

TOWARDS EDCTP2

GLOBAL HEALTH TRIALS MEETING

1 February 2013, Cape Town

Michael Makanga, MD PhD

- ☐ **Established in 2003 as a European response to the global health crisis caused by the three main PRDs of HIV/AIDS, TB and malaria (HTM)**
- ☐ **Primary goal is to accelerate the development of new or improved interventions (drugs, vaccines, microbicides and diagnostics) to fight HTM**
- ☐ **Through the coordination and cooperation of European national research programmes on PRDs in partnership with their African counterparts.**



EDCTP Partnership



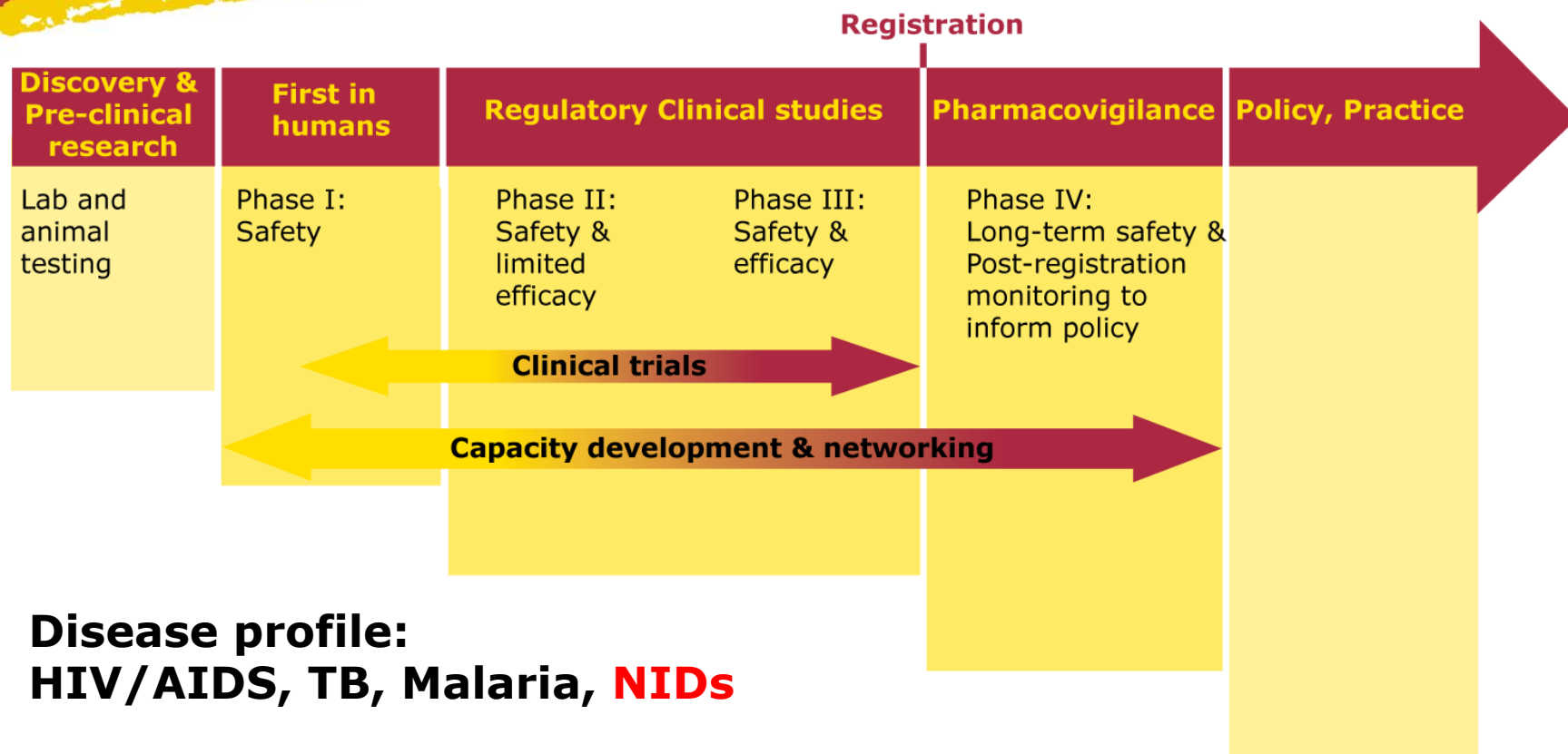
16 European Countries

14 EU countries + Norway and Switzerland

Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden and United Kingdom

47 sub-Saharan Africa Countries

