



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

15 December 2008

Rome

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EDCTP Executive Director





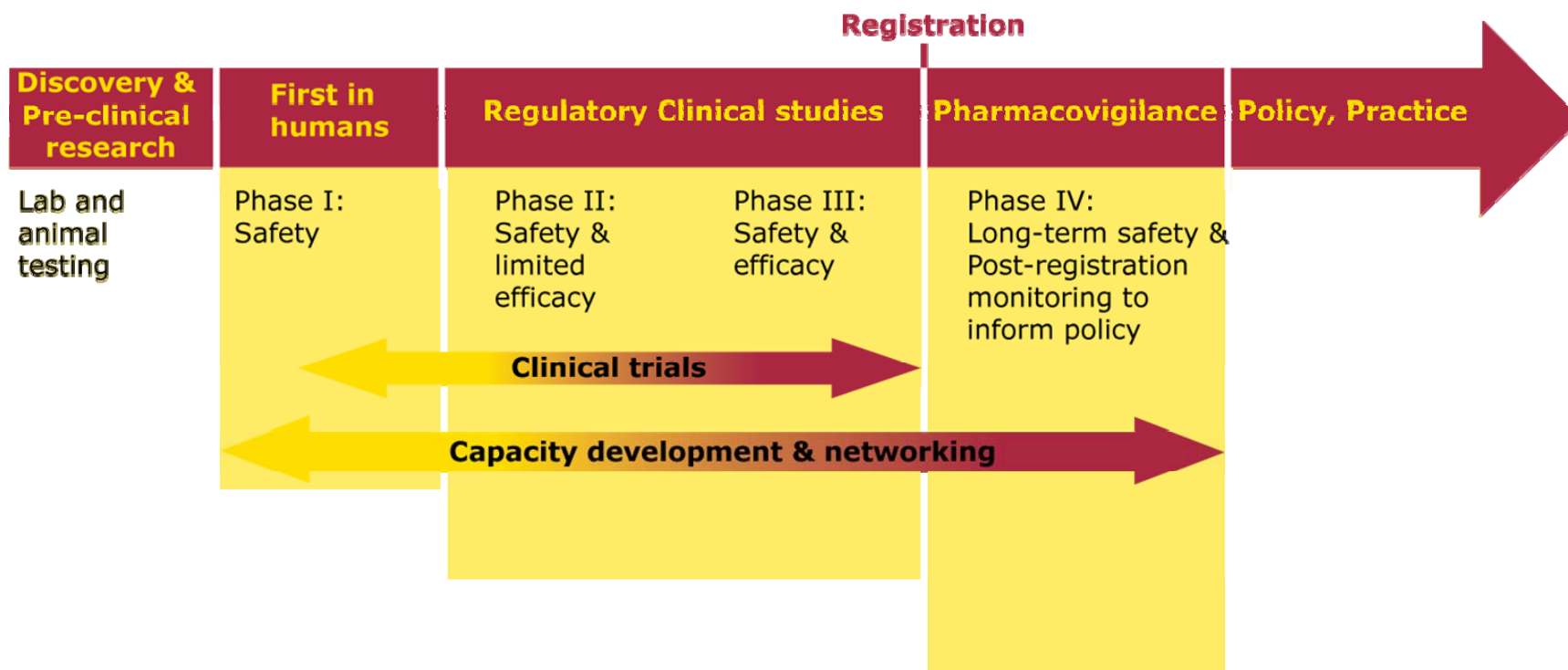
EDCTP Mission

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





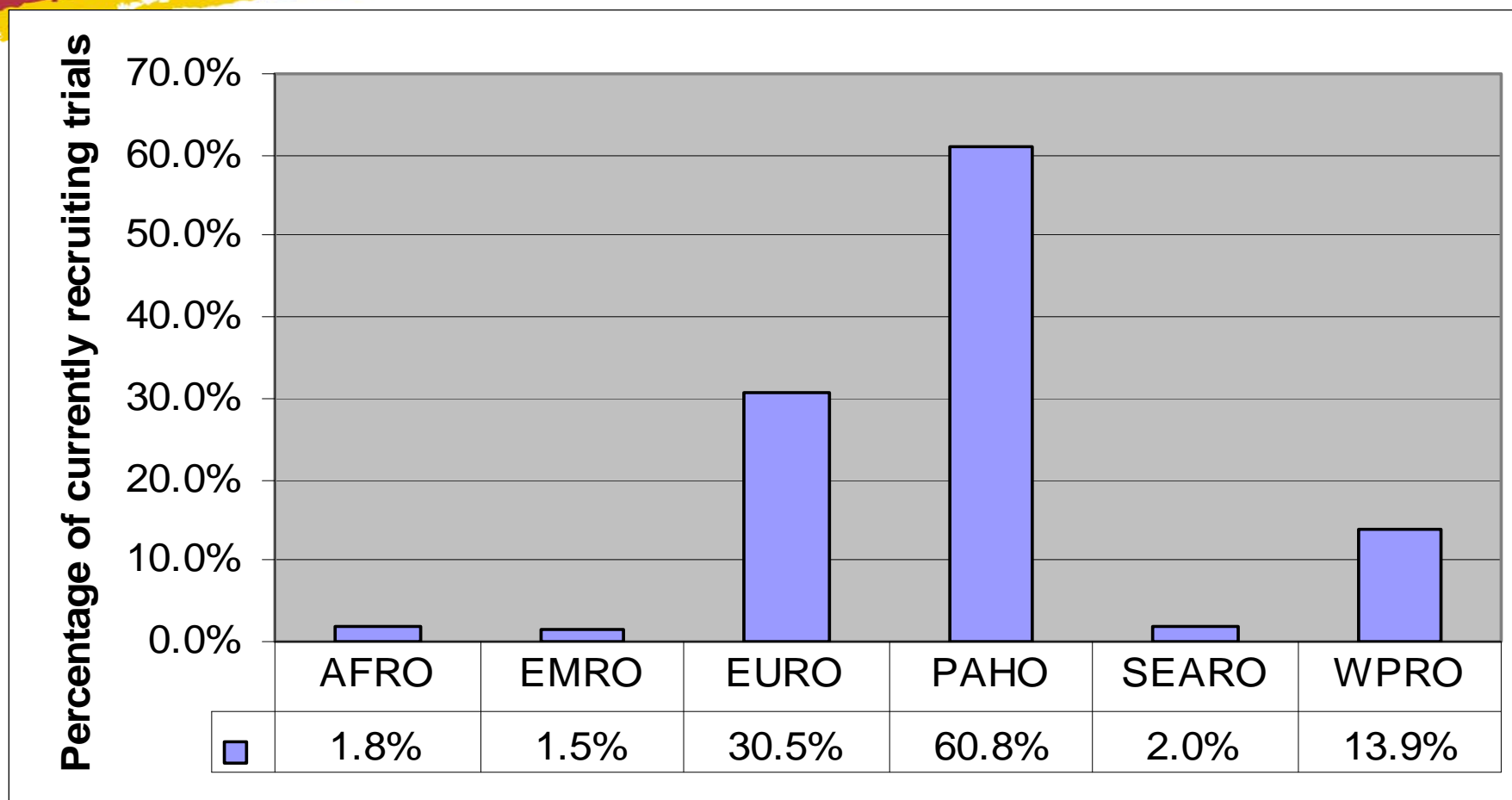
Identified problems in conduct of clinical trials

