



# The European & Developing Countries Clinical Trials Partnership (EDCTP) Plans and Progress



## Neglected Infectious Diseases Stakeholders' Meeting

27-28 June 2013

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# Mission and objectives of EDCTP



## Mission

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

## Objectives

- To accelerate 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 African countries and other global product development partners.

# EDCTP Governance



# Working in partnerships

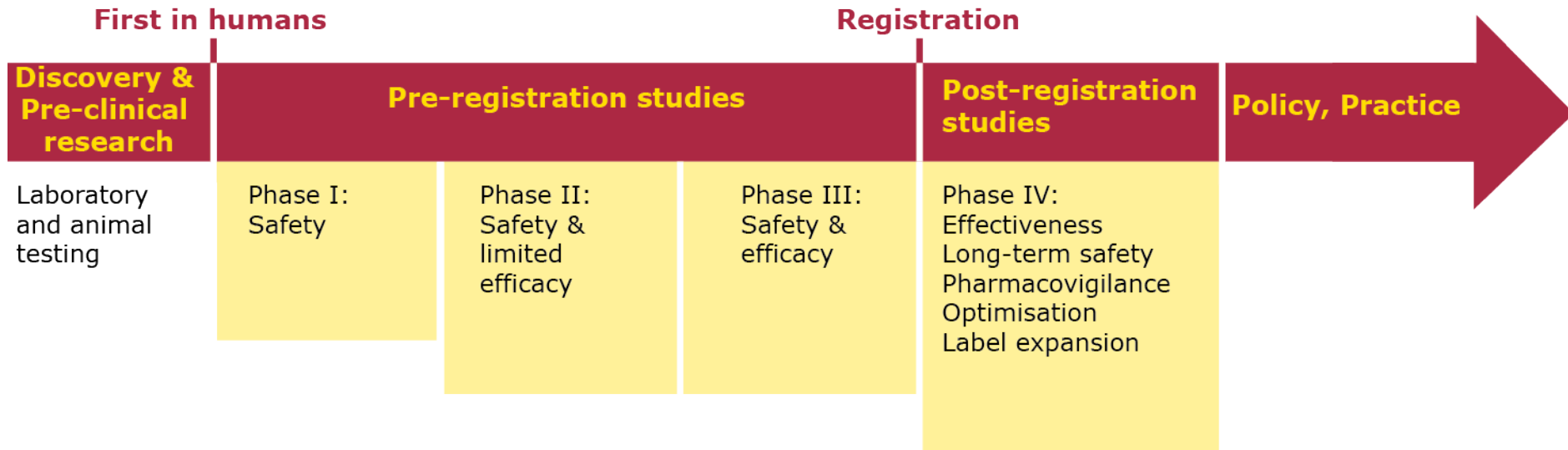
- Coordination of European national programmes
- **Partnerships** with sub-Saharan Africa
- Synergy among R&D international partners



