Plans and progress towards EDCTP2

Stakeholders' meeting on Regulatory Affairs

29 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

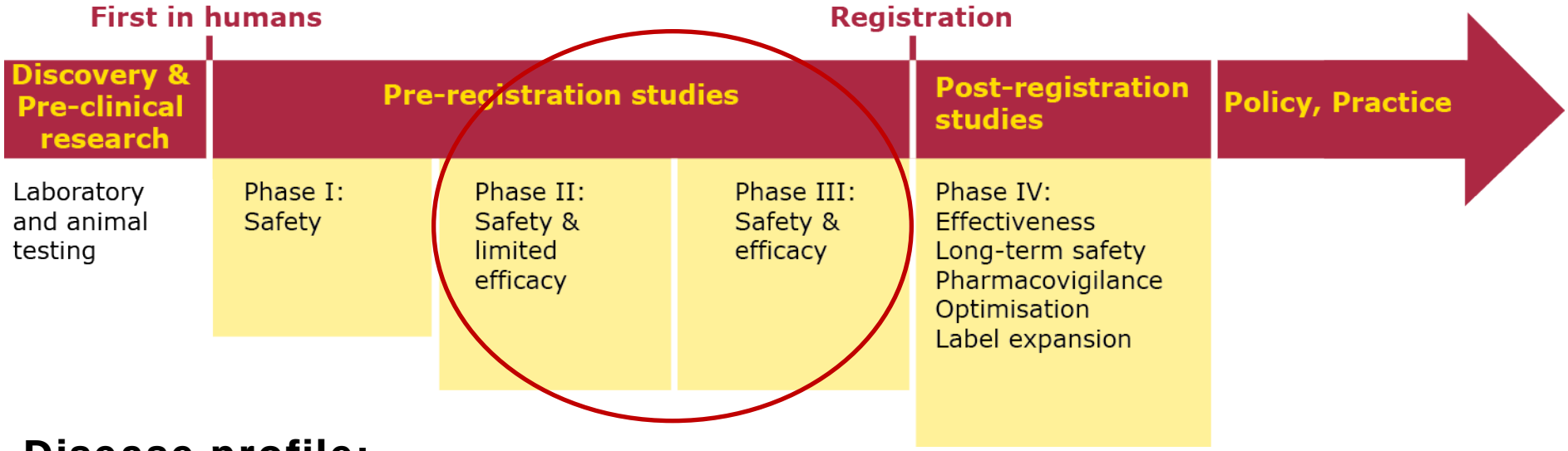
EDCTP Partnership

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

EDCTP scope



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).