- 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

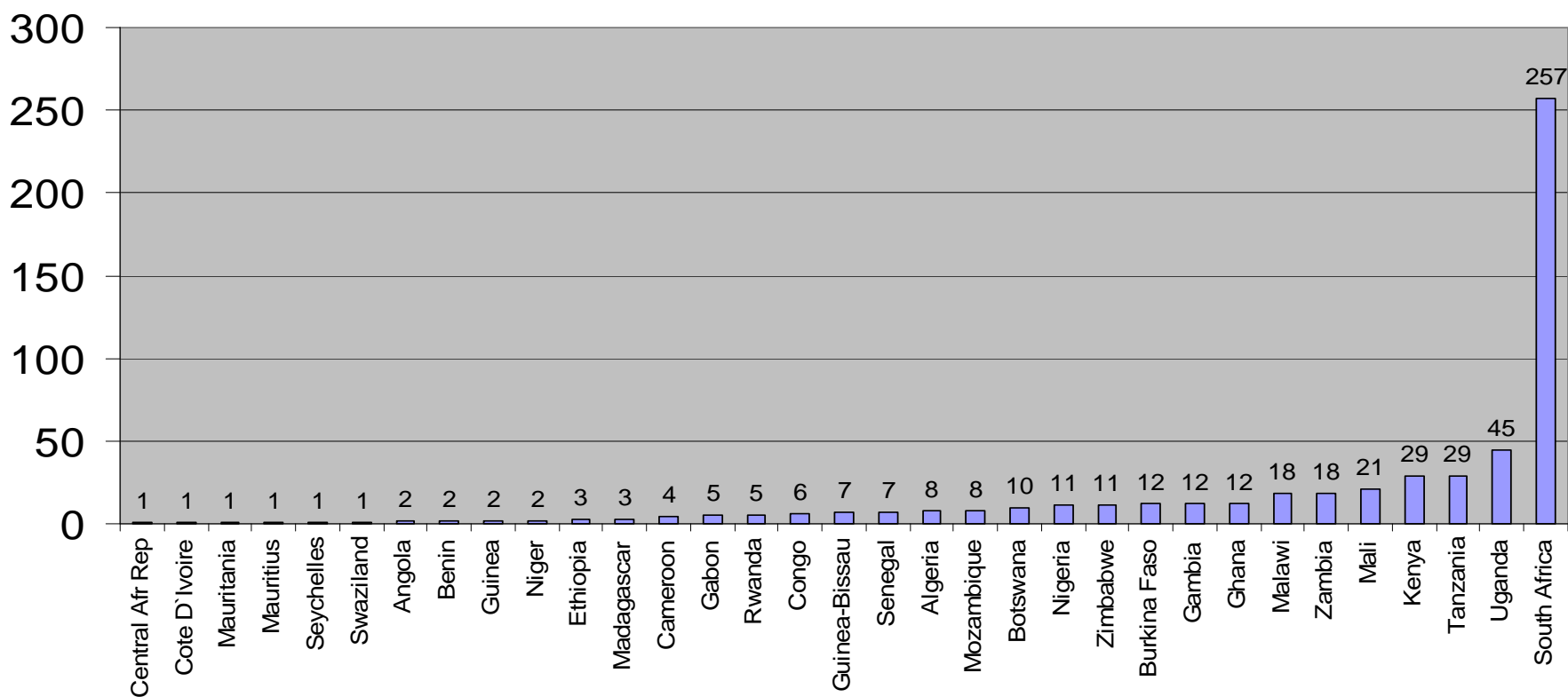
(From D Gherzi)