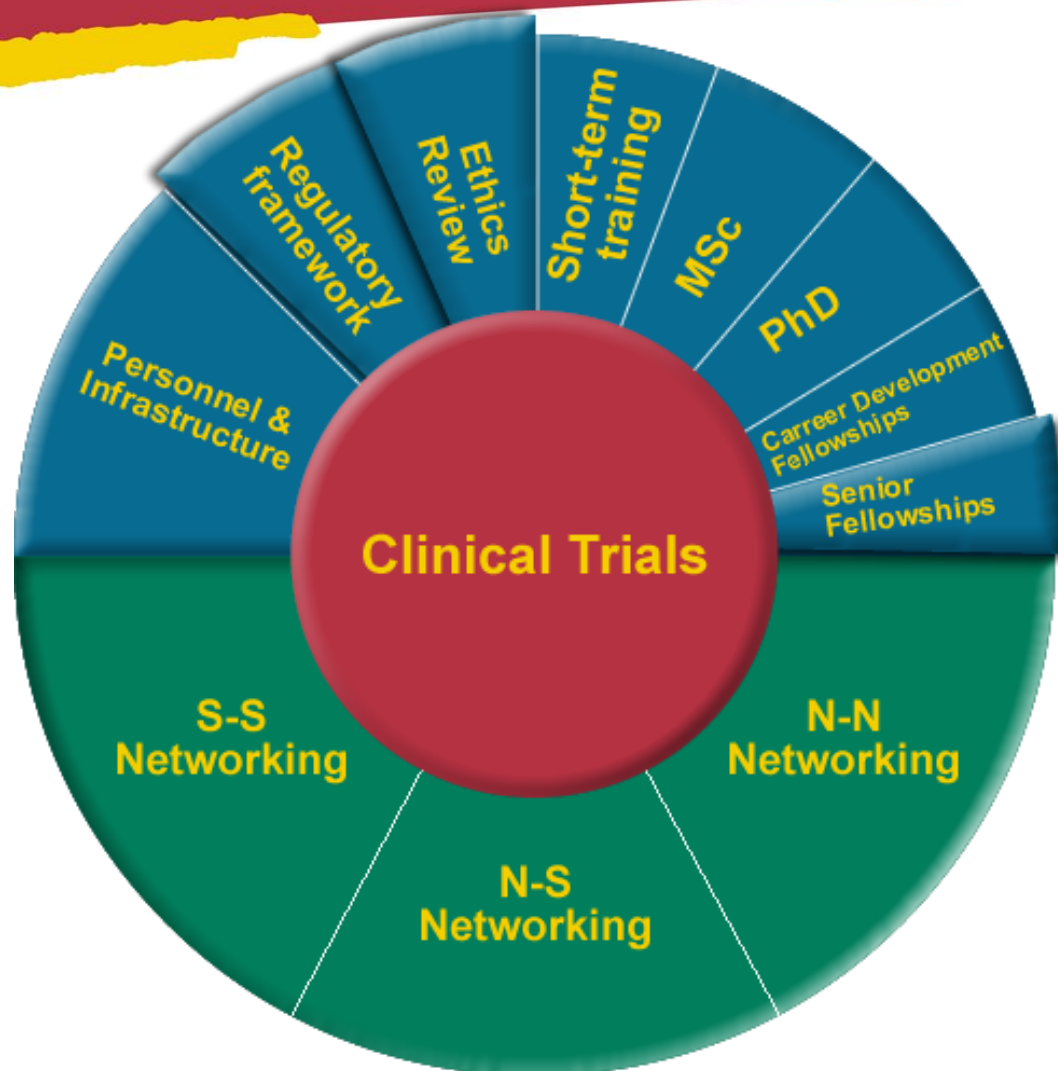
EDCTP scope



Disease profile:
HIV/AIDS, TB, Malaria, **NIDs**

Interventions:
Drugs, Vaccines , Microbicides, Diagnostics

EDCTP Business Model



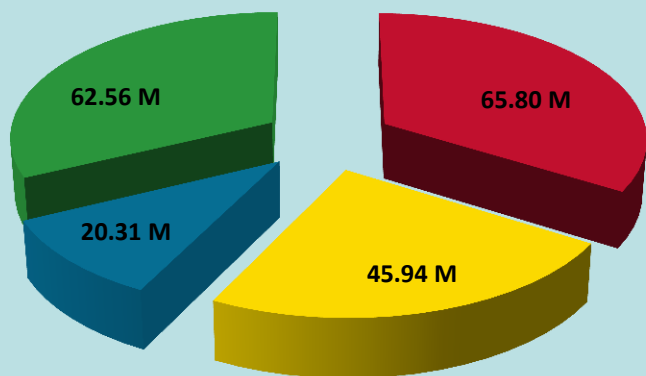
Grant schemes



- Integrated Projects (clinical trials, project management, capacity building and networking)
- Senior Fellowships (open or through Networks of Excellence)
- Health Research Ethics Capacity Development
- Member State Initiated (MSI) projects
- Joint Call by Member States (JCMS)
- Strategic Primer Grants

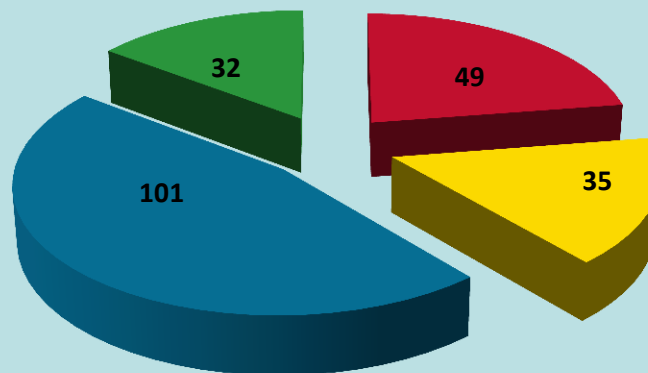
EDCTP grants by disease

Value of grants



■ HIV/AIDS ■ MALARIA ■ NON-DISEASE SPECIFIC ■ TUBERCULOSIS

Number of grants



■ HIV/AIDS ■ MALARIA ■ NON-DISEASE SPECIFIC ■ TUBERCULOSIS

