Plans and progress towards EDCTP2

Stakeholders’ meeting on Ethics

28 November 2013
Institute of Tropical Medicine
Antwerp, Belgium.

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Director South-South Cooperation.
**Mission**
To reduce the burden of poverty related diseases (HIV/AIDS, **malaria** and tuberculosis) and generally **improve the health** of people living in developing countries

**Objectives**
- Accelerate research and development of new or improved interventions against PRDs
- Coordination of the European member state national programmes working in **partnership** with sub-Saharan African countries
- Collaboration with the private sector and like-minded organisations
16 European Countries

- **14 EU countries**: Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden and United Kingdom

- **2 Associated Countries**: Norway and Switzerland

- **New members**: Finland - Latvia, Poland and Slovakia

48 sub-Saharan African Countries
**EDCTP scope**

**Disease profile:**
HIV/AIDS, TB, Malaria, NIDs

**Interventions:**
Drugs, Vaccines, Microbicides, Diagnostics
EDCTP grants scheme

- Integrated Projects (Clinical trials; project management; capacity strengthening; and networking)
- Senior Fellowships
- Strategic Primer Grants (SPG)
- Ethics and Regulatory Projects
- Networks of Excellence
- Member State Initiated projects (MSI)
- Joint Call by Member States (JCMS).
EDCTP Regional Networks of Excellence for clinical trials

Western Africa: WANETAM
Website: www.wanetam.org
Project Coordinator: Prof. Soleymane Mboup
- Burkina Faso
- The Gambia
- Ghana
- Guinea-Bissau
- Mali
- Nigeria
- Senegal
- United States

Central Africa: CANTAM
Website: www.cantam.org
Project Coordinator: Prof. Francine Ntoumi
- Cameroon
- Congo, Republic of the
- Gabon
- France
- Germany

Eastern Africa: EACCR
Website: www.eaccr.org
Project Coordinator: Dr Pontiano Kaleebu
- Kenya
- Sudan
- Ethiopia
- Tanzania
- Uganda
- Germany
- Sweden
- United Kingdom
- United States

Southern Africa: TESA
Website: www.tesafrica.org
Project Coordinator: Prof. Gerard Walzl
- Botswana
- Malawi
- Mozambique
- South Africa
- Zambia
- Zimbabwe
- France
- Germany
- Netherlands
- United Kingdom
- United States

Map showing the regions and countries covered by each network.
Current EDCTP projects in a nutshell

- 246 Grants involving 30 African and 16 European countries and 255 institutions (participating & receiving funds from EDCTP)
- Current total project value is ~375 M€ (EDCTP funds + co-funding)
- Trained 421 African research scientists (MSc, PhD, Fellowships, Post docs, clinical trials related)
- Building African leadership in science with >50% of projects being led by Africans
Details on EDCTP grants

**Malaria**
**Treatment:**
- Uncomplicated malaria
- Malaria in pregnancy
- Severe malaria in children

**Prevention:**
- Vaccine development

**HIV/AIDS**
**Treatment:**
- Paediatric
- Second line ARVs
- HIV/TB coinfection

**Prevention:**
- PMTCT
- Preparatory studies for microbicides and vaccine development

**Tuberculosis**
**Diagnostics**
- PoC diagnostics and markers

**Treatment**
- Treatment shortening/simplification

**Prevention:**
- Preparatory studies for vaccine development and vaccine development
Recommendations from previous SHM (Geneva 2007)

High quality ethics review of clinical research is required to be done by ethics committees in the host countries.