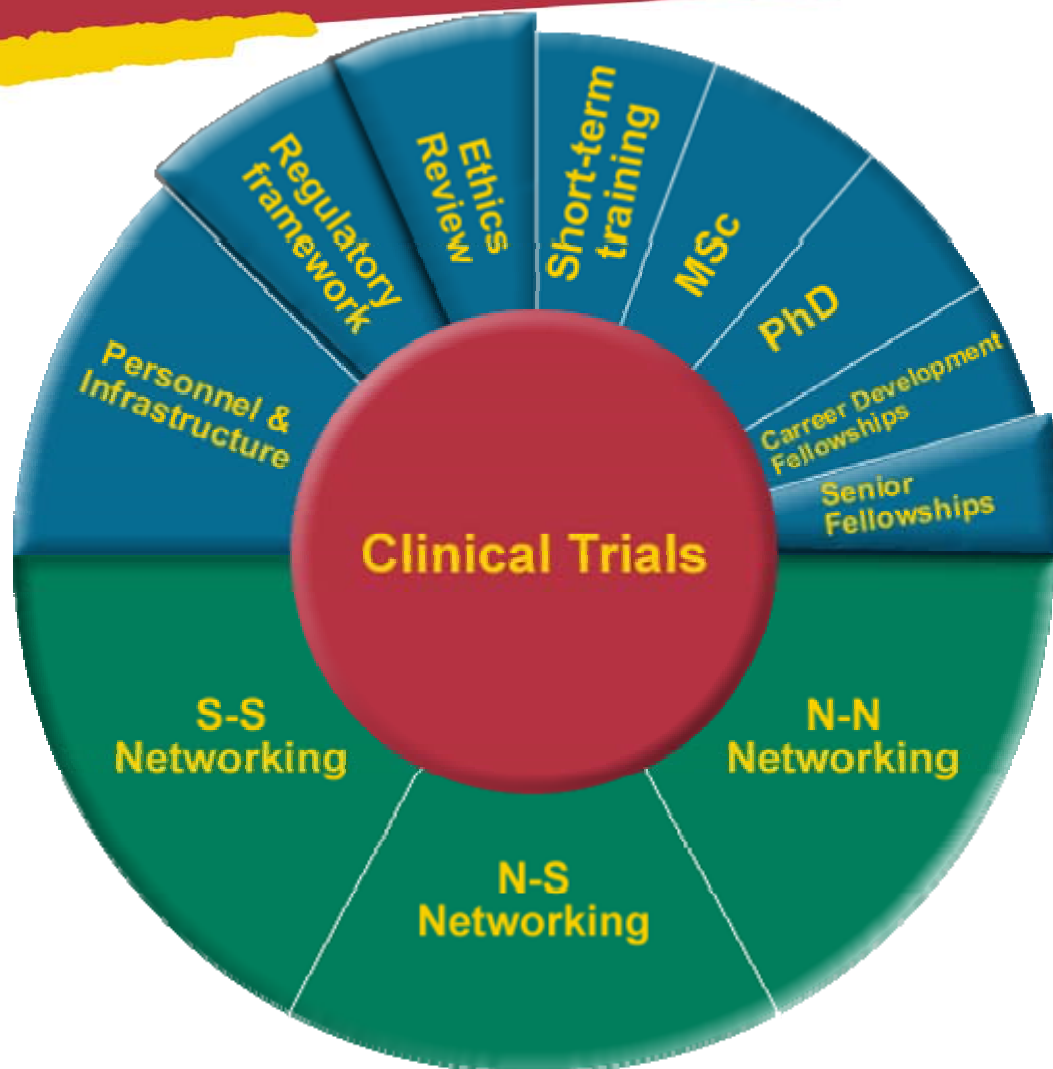
Registered clinical trials in sub-Saharan Africa

Recruiting at 