Individual, institutional, national and regional

- Short- and long-term training
 - Good clinical and laboratory practice
 - MSc, PhD, Senior and Career Development Fellowships
- Infrastructure improvements
 - Equipment
 - Renovation
 - Accreditation of clinical research laboratories
- Improvement of enabling research environment
 - Institution Review Board/Health Research Ethics Committees
 - National Ethics Committee
 - National Regulatory Authorities
 - Clinical trial registration

EDCTP Capacity Development activities in Africa



Integrated Clinical Trials Projects

All clinical trial projects include capacity development work packages

Regulatory Capacity Strengthening

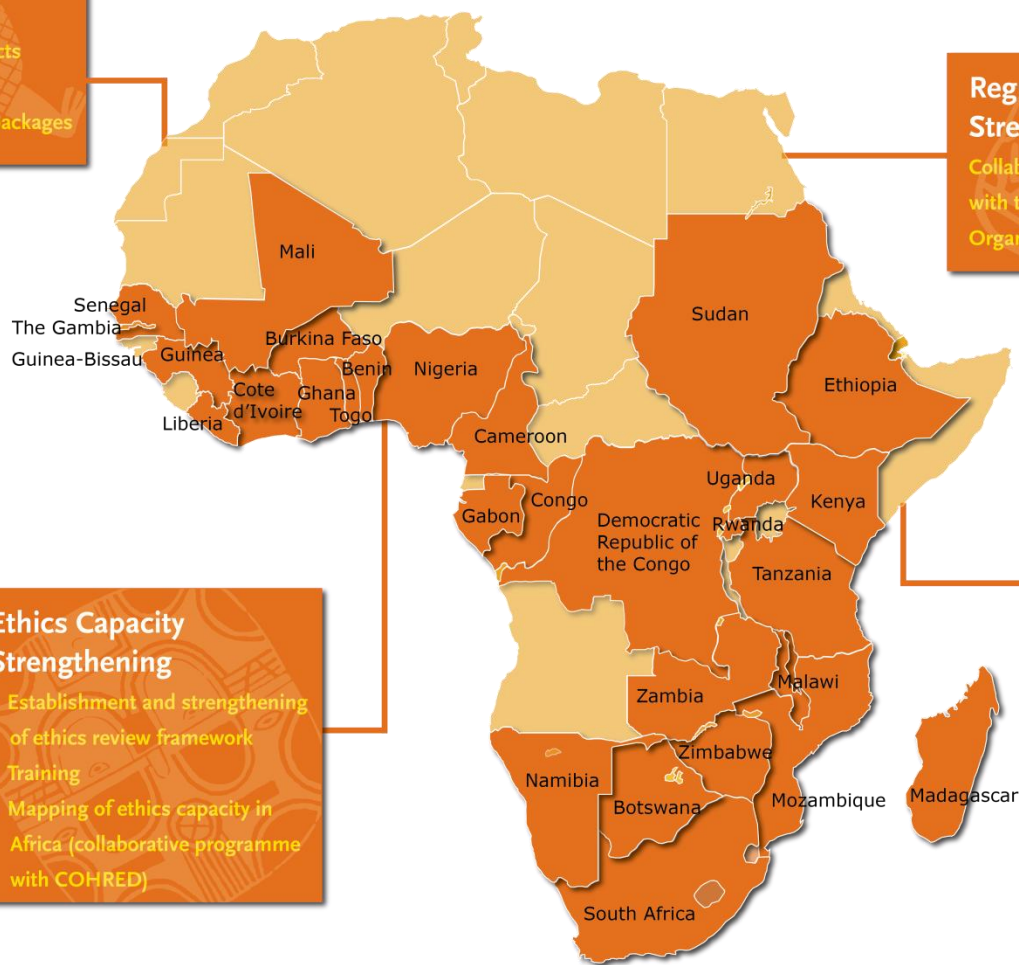
Collaborative programme with the World Health Organization (WHO)

