Strengthening Research Partnerships for Better Health and Sustainable Development

AIFA-UNICRI-OPBG-NIMR Training Course on GCP in Developing Settings: the promotion of international harmonisation for respect of ethical principles, human rights and justice

11-14 June 2012

Mission and objectives of EDCTP

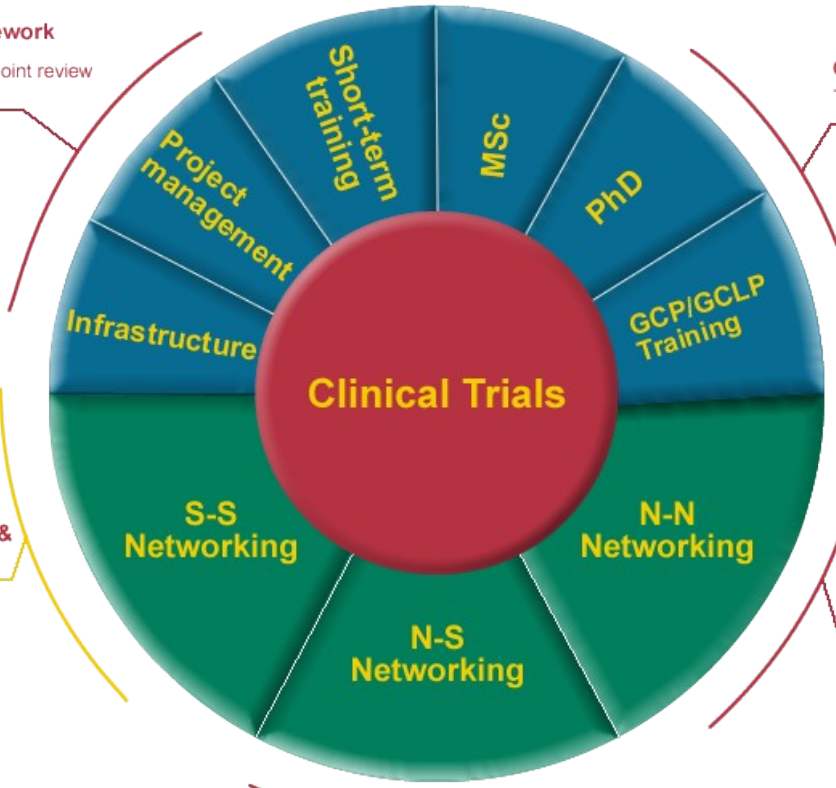
To reduce the burden of poverty related diseases (HIV/AIDS, malaria and tuberculosis) and generally **improve the health** of people living in developing countries by accelerating research and development of new or improved interventions against these diseases through the coordination of the European member state national programmes working in **partnership** with sub-Saharan countries

Strengthening of clinical trials capacity and the enabling environment

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

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

3 **Clinical trials registry**
- Collaboration with NRA and ERC



6 **Site preparation & networking**

Networks of Excellence
- Capacity Building
- S-S / N-N networking
- Synergy with other networks

