

Stakeholders' meeting on Ethics

28 November 2013
Institute of Tropical Medicine
Antwerp, Belgium.

Michael Makanga, MD MSc PhD
Director South-South Cooperation.





Mission and objectives of EDCTP



Mission

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

Objectives

- Accelerate research and development of new or improved interventions against PRDs
- Coordination of the European member state national programmes working in **partnership** with sub-Saharan African countries
- Collaboration with the private sector and like-minded organisations



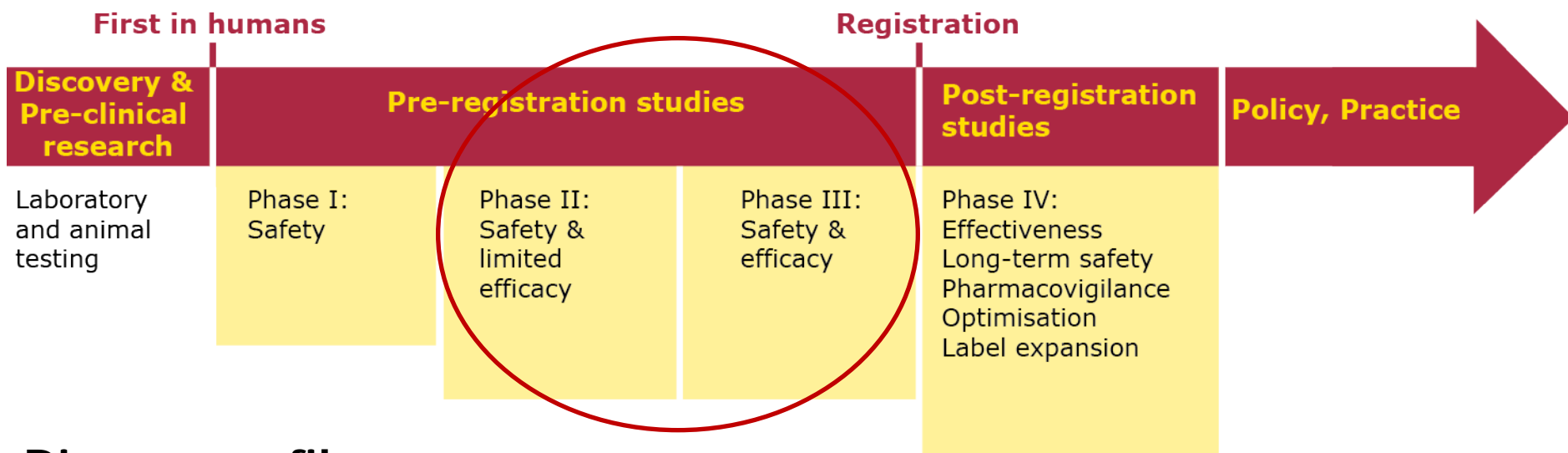
EDCTP Partnership



16 European Countries

- **14 EU countries:** Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden and United Kingdom
- **2 Associated Countries:** Norway and Switzerland
- **New members:** Finland - Latvia, Poland and Slovakia

48 sub-Saharan African Countries



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

Interventions:
Drugs, Vaccines, Microbicides, Diagnostics



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).