Ethics Capacity Strengthening

- Establishment and strengthening of ethics review framework
- Training
- Mapping of ethics capacity in Africa (collaborative programme with COHRED)

EDCTP Fellowship Programme

- Senior Fellowships
- Postdoctoral Fellowships
- Other training awards (Masters, PhD)



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

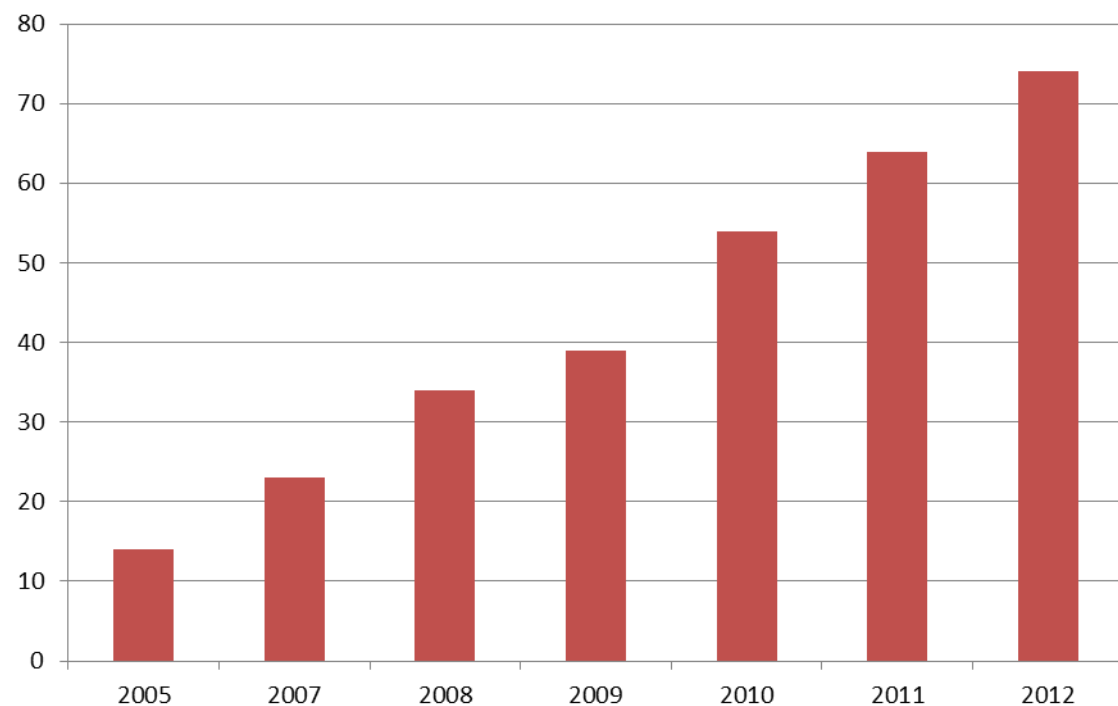
Website: www.tesafrica.org

Project Coordinator: Dr Alexander Pym

- Botswana
- Malawi
- Mozambique
- South Africa
- Zambia
- Zimbabwe
- France
- Germany
- Netherlands
- United Kingdom



- Development of 24 selected labs in preparation for future accreditation
- Information and computer technology infrastructure upgrades
- Training: Long term and short term (GCP, GCLP, data management & biostatistics, CT monitoring exchange programmes and training in laboratory techniques)
- Finance management training and systems development.