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**

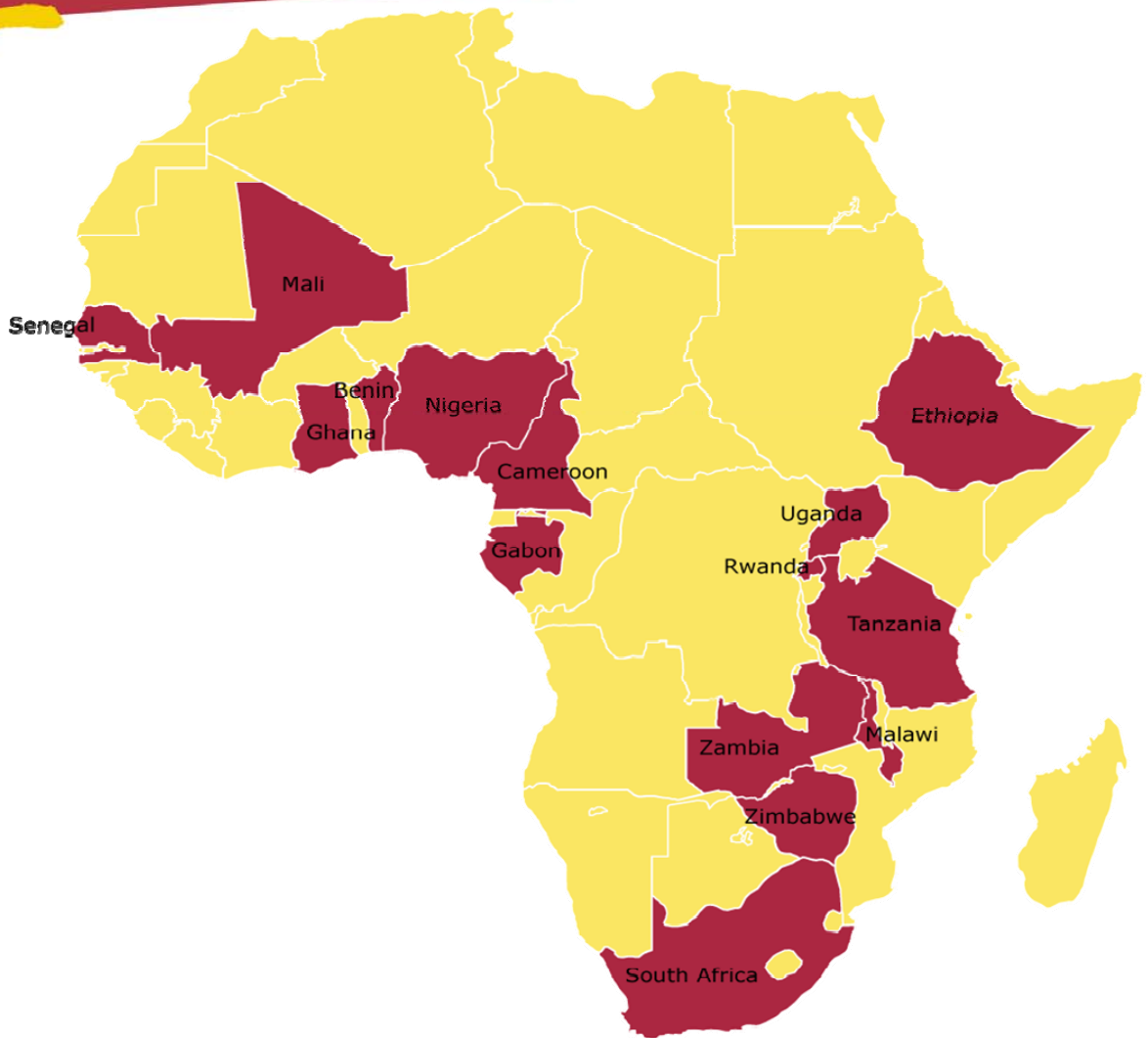
- Linking EC/IRBs, NRA and Clinical Trials Registration