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: Prof. Gerard Walzl

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

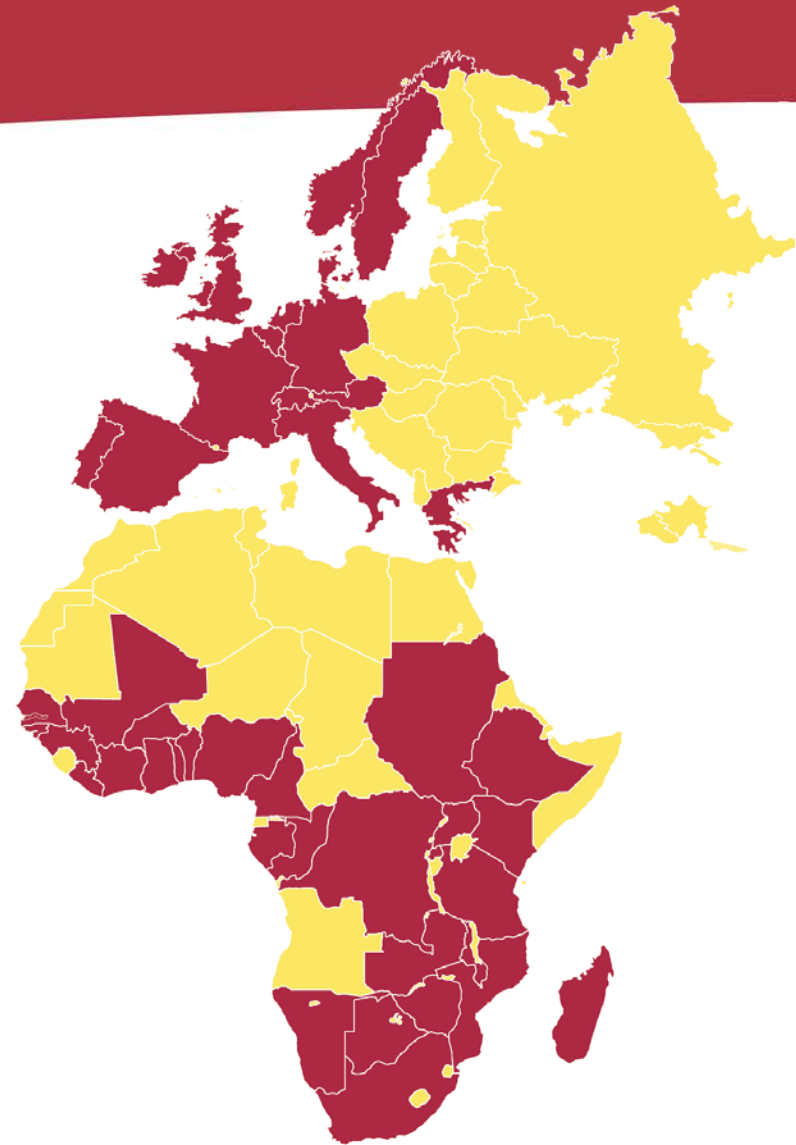




Current EDCTP projects in a nutshell

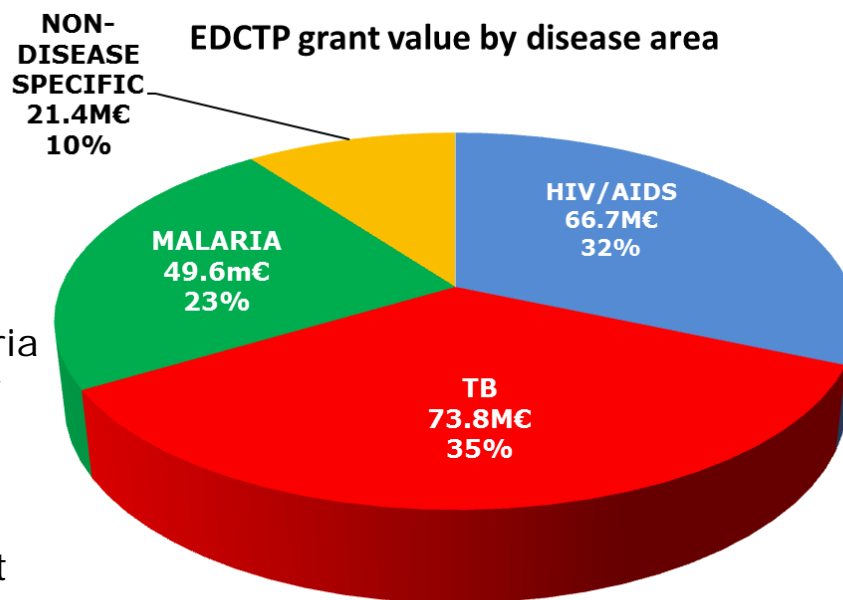


- 246 Grants involving 30 African and 16 European countries and 255 institutions (participating & receiving funds from EDCTP)
- Current total project value is ~375 M€ (EDCTP funds + co-funding)
- Trained 421 African research scientists (MSc, PhD, Fellowships, Post docs, clinical trials related)
- Building African leadership in science with >50% of projects being led by Africans