4

5 **Senior Fellowships**

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

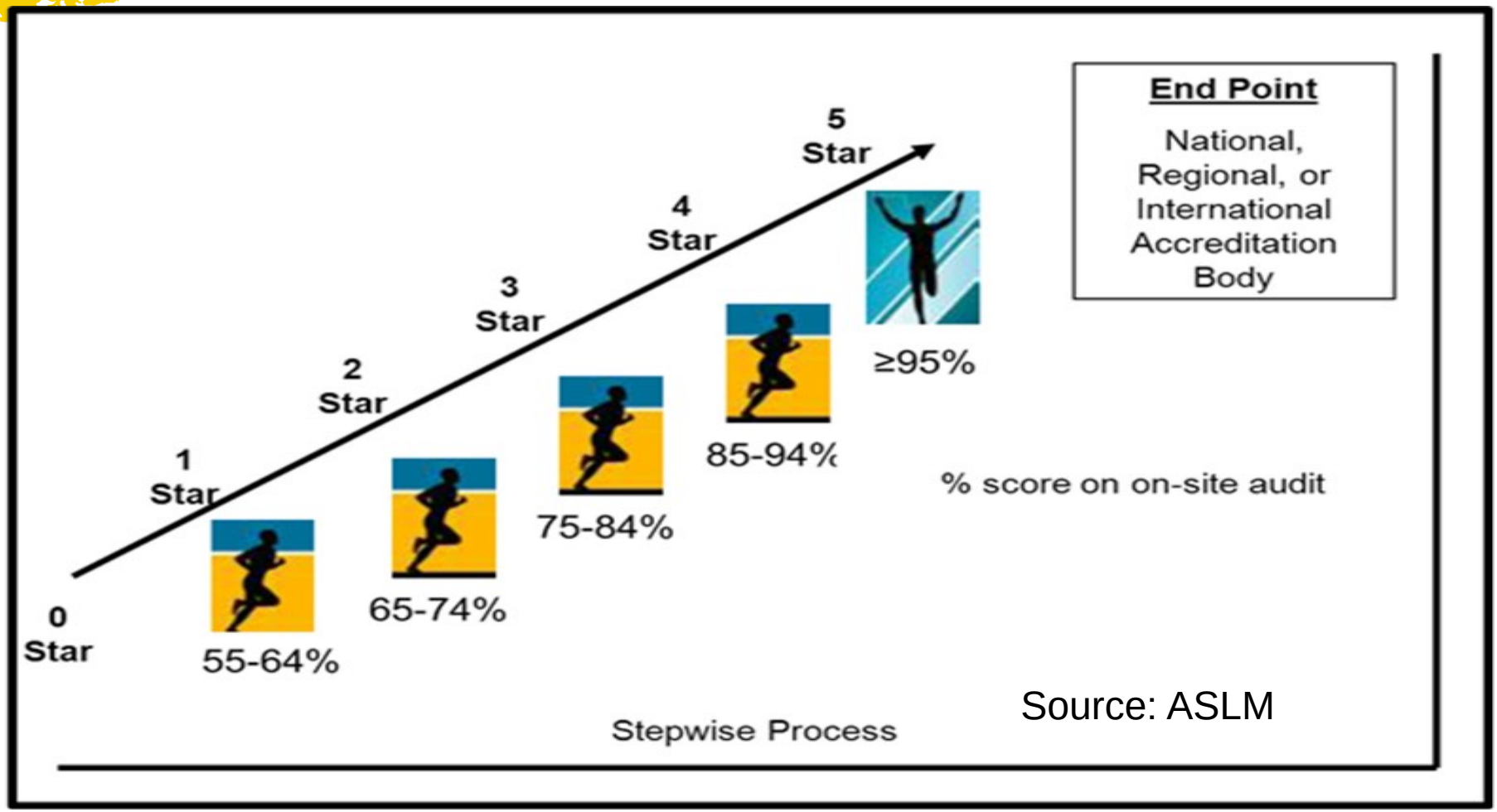
Southern Africa: TESA

Website: **www.tesafrica.org**

Project Coordinator: Dr Alexander Pym

· Botswana
· Malawi
· Mozambique
· South Africa
· Zambia

Good clinical laboratory practice



Source: ASLM

Regulatory framework

- Ineffective regulatory systems pose public health risks
  - May allow marketing of unsafe and inefficacious products

- Weakness and lack of harmonisation in regulatory framework create barriers to free movement of products and access between countries
  - May deprive patients of the needed products

African Vaccines Regulatory Forum (AVAREF)

- Training
- Joint review of clinical trial applications and GCP inspections
- Harmonisation in collaboration with the African Medicines Regulatory Harmonisation (AMRH) initiative
- Cordination of activities with National Ethics Committee and the Pan African Clinical Trials Registry (PACTR)

Ethics committes

- Establishment and day-to-day running of ethics committees/institutional review boards
  - Office equipment
  - Standard Operating Procedures
  - Administration
  - Communication
- Mapping of ethics review and regulatory capacity (MARC)
  - Sustainable, interactive and self-updating web-based African map of research ethics review and drug regulation capacity
- Tranining/workshops
  - e-learning: AMANET, TRREE

Mapping of Research Ethics Review and Regulatory Capacity in Africa (MARC)