Year	Number of projects	Cumulative total
2005	14	14
2007	9	23
2008	11	34
2009	5	39
2010	15	54
2011	10	64
2012	10	74

Senior Fellowships – October 2012



Status	HIV	TB	Malaria	Total
Completed	8	5	10	23
On-going	12	7	9	28
Totals	20	12	19	51

Gender distribution:

Male = 40

Female = 11

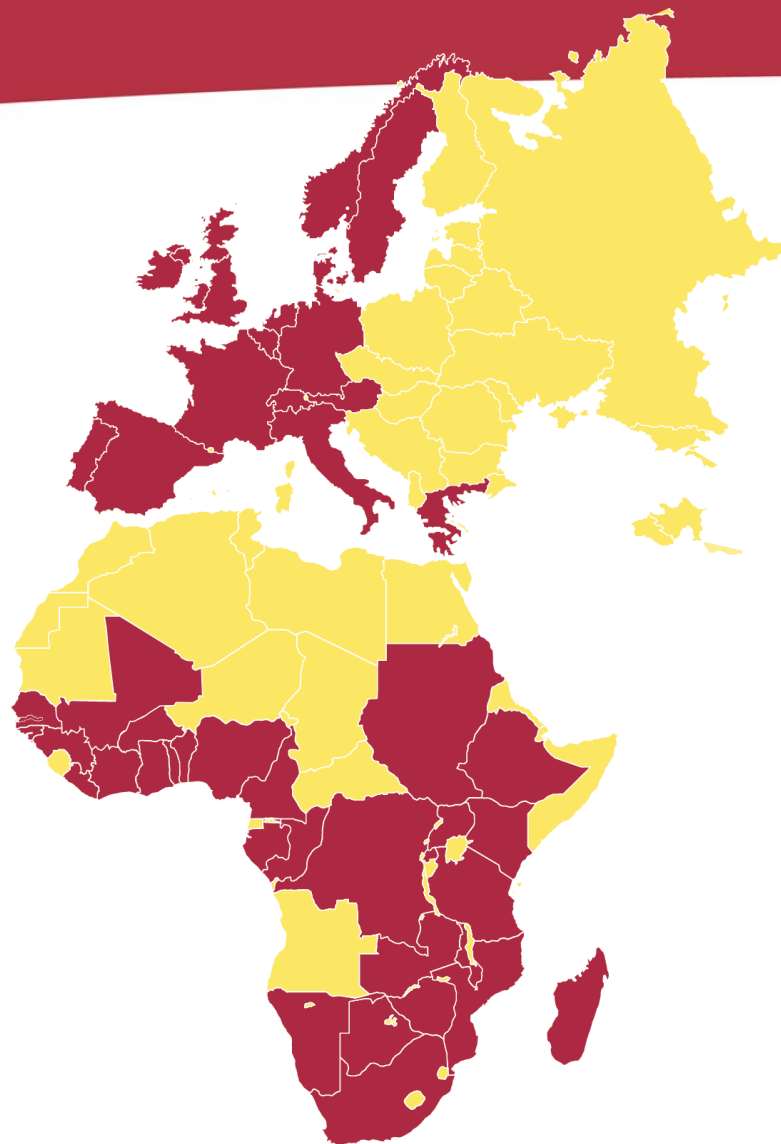
Current EDCTP Partnership

EDCTP-EEIG partner countries

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

Sub-Saharan African partner 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
- Mali
- Mozambique
- Namibia
- Nigeria
- Rwanda
- Senegal
- South Africa
- Sudan
- Tanzania
- The Gambia
- Togo
- Uganda
- Zambia
- Zimbabwe



- Independent external review, impact assessment and internal consultation recommended expansion of the scope while maintaining focus
 - All phases of clinical trials (phase I-IV), but special attention to phase III
 - Include neglected infectious diseases
 - Collaboration with other DCs outside Africa when required
 - 10-year programme
- Closer collaboration with pharmaceutical industry and other like-minded organisation

Thank you



<http://www.edctp.org>