Details on EDCTP grants

EDCTP grant value by disease area



Malaria

Treatment:

- Uncomplicated malaria
- Malaria in pregnancy
- Severe malaria in children

Prevention:

- Vaccine development

Tuberculosis

Diagnostics

- PoC diagnostics and markers

Treatment

- Treatment shortening/simplification

Prevention:

- Preparatory studies for vaccine development and vaccine development

HIV/AIDS

Treatment:

- Paediatric
- Second line ARVs
- HIV/TB coinfection

Prevention:

- PMTCT
- Preparatory studies for microbicides and vaccine development



Recommendations from previous SHM (Geneva 2007)



High quality ethics review of clinical research is required to be done by ethics committees in the host countries.

- Primary focus was to strengthen ethics review capacity in countries and areas where EDCTP was supporting clinical trials
- Support training and strengthen NEC/IRB infrastructure
- Open calls for proposal approach recommended
- Collaboration was encouraged where possible, to avoid duplication and where there would be added value
- Encourage applications from countries and geographical areas known to have inadequate ethics review capacity
- Dynamic mapping of existing and new ethics capacity and organisations involved in developing this capacity in Africa.

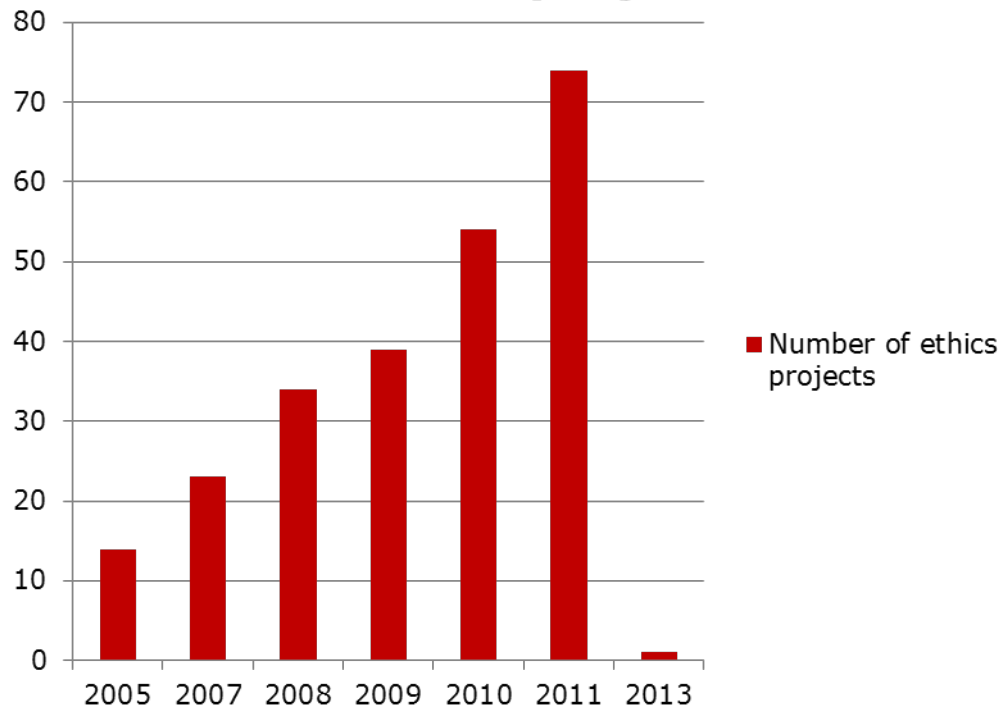


Ethics Projects



- EDCTP1 has funded 75 ethics projects
- Project status: 53 completed and 22 in progress
- No calls launched in ethics in 2012 and 2013
- Ethics capacity for health research remains priority in EDCTP2 strategic plan.