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

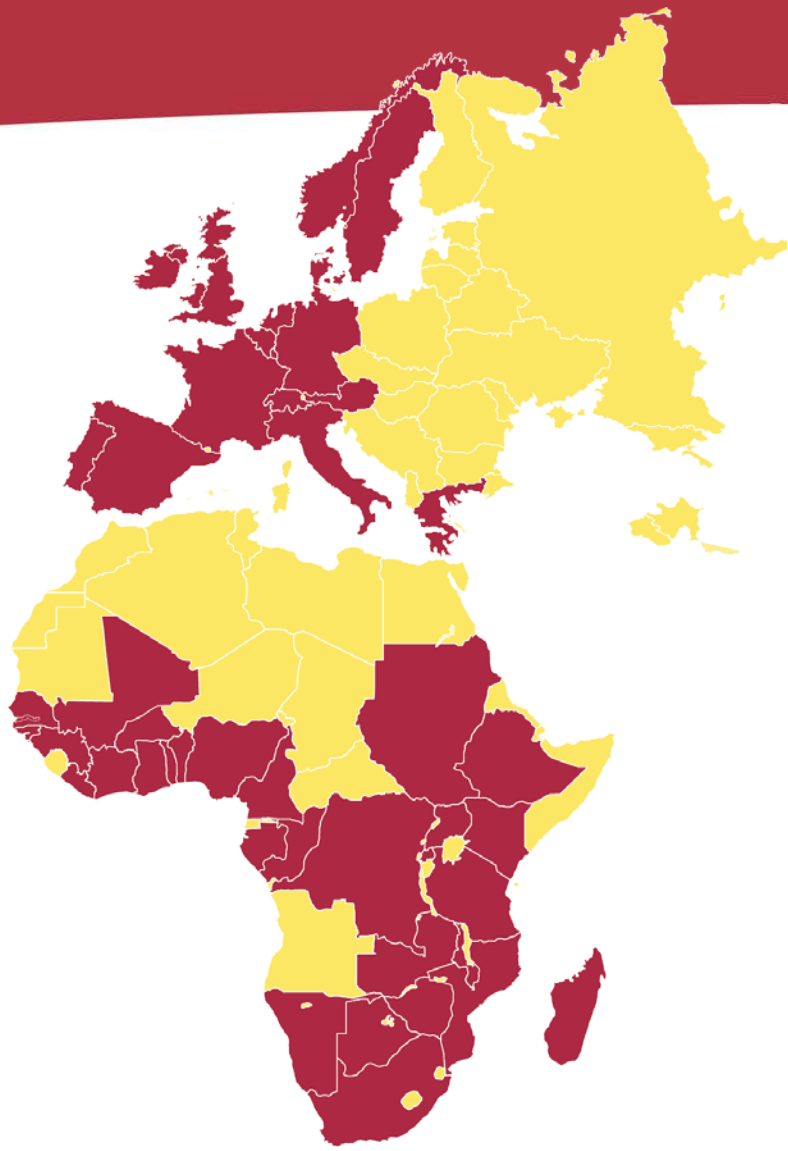
Website: www.tesafrica.org

Project Coordinator: Prof. Gerard Walz

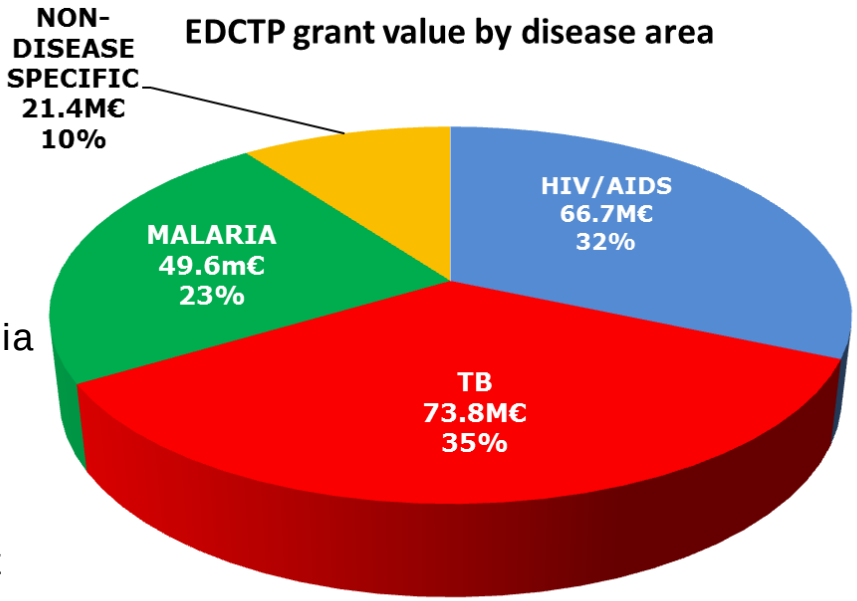
- Botswana
- Malawi
- Mozambique
- South Africa
- Zambia
- Zimbabwe
- France
- Germany
- Netherlands
- United Kingdom

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



Malaria

Treatment:

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

Prevention:

- Vaccine development

HIV/AIDS

Treatment:

- Paediatric
- Second line ARVs
- HIV/TB coinfection

Prevention:

- PMTCT
- Preparatory studies for microbicides and vaccine development

Tuberculosis

Diagnostics

- PoC diagnostics and markers

Treatment

- Treatment shortening/simplification

Prevention:

- Preparatory studies for vaccine development and vaccine development

Recommendations from previous SHM (Geneva 2007)

- To work with WHO and other partners in the implementation of the priority regulatory activities in Africa
- Develop a strategic approach to facilitate regulatory capacity alignment including mapping of regulatory capacity using the experience of the WHO RNA assessment and institutional analysis and scenario planning
- Support training and systems development in pharmacovigilance and in drug safety monitoring and evaluation, particularly in resource-poor countries
- Establish joint training and dialogue between research and clinical scientists, professional members of ethics committees, product developers and evaluators who serve in regulatory authorities, to foster mutual understanding and collaboration and to facilitate the decision making process
- Develop self-assessment tools for national regulatory authorities that would encourage and support capacity development. (Effectiveness and efficiency measurement tools)

Recommendations from previous SHM (cont'd)

- Develop systems for situation analysis and mapping of capacity that address, *inter alia*, institutional needs, the legal framework for assessment of clinical trials (including ethics issues), core technical issues, individuals with key functions and responsibilities, and bottlenecks

- Explore ways of expanding the WHO existing data base with internet access (e.g. Sharepoint) to enable ready sharing of information, cross-cutting activities between vaccines and other pharmaceuticals, and complementary activities e.g sharing of country information and experience, and access to reports including expert reports from EMEA, Canada, US FDA etc.

EDCTP support to regulatory affairs in sub-Saharan Africa (2006 – 2010)

- Regulatory activities have been implemented through collaboration with WHO
- Supported the assessment and capacity strengthening of the national regulatory environment of various African countries through training, ↑ regulatory pathway link to clinical trials and support of the development of a common regulatory framework.

Summary of key achievements:

- EDCTP and NACCAP funding provided the foundation that resulted in formation of the African Vaccine Regulators Forum (AVAREF)
- Training of both regulators and members of ethics committees from Botswana, Ethiopia, Ghana, Malawi, Tanzania, The Gambia, Uganda and Zimbabwe on clinical trial authorisation
- Training on Vaccine Quality, GCP and Site Inspection for regulators from Botswana, Ethiopia, Ghana, Malawi, Mozambique, Nigeria, The Gambia, Tanzania, Uganda and Zimbabwe

Summary of key achievements cont'd

- Joint regulatory reviews of clinical trials by regulators from Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique and Tanzania and with expert support from the Belgium National Regulatory Authority and EMA
- The establishment of PACTR: WHO primary clinical trials registry (http://www.pactr.org)
- Continuation of training activities of the Global Training Network Programme implemented by WHO
- Support for monitoring of regulatory functions and development of Institutional Development Plans (IDPs) of NRAs in sub-Saharan Africa.

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

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

Participating States Initiated Activities: Joint Calls

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 Regulatory Affairs stakeholders' meeting

- Review of the current status of regulatory capacity in SSA
- Identification of key regulatory capacity gaps, opportunities and barriers to progress
- Recommendations that will contribute towards the EDCTP strategy for supporting regulatory capacity development:
  - Regulatory activities to prioritise for future funding
  - Areas of potential synergy with other regulatory capacity strengthening initiatives.

Thank you

www.edctp.org