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

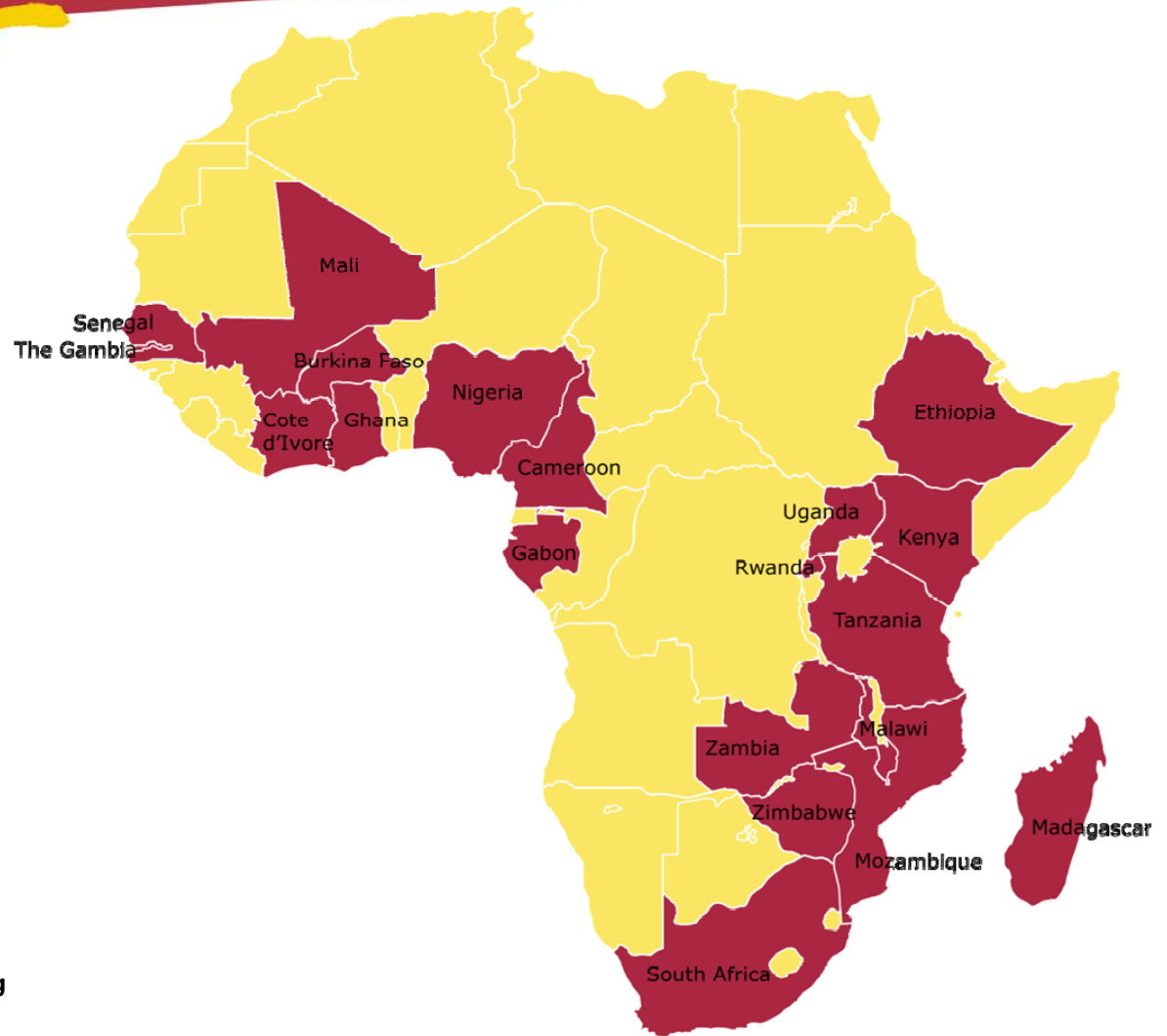




EDCTP Regulatory Capacity Strengthening

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

