
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<tr>
<td><strong>Minimum participants (RIA)</strong></td>
<td>3 MS/AC</td>
<td>2 <strong>PS</strong> + 1 SSA</td>
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<tr>
<td><strong>Indirect costs (overhead rate)</strong></td>
<td>25%</td>
<td>25%</td>
</tr>
<tr>
<td><strong>Who can participate?</strong></td>
<td>Almost all</td>
<td>Almost all</td>
</tr>
<tr>
<td><strong>Who can receive funding?</strong></td>
<td>Most, except OECD and BRIC</td>
<td>Only EU/AC + SSA</td>
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<tr>
<td><strong>Electronic proposal submission</strong></td>
<td>Participant portal</td>
<td>EDCTPgrants</td>
</tr>
<tr>
<td><strong>Model grant agreement</strong></td>
<td>H2020</td>
<td>Modified H2020</td>
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Funding instruments in EDCTP2

1. Research and Innovation Actions (RIA)
   - Consortia of ≥ 2 European PS and ≥ 1 sub-Saharan African country
   - 100% funding or co-funding

2. Training and Mobility Actions (TMA)
   - Fellowships to individuals
   - Career development (0-5 years); Senior (5+ years); specialised
   - 100% funding

3. Coordination and Support Actions (CSA)
   - Capacity development of institutions, networking and supporting activities
   - 100% funding
## Calls for Proposals in EDCTP2: outcome

<table>
<thead>
<tr>
<th>Call</th>
<th>Scheme</th>
<th>Proposals</th>
<th>Grants</th>
<th>Success rate</th>
<th>Funding per grant (max)</th>
<th>Total Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnostic tools</strong></td>
<td>RIA</td>
<td>96</td>
<td>6</td>
<td>6%</td>
<td>€ 3,000,000</td>
<td>€ 15M</td>
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<tr>
<td>• Validation of new or improved diagnostic tools</td>
<td></td>
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<tr>
<td><strong>Maximizing impact</strong></td>
<td>CSA</td>
<td>14</td>
<td>5</td>
<td>36%</td>
<td>€ 500,000</td>
<td>€ 3M</td>
</tr>
<tr>
<td>• Translation of research findings from EDCTP-funded projects into policy and practice</td>
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<tr>
<td><strong>EDCTP-TDR Clinical Research &amp; Development Fellowship</strong></td>
<td>TMA</td>
<td>149</td>
<td>21</td>
<td>14%</td>
<td>€ 200,000</td>
<td>€ 3M</td>
</tr>
<tr>
<td>• Support individual researchers from Africa to train for 6-24 months in pharma companies</td>
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<tr>
<td><strong>Research capacity development in support of the EVD response</strong></td>
<td>CSA</td>
<td>38</td>
<td>(5-7)</td>
<td>TBC</td>
<td>€ 250,000</td>
<td>€ 3M</td>
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<tr>
<td>• Capacity strengthening for confronting emerging epidemics</td>
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Calls for Proposals 2015: Improved treatment and clinical management of PRDs

• Clinical evaluation of new or significantly improved drugs or drug regimens in humans or to optimise the efficacy and use of existing therapeutics for PRDs, including co-infections of PRDs

• Should include one or more clinical trial(s) (phase I to IV) of therapeutics for PRDs to be conducted in sub-Saharan Africa.

Call open; deadline on 15 October

<table>
<thead>
<tr>
<th>Grant scheme</th>
<th>RIA (100% funding + 25% overhead)</th>
</tr>
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<tbody>
<tr>
<td>Call budget:</td>
<td>€ 35.0 M</td>
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<tr>
<td>Maximum funding per project:</td>
<td>€ 15.0 M</td>
</tr>
<tr>
<td>Expected nr/duration of grants:</td>
<td>3-5 / 36-60 months</td>
</tr>
<tr>
<td>Minimum consortium criteria:</td>
<td>≥ 2 European PSs &amp; ≥1 SSA country</td>
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<tr>
<td>Submission/evaluation process:</td>
<td>Two-stage (LoI; full proposal)</td>
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Calls for Proposals 2015:
Strategic actions supporting large-scale clinical trials

• Strategically important, ambitious, large-scale clinical trials with potential to achieve rapid advances in the clinical development of new or improved medical interventions against PRDs

• Total activity cost ≥ € 3.0 M

• Financial commitment from other funders (PSs and/or third parties) of ≥ 50% of activity costs

Call open; deadline on 15 October

<table>
<thead>
<tr>
<th>Grant scheme</th>
<th>RIA</th>
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<tbody>
<tr>
<td>Call budget:</td>
<td>€ 28 M</td>
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<tr>
<td>Maximum funding per project:</td>
<td>€ 10.0 M</td>
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<tr>
<td>Expected duration of grants:</td>
<td>36-60 months</td>
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<tr>
<td>Minimum consortium criteria:</td>
<td>≥ 2 European PSs &amp; ≥1 SSA country</td>
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Other Planned Calls in 2015:
Capacity Development

• EDCTP Regional Networks (CSA)
  (open: 1 Oct; deadline: 26 November; € 12M - TBC)

• Ethics and regulatory capacities (in collaboration with the Calouste Gulbenkian Foundation) (CSA)
  (open: 1 Oct; deadline: 26 November; € 1.5M - TBC)

• Fellowships (TMA)
  ➢ Senior fellowships
  ➢ Career development fellowships
  (open: 1 Oct; deadline: 26 November; € 4.0M - TBC)

• EDCTP-TDR Clinical Research and Development Fellowships (TMA)
  (open: 15 Oct; deadline: 27 January 2016; € 3.0M - TBC)
Future Calls: Workplan 2016 (and beyond)

**Thematic topics: ~60-70% of WP?**

- Research and Innovation actions addressing specific gaps (RIA)
- Capacity and networking activities addressing specific gaps (CSA)
- Joint calls with other organisation

**Annually recurring topics: ~30-40% of WP?**

- Strategic actions supporting large-scale clinical trials (RIA)
- Ethics and regulatory capacities (in collaboration with the Calouste Gulbenkian Foundation) (CSA)
- Fellowships (TMA)
  - Senior fellowships
  - Career development fellowships
- EDCTP-TDR Clinical Research and Development Fellowships (TMA)
Joint activities with other organisations

**What we cannot do:**
- Provide direct funding to an organisation (core funding)
- Provide direct funding to a specific activity (contract research)

**What we can do:**
- Leverage funding with other organisations (Strategic actions supporting large-scale..)
- Joint calls with other organisations

**Principles:**
- Equal treatment, transparency, fairness, independent peer review on the basis of pre-defined evaluation criteria
- Joint call included in EDCTP2 workplan (endorsed by SAC, approval by EC and GA)
Other ways to engage with EDCTP

- Participating States’ Initiated Activities (PSIA)
  Managed independently by the EDCTP Participating States. Implemented by national funding agencies (e.g. MRC or DFID in the UK, BMBF in Germany etc)

- Engage with national EDCTP representative, ministries, research councils and development cooperation agencies

- Register as EDCTP expert reviewer: http://www.edctp.org/calls-and-grants/information-for-reviewers/call-for-expert-reviewers/

- EDCTP bi-annual Forum (next time in October 2016) gathers about 500 scientists, stakeholders, policy makers

- EDCTP thematic stakeholder meetings
Thank you!

EDCTP Operations and networking teams

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Project Officer

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Ana Lúcia Cardoso
Networking Officer

Lara Pandya
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