**Accelerated development of tools to fight poverty-related diseases**

**Support to capacity development and networking**

# EDCTP scope



**Disease profile:**  
HIV/AIDS, TB, Malaria and **NID**s

**Interventions:**  
Drugs, Vaccines, Microbicides and Diagnostics

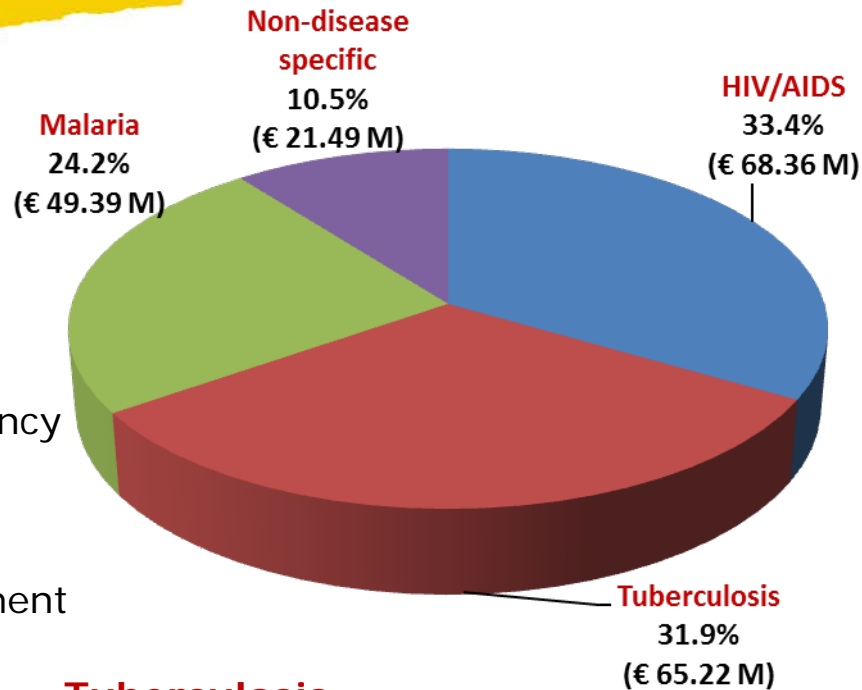


# EDCTP grants scheme



- 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)

# Details on EDCTP grants



## Malaria

### Treatment:

- 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

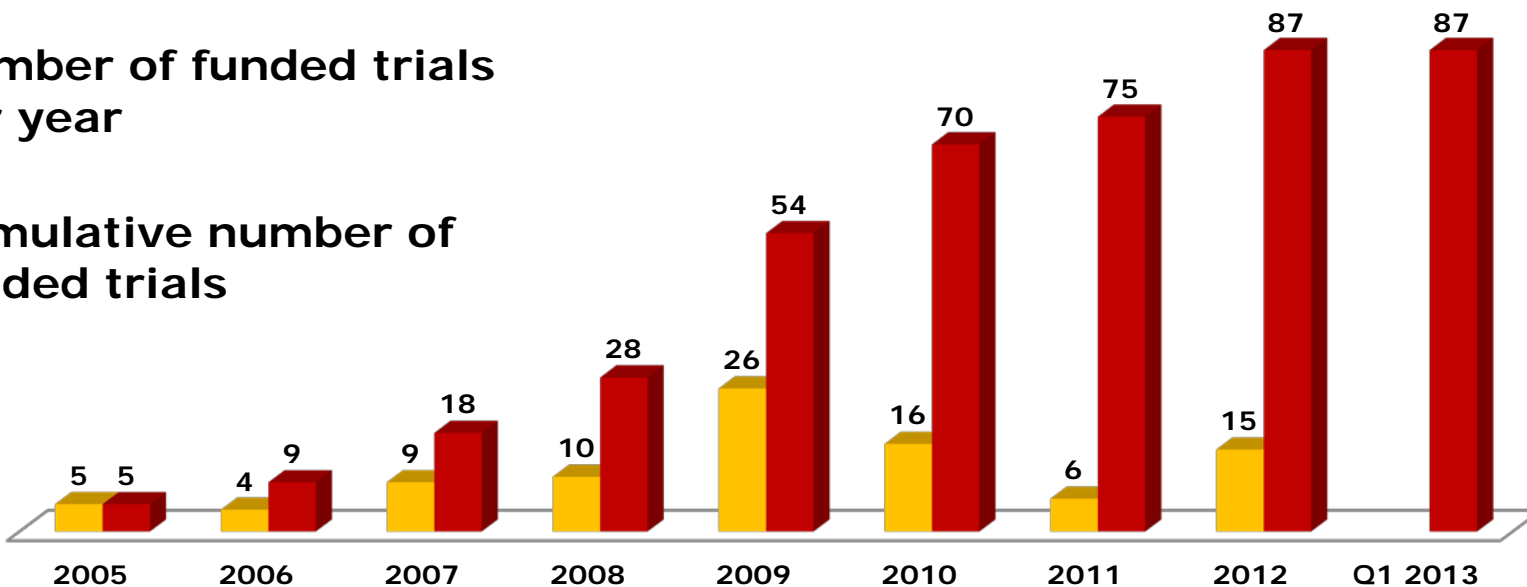
### Prevention:

- PMTCT
- Preparatory studies for microbicides and vaccine development

## Number of funded clinical trials

■ Number of funded trials per year

■ Cumulative number of funded trials





## Western Africa: WANETAM

Website: [www.wanetam.org](http://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](http://www.cantam.org)

Project Coordinator: Prof. Francine Ntoumi

- Cameroon
- Congo, Republic of the
- Gabon
- France
- Germany

## Eastern Africa: EACCR

Website: [www.eaccr.org](http://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](http://www.tesafrica.org)