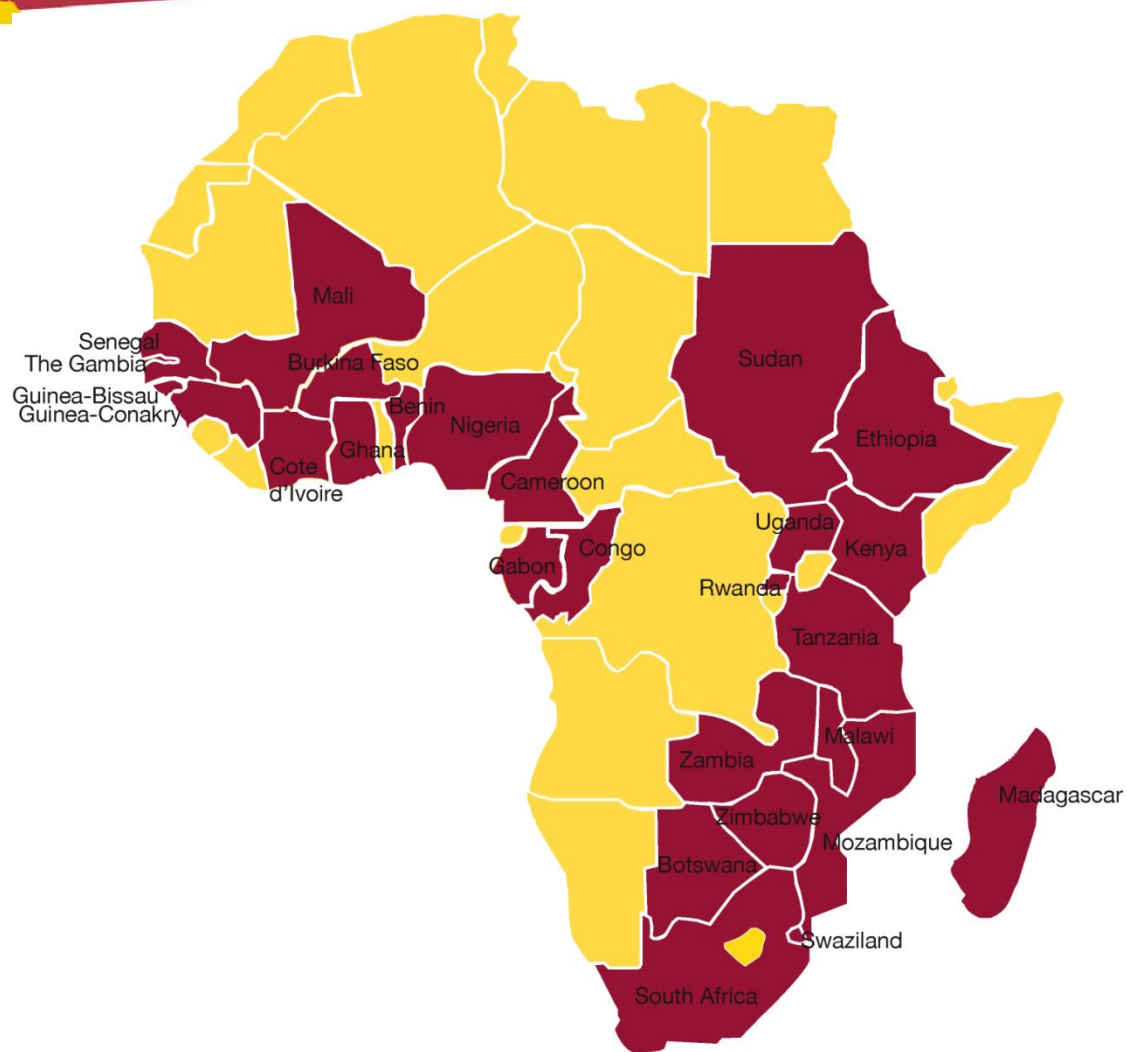
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-  Training Awards
-  Ethics Capacity Strengthening
-  **Regulatory Capacity Strengthening**
-  Networks of Excellence





