The European & Developing Countries Clinical Trials Partnership (EDCTP) Plans and Progress

HIV/AIDS Stakeholders’ Meeting

03-04 September 2013
ISCTE-IUL, Lisbon, Portugal

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EDCTP Executive Director
Mission and objectives of EDCTP

Mission
• To reduce the burden of poverty related diseases (HIV/AIDS, malaria, tuberculosis and NIDs) and generally improve the health of people living in developing countries

Objectives
• To accelerate research and development of new or improved interventions against these diseases through the coordination of the European member state national programmes working in partnership with sub-Saharan African countries and other global product development partners.
EDCTP Governance

General Assembly
Representatives and Deputies:
- Policy making body
- 16 European countries
- 4 African representatives:
  - Regional Economic Communities
  - African Union
  - WHO/AFRO Regional Health Ministries
  - Ministries of Finance/S&T

Strategic Advisory Committee
Scientific and strategic advisory body with membership from Africa, Europe and elsewhere

Executive Secretariat
- Europe Office
- Africa Office
Working in partnerships

- Coordination of national programmes
- Partnerships with sub-Saharan Africa
- Synergy among R&D international partners
  - Accelerated development of tools to fight poverty-related and neglected infectious diseases
  - Support to capacity development
**Disease profile:**
**HIV/AIDS, TB, Malaria and NIDs**

**Interventions:**
**Drugs, Vaccines, Microbicides and Diagnostics**

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<tr>
<th>Discovery &amp; Pre-clinical research</th>
<th>Pre-registration studies</th>
<th>Post-registration studies</th>
<th>Policy, Practice</th>
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<td>Laboratory and animal testing</td>
<td>Phase I: Safety</td>
<td>Phase III: Safety &amp; efficacy</td>
<td>Phase IV: Effectiveness, Long-term safety, Pharmacovigilance, Optimisation, Label expansion</td>
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<td>Phase II: Safety &amp; limited efficacy</td>
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Strengthening of clinical trials capacity and the enabling environment

1. Regulatory framework
   - AVAREF
   - Harmonisation and joint review
   - Training

2. Ethics review
   - Operational support
   - Training (e-based workshops)
   - Mapping

3. Clinical trials registry
   - Collaboration with NRA and ERC

4. Networks of Excellence
   - Capacity building
   - S-S / N-N networking
   - Synergy with other networks

5. Senior fellowships

6. Site preparation & networking
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](http://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](http://www.cantam.org)
Project Coordinator: Prof. Francine Ntoumi
- Cameroon
- Congo, Republic of the
- Gabon
- France
- Germany

**Eastern Africa: EACCR**
Website: [www.eaccr.org](http://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](http://www.tesafrica.org)
Project Coordinator: Dr Alexander Pym
- Botswana
- Malawi
- Mozambique
- South Africa
- Zambia
- Zimbabwe
- France
- Germany
- Netherlands
- United Kingdom
EDCTP Regional Networks of Excellence for clinical trials – Main achievements

• Central Africa: CANTAM
  • Establishing reference values of CD4+ cell counts in HIV-negative pregnant women in Cameroon
  • Assessment of the impact of ARV on glycaemia and transaminase levels in HIV patients in Cameroon. Data will be used in monitoring patients on ARV in Central Africa
  • Comparison of automated versus manual method for quantification of HIV-1 RNA in plasma samples
  • Investigating the impact of malaria on haematological parameters in HIV-positive patients
• Eastern Africa: EACCR
  • Mentorship visits on paedriatic HIV-malaria coinfection

• Southern Africa: TESA
  • Finalisation of an HIV incidence study protocol in Malawi

• Western Africa: WANETAM
  • Study on building research infrastructure and capacity to implement an HIV/STD prevention trial in post-conflict Liberia
Details on EDCTP grants

**Tuberculosis**
- Diagnostics
  - PoC diagnostics and markers
- Treatment
  - Treatment shortening/simplification
- Prevention:
  - Preparatory studies for vaccine development and vaccine development

**HIV/AIDS**
- Treatment:
  - Paedriatic
  - Second line ARVs
  - HIV/TB coinfection
- Prevention:
  - PMTCT
  - Preparatory studies for microbicides and vaccine development

