Strengthening ethics and regulatory mechanisms in sub-Saharan Africa through partnerships

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EDCTP Mission

Alleviate poverty by accelerating the development of new or improved tools (drugs, vaccines, diagnostics and microbicides) against HIV/AIDS, malaria and tuberculosis, and to generally improve health research in developing countries

- Through **integration** of EU Member States national health research programmes
- Through equal and effective **partnership** with Africa and African researchers
EDCTP Scope

Discovery & Pre-clinical research
- Lab and animal testing

First in humans
- Phase I: Safety

Regulatory Clinical studies
- Phase II: Safety & limited efficacy
- Phase III: Safety & efficacy

Pharmacovigilance
- Phase IV: Long-term safety & Post-registration monitoring to inform policy

Policy, Practice

Clinical trials

Capacity development & networking
Identified problems in conduct of clinical trials

- Lack of trained personnel and compliance with international standards
- Lack of consistency in conduct and oversight (standards, decision making, timeframes resulting in "shopping" for ERCs and NRAs)
- Lack of awareness
- Poor registration resulting in lack of transparency and trust
- Lack of communication
Clinical trials registration according to WHO region
(From D Ghersi)
Registered clinical trials in sub-Saharan Africa

Recruiting at Oct 21 2008

Central Afr Rep: 1
Cote D'Ivoire: 1
Mauritania: 1
Seychelles: 1
Swaziland: 1
Angola: 2
Benin: 2
Guinea: 2
Niger: 2
Ethiopia: 3
Madagascar: 4
Cameroon: 5
Gabon: 5
Rwanda: 6
Congo: 7
Guinea-Bissau: 7
Senegal: 8
Algeria: 8
Mozambique: 10
Botswana: 11
Nigeria: 11
Zimbabwe: 12
Burkina Faso: 12
Gambia: 18
Ghana: 18
Malawi: 18
Zambia: 21
Mali: 21
Kenya: 29
Tanzania: 29
Uganda: 29
South Africa: 257

Graph showing the number of registered clinical trials in various countries as of Oct 21 2008.
EDCTP’s approach towards conduct of clinical trials
Strengthening of Regulatory Framework, Ethics Review and Clinical Trials Registration

- **Regulatory framework**
  - Joint review, assessment and monitoring of clinical trials
  - Harmonisation
  - African Vaccine Regulatory Forum (AVAREF)
  - Monitoring of regulatory function and progress
  - Training

- **Ethics review**
  - Mapping of needs and capacity
  - Making EC/IRBs functional
  - Training

- **Clinical Trials Registration**
  - Linking EC/IRBs, NRA and Clinical Trials Registration
EDCTP Ethics Capacity Strengthening

- Benin
- Cameroon
- Ethiopia
- Gabon
- Ghana
- Malawi
- Mali
- Nigeria
- Rwanda
- Senegal
- South Africa
- Tanzania
- Uganda
- Zambia
- Zimbabwe

- Clinical Trials - all PRD’s
- Clinical Trials - HIV
- Clinical Trials – Malaria
- Clinical Trials – TB
- Training Awards
- Ethics Capacity Strengthening
- Regulatory Capacity Strengthening
- Networks of Excellence
EDCTP Regulatory Capacity Strengthening

- Burkina Faso
- Cameroon
- Cote d’Ivore
- Ethiopia
- Gabon
- Ghana
- Kenya
- Madagascar
- Malawi
- Mali
- Mozambique
- Nigeria
- Rwanda
- Senegal
- South Africa
- Tanzania
- The Gambia
- Uganda
- Zambia
- Zimbabwe

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EDCTP supported projects

- Benin
- Botswana
- Burkina Faso
- Cameroon
- Congo
- Cote d’Ivoire
- Ethiopia
- Gabon
- Ghana
- Guinea-Bissau
- Guinea-Conakry
- Kenya
- Madagascar
- Malawi
- Mali
- Mozambique
- Nigeria
- Rwanda
- Senegal
- South Africa
- Sudan
- Swaziland
- Tanzania
- The Gambia
- Uganda
- Zambia
- Zimbabwe
AVAREF recommendation

- To establish a Pan African Clinical Trial Registry (PACTR) that meets the requirements of a WHO Primary Registry

- PACTR will be the link between NRAs and ECs/IRBs of all AFRO countries as well as at a national level
Need for a regional network

Work towards compliance with international ethical and regulatory standards to assure the safety and well-being of clinical trial participants and validity of generated data.

Facilitate the conduct of good quality clinical trials in Africa by sharing information, benchmarking on positive examples and capacity development.

Promote good research and regulatory practices and contribute to elimination of unnecessary regulatory barriers.
The area of overlap where better linkage is necessary.
EDCTP Networks of Excellence

- Botswana
- Burkina Faso
- Cameroon
- Congo
- Ethiopia
- Gabon
- Ghana
- Guinea-Bissau
- Guinea-Conakry
- Kenya
- Malawi
- Mali
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- Clinical Trials - all PRD's
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- Clinical Trials – Malaria
- Clinical Trials – TB
- Training Awards
- Ethics Capacity Strengthening
- Regulatory Capacity Strengthening
- Networking projects
Thank you

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