- Primary focus was to strengthen ethics review capacity in countries and areas where EDCTP was supporting clinical trials
- Support training and strengthen NEC/IRB infrastructure
- Open calls for proposal approach recommended
- Collaboration was encouraged where possible, to avoid duplication and where there would be added value
- Encourage applications from countries and geographical areas known to have inadequate ethics review capacity
- Dynamic mapping of existing and new ethics capacity and organisations involved in developing this capacity in Africa.
• EDCTP1 has funded 75 ethics projects

• Project status: 53 completed and 22 in progress

• No calls launched in in ethics in 2012 and 2013

• Ethics capacity for health research remains priority in EDCTP2 strategic plan.
Summary

Number of ethics projects

<table>
<thead>
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<th>Call</th>
<th>Number of projects</th>
<th>Cumulative total</th>
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<td>2013</td>
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Project categories

- Ethics training in sub-Saharan Africa through:
  - Development of online training programmes
  - Funding courses on ethics through formal training courses, such as diplomas or certificates
  - Projects with training components such as GCP and human subjects protection training.

- Establishment and strengthening of ethics capacity at both the institutional and national levels with objective of making these committees functional and independent

- Coordination and mapping ethics and regulatory activities.
EDCTP supported clinical trials
EDCTP supported ethics committees
Ethics grants by country

Number of ethics projects by country

*Grant coordinated from a European country
Expanded scope under EDCTP2

- 10-year programme 2014-2023
- All phase of clinical trials (I-IV) including implementation research on the optimisation of health services
- Inclusion of neglected infectious diseases.

- Increased budget
  - EC proposal for funding: € 648 Million under Horizon 2020 (2014-2023)
  - Contributions from Participating States
Transition to EDCTP2

• End of no-cost extension for EDCTP – May 2015
• EDCTP-Plus 2012-2013
  • Landscape mapping
  • Stakeholders’ meetings
  • Upgrading and accreditation of clinical laboratories
  • Continued capacity strengthening of NoE
  • Strategic and operational business plans, 2014
    EDCTP work programme
  • Establishment of the Strategic Advisory Committee
  • Expansion of the Secretariat
  • Call on Epidemiological studies and capacity development in biostatistics and data management
  • Inviting new EU Member States and Associated Countries
Funding Schemes/Activities under EDCTP2

- Integrated Activities
- Participating States Initiated Activities (PSIA)
- Joint Calls
Integrated Activities

Activities that are selected, funded and managed by EDCTP from EC contribution and cash contributions from the PS* or 3rd parties

EDCTP will manage the activities
- Centralised peer-review, administration, evaluation and monitoring of grants
- Simple cofunding requirements

Horizon 2020 Rules of participation apply with any derogations 2 EU and 1 sub-Saharan Africa

*Participating States = EU Member States, associated countries and sub-Saharan African countries participating in the EDCTP programme
Integrated Activities

• EDCTP Calls for Proposals include 2 categories of activities:
  1. Clinical research projects
     - Integrated projects
     - Strategic primer grants
  2. Capacity Building
     - Fellowships
     - Networks of Excellence
     - Ethics and Regulatory
Participating States Initiated Activities (PSIAs)

Selected, funded and managed by EDCTP Participating States

**Single PS call:** if call fits scope of EDCTP, contribution PS matched with funds EC

**Joint PS call(s):** EDCTP may award top-up funding to the call to increase impact or expand access

Combination of national rules and Horizon 2020 rules – in development

All PSIAs should be included and approved as part of EDCTP annual work programme
Participating States Initiated Activities: Joint Calls

Joint Calls

Undertaken by EDCTP or any PS with other countries or third parties

Consortium model of funding

Included and approved in EDCTP annual work programme

Joint rules of participation to be established

- Early involvement of EDCTP
- Positive recommendation of the EDCTP SAC
- Inclusion in EDCTP annual work programme
- Involvement of EDCTP in the grant management (review, monitoring and evaluation)
Expected outcomes of the Ethics stakeholders’ meeting

- Review of the current status of ethics capacity in SSA
- Receive feedback from external evaluation of EDCTP1 ethics programme
- Identification of key ethics capacity gaps, opportunities and barriers to progress
- Recommendations that will contribute towards the EDCTP strategy for supporting ethics capacity development:
  - Priority areas to address in ethics Calls for Proposals
  - Areas of potential synergy with other ethics capacity strengthening initiatives.
Thank you

www.edctp.org