The European & Developing Countries Clinical Trial Partnership

The Role of Clinical Trial Partnerships

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Joint Programme Manager
“To accelerate the development of new clinical interventions to fight HIV/AIDS, malaria and tuberculosis in developing countries, particularly sub-Saharan Africa, and to improve generally the quality of research in relation to these diseases”
Mission to be achieved by:

- Integration of European National Research programmes on Poverty Related Diseases
- Development of a genuine partnership between:
  - European Member States
  - The European Commission
  - Sub-Saharan African countries
  - African researchers
  - European researchers

Vision: that by 2012, European research within the 3 poverty related diseases may operate as joint programs with pooling of resources and thus maximizing research benefit and efficiency through the integration of MS’s national research programmes.
European & Developing Countries Clinical Trial Partnership

**EDCTP legal framework:**

Co-decision 16 June 2003 based on Article 169 of the European Treaty

- European Parliament
- EU council

**Structure**

- Private legal entity EEIG
- MS National Program organisations as Members

**Funding structure (until 2010):**

- € 200M from EC, € 200M from MS, € 200M from other sources
Current EDCTP Partnership

- 16 European Countries
  - 14 EU countries + Norway + Switzerland
    - Austria, Belgium, Denmark, France, **Germany**, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom

- 46 Sub-Saharan Africa Countries
EDCTP scope

- **Discovery & Pre-clinical Research**
- **First In Humans**
- **Regulatory Clinical studies (Phase II, III)**
- **Registration**
- **Post-registration studies to inform policy**

**HIV, TB, Malaria Vaccines, HIV Microbicides**

**Optimise synergies between research programmes of stakeholders and partners**

**HIV, TB, Malaria Drugs, Combined interventions**

**Strengthen capacities & capabilities for sustained, durable clinical research in Developing Countries**
What Makes EDCTP Different?

- **First “Article 169” activity:**
  - Enables the European Community to participate in research programmes undertaken jointly by several Member States.

- **Requires true partnership** including:
  - Committed funding from the EC
  - Committed funding from EDCTP Member States
  - Third party funding including industry, PPPs and national funding by African countries
  - Commitment by MS to revise and develop internal structures to enable and facilitate joint programme funding of projects
  - Equal partnership between European and African researchers
  - Promotion of African leadership.
Networking and Coordination of European national research programmes on PRD and supporting activities in developing countries.

3 key Strategies:

- **Project Integration**
  - Linking existing projects and developing new ones

- **Institutional Collaboration**
  - Forging alliances between national programmes

- **Coordination of National Funding**
  - At the level of national ministries and funding agencies, development of joint research calls and promoting removal of barriers to cooperation
Research calls launched and activities funded (2003 – 2006)

- Call for proposals on
  - clinical trials
    - Trials of studies of surrogate markers of drug efficacy following anti-TB therapy
    - Phase II-III trials of drug regimens that shorten or simplify current antituberculous treatment
    - Phase II-III drug trials for the treatment of severe malaria using artemisinin compounds
    - Trials assessing the effectiveness and safety of simplified anti-retroviral drug regimens and monitoring
    - Prevention of Mother to Child Transmission of HIV/AIDS
  - capacity building (including ethics)
  - networking
  - training
Capacity building in preparation for the conduct of preventive HIV vaccine trials

**Expected deliverables:**

- **A research plan** include one or more of the following:
  - Epidemiological baseline (cohort studies, retention, HIV incidence)
  - Virus isolation and characterisation
  - Immunological and virological characterisation of early infections
  - Population genetics
  - Studies in adolescent age groups
  - Studies on HIV exposed non-infected individuals (including discordant couples)
  - Social and behavioural studies relevant to HIV vaccine trials.
  - Other clinical research protocols (including other HIV interventions or non-HIV vaccines)
  - Phase II clinical trials of preventive HIV candidate vaccines.

- **A capacity building plan**, including a description of training activities, upgrading of infrastructure activities and networking activities.

- **A consortium** of competent investigators committed to the project, which should include participants from at least two European countries that are members of the EDCTP, from an Africa site with track record on HIV vaccine or related research (“core” site) and one or more additional sites in Africa, which could serve as expansion of the “core” sites for future large scale trials.

*Call closed: 31 March 2007!*
EDCTP present in 17 countries
Support 64 African investigators
New Strategy 2007-2010

Integration of National Programmes

New projects:
Funding of new projects in collaboration with the Member States through Joint Calls

Joint Programme Activities:
Identifying, coordinating & formal acknowledging of relevant (ongoing) projects funded by Member States and potential enhancement with EDCTP funds
From 2007: New Strategy

Three strands of activity

- **New projects** to be funded on 9 topics through:
  - **Joint calls** (applicants must propose a research package that includes CT, networking, training and addresses ethical issues)
  - **Brokering** initiatives
- **Joint Programme** identification, verification and enhancement
- Calls for ethics

All proposals for funding by EDCTP, including brokering initiatives are evaluated by independent peer review.
New Projects

Based on:

Comprehensive research proposals incorporating workpackages on capacity building and training, clinical trials and networking.