**Malaria**
- Treatment:
  - Malaria in pregnancy
  - Severe malaria in children
- Prevention:
  - Vaccine development

**Non-disease specific**
- 10% (€ 21.4 M)

**HIV/AIDS**
- 32% (€ 67.14 M)

**Tuberculosis**
- 35% (€ 73.3 M)

**Malaria**
- 23% (€ 49.5 M)
HIV/AIDS Clinical Trials supported on EDCTP grants

- Vaccines: 35% (€ 23.7 M)
- Microbicides: 16% (€ 10.3 M)
- Non-clinical trial specific: 4% (€ 2.9 M)
- Drugs: 45% (€ 29.9 M)
- Diagnostics: 0% (€ 0.2 M)
HIV/AIDS Clinical Trials supported on EDCTP grants

Number of clinical trials

Non phase | Phase I | Phase II | Phase III | Phase IV
---|---|---|---|---
1 | 7 | 9 | 10 | 3

30 clinical trials/ 11 completed
Achievements of EDCTP funded grants

- Contributed to the evidence base that led FDA approval and WHO prequalification of a fixed-drug combination formulation for the treatment of HIV in children (CHAPAS trial)
- Influenced revision of 2010 WHO guidelines on PMTCT: 43% reduction in HIV infections in infants and >50% reduction of PMTCT (Kesho Bora)
- Demonstrated that the prime/boost HIV-1 DNA multigene/multiclade-MVA/CMDR vaccine is safe and highly immunogenic when administered intradermally (TaMoVac)
- Contributed to results on efficacy of a treatment strategy to prevent mother-child transmission of HIV1 during 12 months of breastfeeding (PROMISE-PEP)
- Demonstrated results on TB/HIV co-treatment. A study completed in 2012 found that there is no need to increase efavirenz dose during concomitant rifampicin based anti-TB therapy (HIV-TB Pharmagene)
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Towards EDCTP2
Independent external review, impact assessment and internal consultation recommended expansion of scope while maintaining focus

- All phases of clinical trials (phase I-IV), special attention to phase III
- Include Neglected Infectious Diseases (NIDs)
- Collaboration with other DCs outside Africa when required
- Health systems optimisation research

- Closer collaboration with pharmaceutical industry and other like-minded organisation
- Expected start in 2014.
EDCTP2: On-going discussions with the European Commission and Member States on funding of EDCTP2

EDCTP2:
- Larger and more costly Phase III clinical trials
- Extension to NIDs, Phase IV

EDCTP1 until May 2015

Overlap period for closure of EDCTP1

Jan 2014 starts EDCTP2
Types of projects under EDCTP2

- Integrated Activities
- Participating States Initiated Activities
- Joint Activities
Integrated Activities

- Activities that are selected and funded by EDCTP from EU contributions and unrestricted contributions from Participating States and third parties
- EDCTP will manage the activities (Centralised peer-review, administration, evaluation and monitoring of grants)
- Horizon 2020 Rules of participation shall apply with any derogations
- Selected, funded and managed by EDCTP Participating States
- With agreement of the EC and subject to the conditions, EDCTP2-IS may award co-funds from the EU contribution to increase its impact or expand its access to researchers from other EDCTP Participating States
- EDCTP Participating States Rules of Participation will apply, with a minimal set of rules provided by EC/EDCTP (for the funds provided by EDCTP from the EU contribution the Participating States will be bound by M&E rules of Horizon 2020)
- Included in EDCTP annual workplan
Joint Activities

- Undertaken by EDCTP-IS or any EDCTP Participating State with other countries or third parties
- Consortium model of funding
- Included in EDCTP annual workplan
- Joint rules of participation will be established
  - Early involvement of EDCTP
  - Positive recommendation of the EDCTP Strategic Advisory Committee
  - Inclusion in annual workplans
  - Involvement of EDCTP in the grant management (review, monitoring)
1. Disease prevalence, burden and need taking into account status of interventions landscape
2. Product opportunities and following the course set in the Strategic Business Plan vis-à-vis the expanded remit i.e. NIDs and post registration programmes including effectiveness studies and pharmacovigilance
3. Timing factor: balance between immediate and long-term priorities
4. Balance among clinical trial phases: major focus on phase III clinical trials depending on existing global product portfolio.
Objectives of HIV/AIDS stakeholder meeting

- Review the current status in the field of HIV/AIDS
- Identify the key research areas, current opportunities and barriers to progress
- Develop recommendations that will contribute towards the EDCTP strategy for supporting HIV/AIDS research on:
  - Priority research topics for Calls for Proposals
  - Proposals for development of cooperative projects
  - Products in the pipeline for evaluation by EDCTP
  - Focused capacity building initiatives
  - Proposals for funding partnerships
Thank you

http://www.edctp.org