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

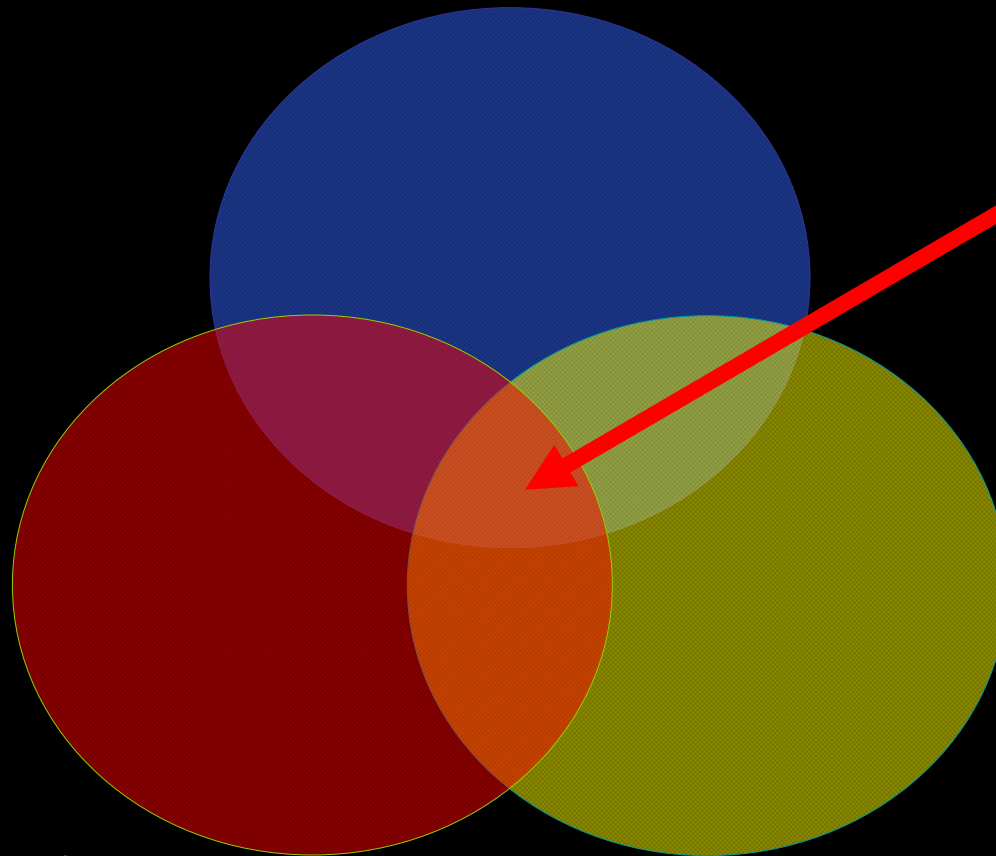
Work towards compliance with international ethical and regulatory standards to assure the safety and well-being of clinical trial participants and validity of generated data

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

EC/IRBs
(Ethics Committees /
Institutional Review Boards)

