Webinar with Industry Liaison Forum

EDCTP Secretariat

The Hague, The Netherlands
20 October 2015
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 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
- EDCTP1: 2003-2015
- EDCTP2: 2014-2024
EDCTP: Mission and objectives

EDCTP aims to support collaborative research that accelerates the clinical development of new or improved interventions to prevent or treat poverty-related diseases in SSA

Objectives:
1. Increase the number of medical interventions for PRDs
2. Strengthen capacity for clinical trials in sub-Saharan Africa
3. Coordinate and align European national research programmes on PRDs
4. Cooperate with other public and private partners
5. Cooperation with EU initiatives, incl. development assistance
EDCTP 1 metrics

EDCTP activities (2003-2014)

65 calls for proposals
254 grants awarded
€ 211.98 million grant value

Participation in projects
16 European countries
30 sub-Saharan African countries
EDCTP 1 grant portfolio

Disease areas

HIV/AIDS
- 56 projects
- €62.5M

HIV/TB co-infection
- 12 projects
- €7.23M

Tuberculosis
- 36 projects
- €70.68M

Malaria
- 42 projects
- €50.69M

HIV Interventions

- 14% of Treatment: €6.6M, N=7
- 27% of Vaccines: €12.8M, N=5
- 5% of Microbicides: €2.5M, N=2
- 54% of HIV/TB co-infection: €24.7M, N=17

Legend:
- Blue: Treatment
- Red: Vaccines
- Green: Microbicides
- Purple: HIV/TB co-infection
Outputs to date

4 Regional Networks of Excellence (CANTAM, WANETAM, TESA and EACCR)

78 ethics and regulatory grants in 23 sub-Saharan African countries

516 Senior Fellows and students (BSc, MSc, PhD, MD)

600+ scientific publications
Studies that led to policy change

2nd line treatment
• EARNEST
• 2LADY

Pharmacogenomics
• ClinPez; EFV toxicity in African patients

TB drug interaction
• Pharmagene: EFV safe to administer with RIF

Paediatrics
• CHAPAS-1 & 3
EDCTP2 Participating States (PSs)

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

14 African Countries

Countries that can receive funding
- All sub-Saharan African countries
- All EU MSs and Associated Countries
EDCTP Governance

- Public-Public partnership between 28 sovereign states and EU
- Minimum annual contribution of €200,000 (cash and/or in-kind)
- Operates as an independent legal entity
  - Association under Dutch Law

**General Assembly**
1 Member from each Participating State (EC as Observer)

**Board**
(5 Members, SAC Chair & EC as Observer)

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

**Scientific Advisory Committee**
(SAC, 16 Members)
The EDCTP2 Programme

Capacity for Clinical Trials in Africa

Synergy

Clinical Trials in Africa on PRDs

Third parties
(Private sector, PDPs, International Development Partners)

≥ € 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
Diseases: HIV/AIDS, TB, Malaria, NIDs, respiratory and diarrheal diseases, emerging infectious diseases of particular relevance for Africa, including Ebola

New tools and interventions: Diagnostics, drugs, vaccines & microbicides

Capacity Development: Fellowships, Networks, Ethics, Regulatory
Funding modalities in EDCTP2

Calls for Proposals

1. Calls for Proposals

Selected, funded and managed by EDCTP Secretariat according to H2020 rules

2. Participating States’ Initiated Activities (PSIAs)

Selected, funded and managed by PSs according to national rules

Annual work plan (AWP):
outline of call topics & tentative timetable

- Priority setting through thematic stakeholder meetings; SAC; other
- Bottom up approach: broad open call

- Internal review; review by external international peer review committee; approval by EC; adoption by EDCTP GA

2016 AWP under review
Funding instruments in EDCTP2

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

2. Coordination and Support Actions (CSA)
   - Capacity development of institutions, networking and supporting activities
   - 100% funding

3. Training and Mobility Actions (TMA)
   - Fellowships to individuals
   - Career development (0-5 years); Senior (5+ years); specialised
   - 100% funding
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 (CSA)
- Fellowships (TMA)
  - Senior fellowships
  - Career development fellowships
  - EDCTP-TDR Clinical Research and Development Fellowships
Calls for Proposals 2016: Vaccines for PRDs

- Accelerating the clinical development of new vaccines (preventive and therapeutic)
- At least one clinical trial (Phase I to IV) in SSA to test the safety, immunogenicity and/or efficacy of the vaccine(s)
- Activities to enhance the capacity of existing trial sites and/or develop new trial sites for future conduct of vaccine trials.
- Support from other funders (e.g. pharma/PDPs) is encouraged

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<td>Call budget:</td>
<td>€ 78M</td>
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<td>Maximum funding per project:</td>
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<td>Expected no/duration of grants:</td>
<td>TBD</td>
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<td>Minimum consortium requirement:</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 2016: Health systems and services optimisation research to fight PRDs in collaboration with EU, national and/or international development assistance initiatives

- Support collaborative actions with EU, national and/or international development assistance initiatives for strengthening the capacity of health systems to effectively deliver new products and to monitor their post-market safety
- Implementation research involving optimisation of delivery and increased access to PRD products
- Development of pharmacovigilance (PV) capacities in sub-Saharan Africa
- Translation of research into policy and practice
- Support of at least 50% from other development assistance initiatives is encouraged

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<th>Call details</th>
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<td>Expected no/duration of grants:</td>
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<td>Minimum consortium requirement:</td>
<td>≥ 1 legal entity from PS or SSA</td>
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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 clinical trials)
- 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\(^{17}\) and GA)
What we can offer Industry?

- High-quality African trial capacity
- R&D global trial needs
- Regulatory capacity development
- Market access
- Engaging public networks
- Access to research and policy platforms
- Clinical trials I-IV
- Product development
- Sustainable health care development
- Growing health care markets
- Improve population health
- R&D risk sharing
- Public-Private funding
- Corporate Social Responsibility
Opportunities for collaboration

Next Steps

• In-depth one on one discussions to understand needs
• Possibility for stakeholder meetings following interviews
• Other?
Thank you!

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