Number of ethics projects



Call	Number of projects	Cumulative total
2005	14	14
2007	9	23
2008	11	34
2009	5	39
2010	15	54
2011	20	74
2013	1	75

Project categories

- Ethics training in sub-Saharan Africa through:
 - Development of online training programmes
 - Funding courses on ethics through formal training courses, such as diplomas or certificates
 - Projects with training components such as GCP and human subjects protection training.
- Establishment and strengthening of ethics capacity at both the institutional and national levels with objective of making these committees functional and independent
- Coordination and mapping ethics and regulatory activities.



EDCTP supported clinical trials

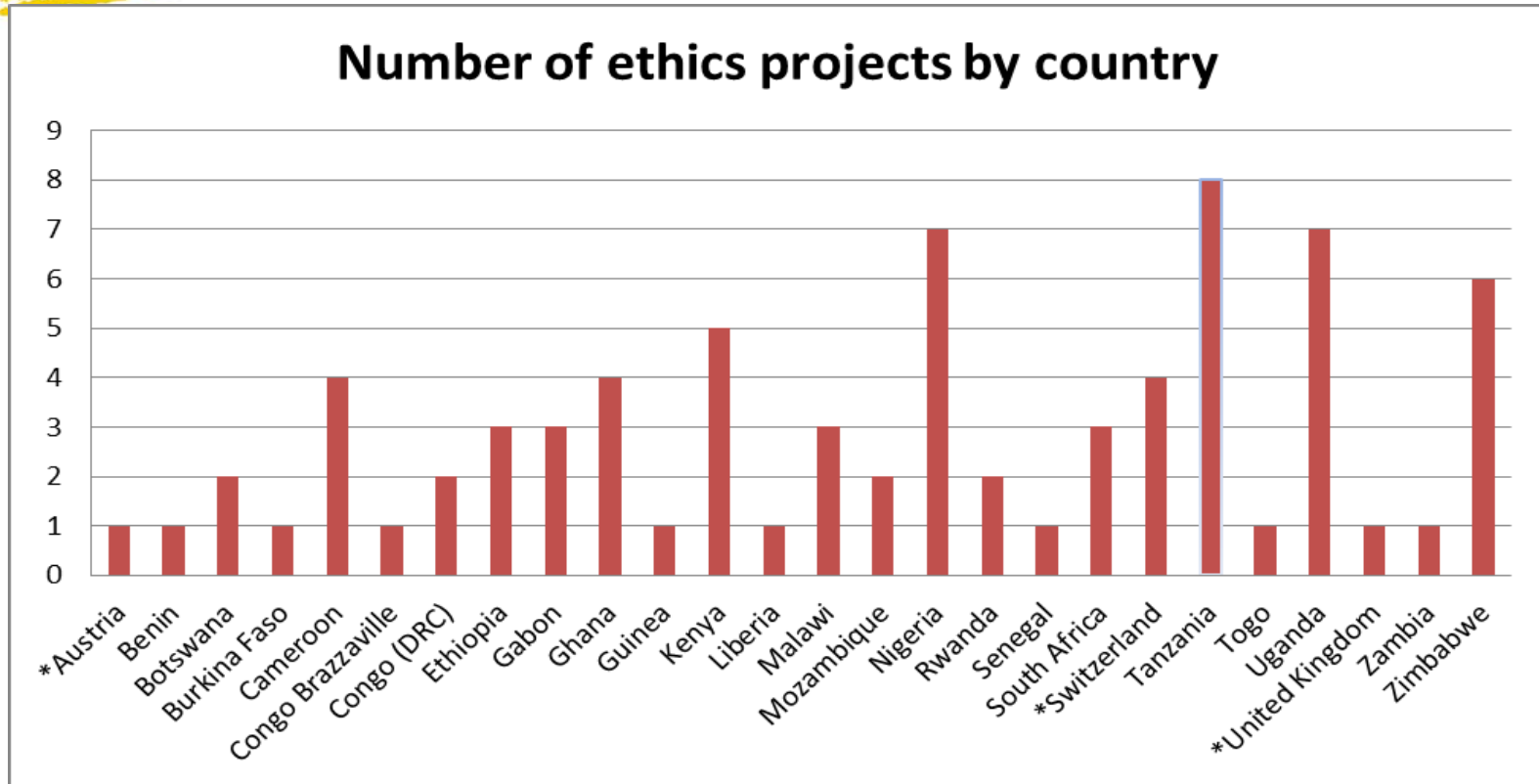




EDCTP supported ethics committees



Ethics grants by country



*Grant coordinated from a European country



Expanded scope under EDCTP2



- 10-year programme 2014-2023
- All phase of clinical trials (I-IV) including implementation research on the optimisation of health services
- Inclusion of neglected infectious diseases.
- Increased budget
 - EC proposal for funding: € 648 Million under Horizon 2020 (2014-2023)
 - Contributions from Participating States

Transition to EDCTP2

- End of no-cost extension for EDCTP – May 2015
- EDCTP-Plus 2012-2013
 - Landscape mapping
 - **Stakeholders' meetings**
 - Upgrading and accreditation of clinical laboratories
 - Continued capacity strengthening of NoE
 - **Strategic and operational business plans, 2014 EDCTP work programme**
 - Establishment of the Strategic Advisory Committee
 - Expansion of the Secretariat
 - Call on Epidemiological studies and capacity development in biostatistics and data management
 - Inviting new EU Member States and Associated Countries



Funding Schemes/Activities under EDCTP2



- Integrated Activities
- Participating States Initiated Activities (PSIA)
- Joint Calls

Integrated Activities

Integrated Activities

Activities that are selected, funded and managed by **EDCTP** from EC contribution and cash contributions from the PS* or 3rd parties