*The area of
overlap
where better
linkage is
necessary*



PACTR
(Pan-African
Clinical Trial Registry)

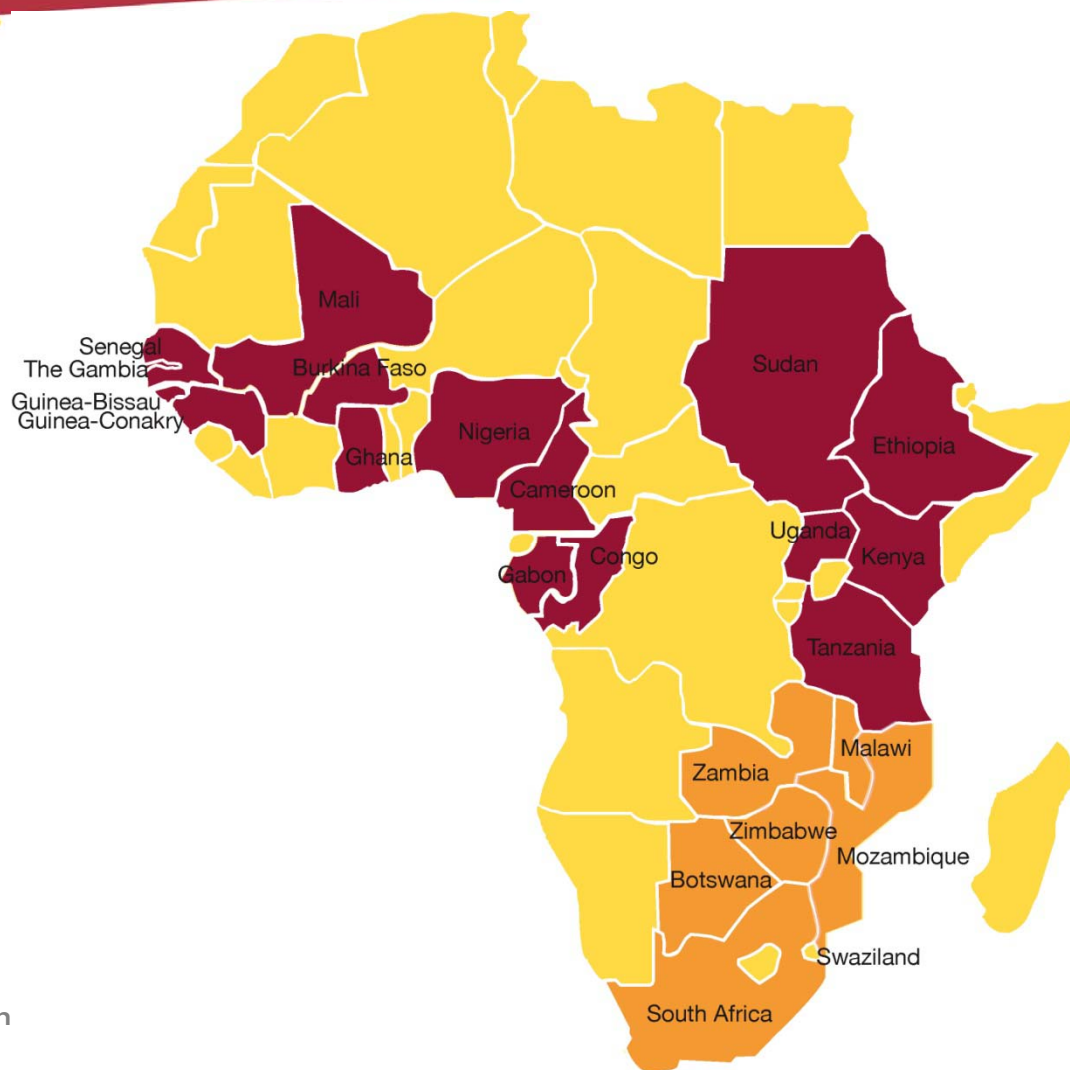
NRAs
(National
Regulatory
Authorities)



EDCTP Networks of Excellence

- Botswana
- Burkina Faso
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-  Training Awards
-  Ethics Capacity Strengthening
-  Regulatory Capacity Strengthenin
-  **Networking projects**





Thank you

www.edctp.org