Further information

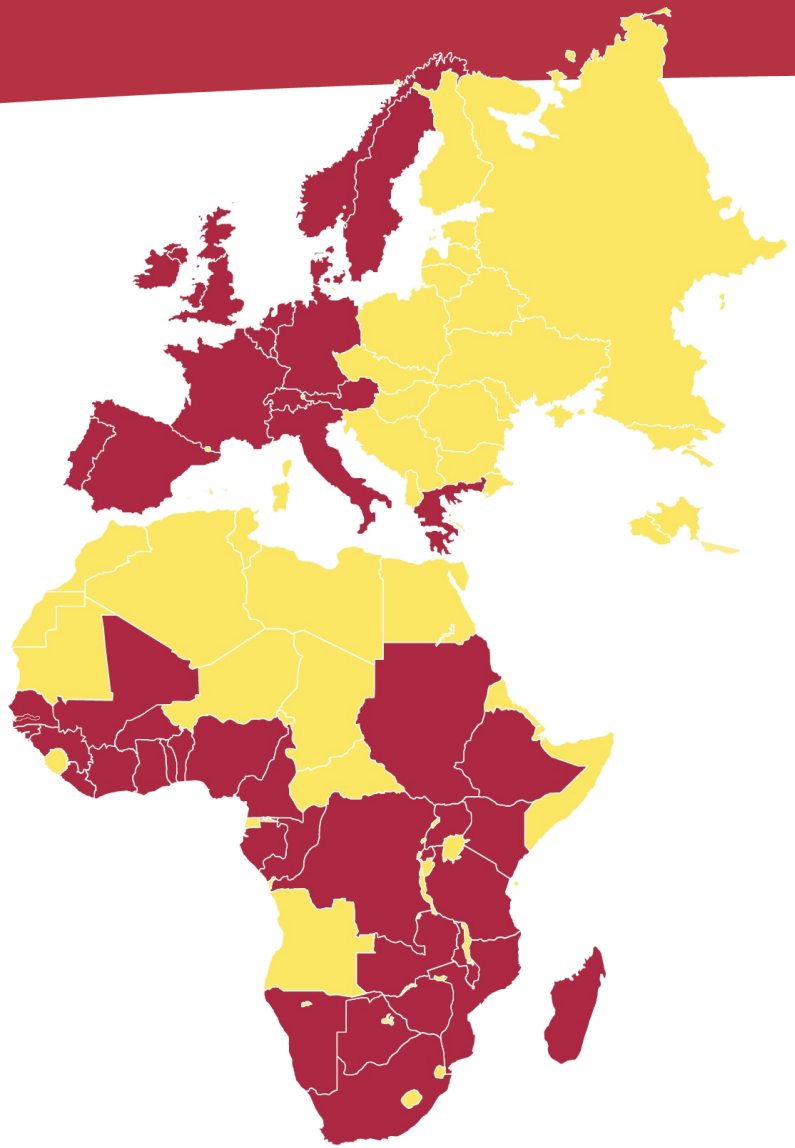
- Gorvenance and policies
- Research ethics review
- Research regulations
- Regional research priorities
- Key institutions and networks
- National doscuments
- Research financing and partnerships
- Information resources
- Country reports

Clinical trials registration

- Why register clinical trials
  - Transparency
  - Avoid duplication/wastage
  - Avoid selective reporting: availability of information on failed projects or negative results

- The Pan-African Clinical Trials Registry (PACTR)
  - Regional register of clinical trials conducted in Africa
  - Searchable electronic database of on-going and planned clinical trials
  - Customised to ease registration bearing in mind difficulties of internet connectivity in Africa – provision for registration by post, emails or facsimile

The EDCTP partnership



EDCTP-EEIG member states

- Austria
- Belgium
- Denmark
- France
- Germany
- Greece
- Ireland
- Italy
- Luxembourg
- Netherlands
- Norway
- Portugal
- Spain
- Sweden
- Switzerland
- United Kingdom

Sub-Saharan African countries

- Benin
- Botswana
- Burkina Faso
- Cameroon
- Congo
- Cote d'Ivoire
- Democratic Republic of Congo
- Ethiopia
- Gabon
- Ghana
- Guinea
- Guinea-Bissau
- Guinea-Conakry
- Kenya
- Liberia
- Madagascar
- Malawi

Thank you

http://www.edctp.org