- EDCTP will manage the activities
- Centralised peer-review, administration, evaluation and monitoring of grants
 - Simple cofunding requirements

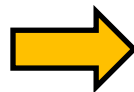
Horizon 2020 Rules of participation apply with any derogations
2 EU and 1 sub-Saharan Africa

*Participating States = EU Member States, associated countries and sub-Saharan African countries participating in the EDCTP programme

Integrated Activities

- EDCTP Calls for Proposals include 2 categories of activities:
 1. Clinical research projects
 - Integrated projects
 - Strategic primer grants
 2. Capacity Building
 - Fellowships
 - Networks of Excellence
 - Ethics and Regulatory

Participating States Initiated Activities (PSIAs)



Selected, funded and managed by
EDCTP Participating States

Single PS call: if call fits scope of
EDCTP, contribution PS
matched with funds EC

Joint PS call(s): EDCTP may award
top-up funding to the call to
increase impact or expand access

Combination of national rules and
Horizon 2020 rules – in
development

All PSIAs should be included and
approved as part of EDCTP annual
work programme

Joint Calls →

Undertaken by EDCTP or any PS with other countries or third parties

Consortium model of funding

Included and approved in EDCTP annual work programme

Joint rules of participation to be established

- Early involvement of EDCTP
- Positive recommendation of the EDCTP SAC
- Inclusion in EDCTP annual work programme
- Involvement of EDCTP in the grant management (review, monitoring and evaluation)



Expected outcomes of the Ethics stakeholders' meeting



- Review of the current status of ethics capacity in SSA
- Receive feedback from external evaluation of EDCTP1 ethics programme
- Identification of key ethics capacity gaps, opportunities and barriers to progress
- Recommendations that will contribute towards the EDCTP strategy for supporting ethics capacity development:
 - Priority areas to address in ethics Calls for Proposals
 - Areas of potential synergy with other ethics capacity strengthening initiatives.

Thank you



www.edctp.org