- Equal funding by EDCTP and Member States
- Additional 3rd party funding
- MS funding may be in cash or in kind.
- Preference however for unearmarked core funding from national research and development budgets where this is possible. This increases flexibility, facilitates funding of the best science and enhances participation of African researchers
Focus on 9 topics:
- TB vaccines
- TB treatment
- Malaria vaccines
- Malaria treatment
- Malaria and pregnancy
- HIV vaccines
- HIV treatment
- HIV microbicides
- Nodes of Excellence

A Stakeholder meeting is organised for each topic
Large project approach with a focus on **products**
Funding through open call or brokering
New Strategy 2007-2010: Funding of new projects

- Aims of Stakeholders meetings (to be held in 2007)
  - Identify products in pipeline
    1. If there is no product available or no MS are interested > postpone the topic
    2. If there are many products available > Joint call
    3. If there is one product available > Brokering
       - Identify suitable sites to manage the trial
       - Identify potential sister sites for capacity building
       - Establish focus for the topic
       - Confirm EDCTP timeline with respect to initiation of funding procedure
New Strategy 2007-2010: Stakeholder meetings for specific Clinical Trial Topics leading to Joint Calls or Brokering initiatives

<table>
<thead>
<tr>
<th>Topic</th>
<th>Stakeholders-meeting</th>
<th>EDCTP Budget from EC funding (Euros)</th>
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<tbody>
<tr>
<td>TB vaccines</td>
<td>April 11, 2007 - NL</td>
<td>11,785,817</td>
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<tr>
<td><em>Malaria vaccines</em></td>
<td>January 31, 2007 - DK</td>
<td>14,286,677</td>
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<tr>
<td>HIV vaccines</td>
<td>August/September 2007 - BE</td>
<td>7,143,338</td>
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<td>HIV treatment</td>
<td>01Q07 - ES</td>
<td>6,643,338</td>
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<tr>
<td>Malaria and pregnancy</td>
<td>June 15, 2007 - AT</td>
<td>9,143,338</td>
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<tr>
<td>HIV microbicides</td>
<td>02Q07 - NO</td>
<td>6,143,338</td>
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<tr>
<td>Malaria treatment</td>
<td>June 14, 2007 - AT</td>
<td>9,143,338</td>
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<tr>
<td>TB treatment</td>
<td>02Q07 - IE</td>
<td>14,286,677</td>
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<tr>
<td>Nodes of Excellence</td>
<td>May 8, 2007 - Cameroon</td>
<td>10,000,000</td>
</tr>
</tbody>
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Joint Programme Activities
New Strategy 2007-2010:
Validation of Joint Programme Activities

Types of activities that can be “validated” as JPAs

- Existing and ongoing activities by 2 or more member states working together on an activity within the scope of EDCTP.

- Existing and/or ongoing activities of 2 or more MS working independently on the same area and where these activities can be developed into a JP activity with or without EDCTP input. E.g. 2 or more MS working separately in same African centre

- Co-ordination between MS of current new calls on a specific topic to generate a JP activity:
  - With EDCTP involvement
  - Without EDCTP involvement

- Co-ordination between MS in development of future programmes or calls on a specific topic to generate a JP activity:
  - With EDCTP involvement
  - Without EDCTP involvement
Criteria for EDCTP validation:

Activity must have:

- Funding by at least 2 member states
- Involvement of at least one African centre
- Contributing to EDCTP objectives
- Within the scope of EDCTP activities
Criteria for EDCTP validation:

Activity must be within the scope of EDCTP’s remit

- **Within scope:**
  - Clinical trials Phase IIb and III
  - In exceptional cases post registration (Phase IV)
  - Clinical trials Phase I and IIa only as part of capacity building exercise
  - Capacity building to enhance the conduct of Clinical Trials in Africa
  - Activities linked to networking and coordination of European National Programmes

- **Only within the scope if they are part of a Clinical Trial Phase IIb/III**
  - Pharmacovigilance studies
  - Diagnostic studies such as markers of infection
  - Epidemiological studies

- **Not within scope:**
  - Pre clinical studies
  - Implementation/health system research
  - Pharmacovigilance studies, diagnostic studies and epidemiological studies if they stand on their own
EDCTP is currently developing its strategy for the future, beyond 2010. This is likely to include proposals for:

- Accelerated integration of MS national programmes through increased core funding to EDCTP and greater collaboration between MS in joint programme activities.
- Broadening of the scope of EDCTP to encompass pre-clinical work on the one side and health policy and prevention activities at the other
- Enlargement of the disease topic areas covered. In particular the inclusion of neglected diseases with the EDCTP remit.
Thank you for your attention

www.edctp.org