Project Coordinator: Dr Alexander Pym

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





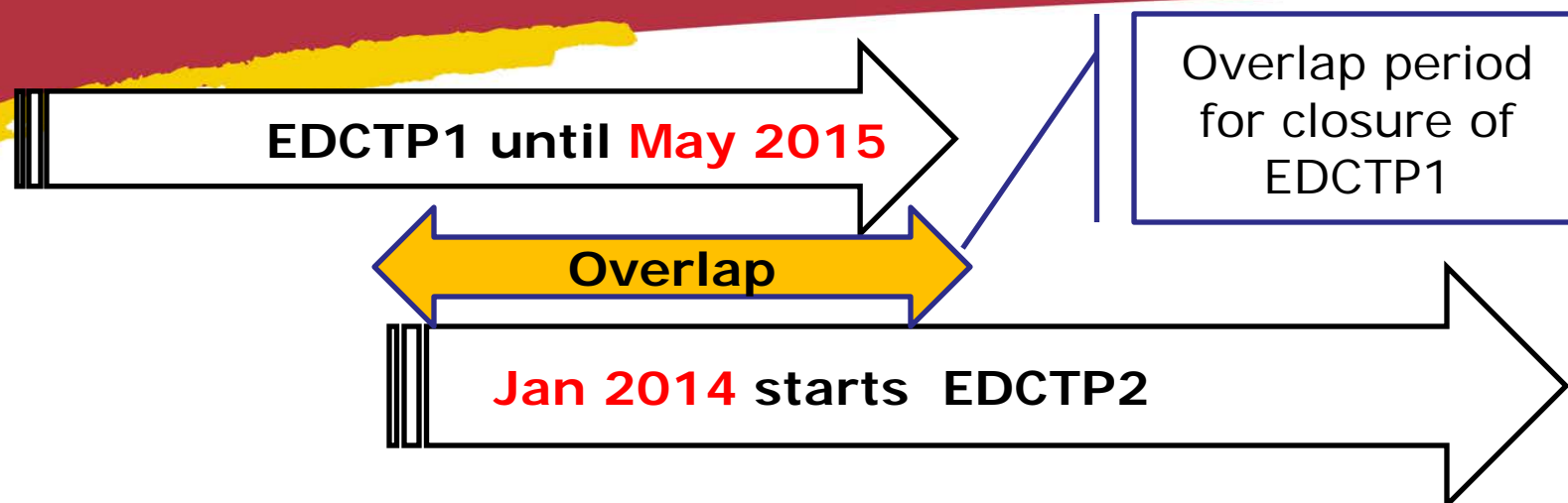
# Towards EDCTP2



# Process towards an EDCTP2



- Independent external review, impact assessment and internal consultation recommended **expansion of scope while maintaining focus**
  - **All phases of clinical trials (phase I-IV), special attention to phase III**
  - **Include Neglected Infectious Diseases (NIDs)**
  - **Collaboration with other DCs outside Africa when required**
  - **Health systems optimisation research**
- Closer collaboration with pharmaceutical industry and other like-minded organisation
- Expected start in 2014.



On-going discussions with the European Commission and Member States on funding of EDCTP2

EDCTP2:

- Larger and more costly Phase III clinical trials
- Extension to NIDs, Phase IV



## Types of projects under EDCTP2



- Integrated Activities
- Participating States Initiated Activities
- Joint Activities



# Integrated Activities/Projects



- Activities that are selected and funded by EDCTP from Participating States and EU contributions
- EDCTP-IS will manage the activities (Centralised peer-review, administration, evaluation and monitoring of grants)
- Horizon 2020 Rules of participation shall apply with any derogations



# Participating States Initiated Activities (PSIA)



- Selected, funded and managed by EDCTP Participating States
- Included in EDCTP annual workplan
- With agreement of the EC and subject to the conditions, EDCTP2-IS may award co-funds from the EU contribution to increase its impact or expand its access to researchers from other EDCTP Participating States
- EDCTP Participating States Rules of Participation will apply, with a minimal set of rules provided by EC/EDCTP

# Joint Activities

- Undertaken by EDCTP-IS or any EDCTP Participating State with other countries or third parties
- Consortium model of funding
- Joint rules of participation will be established
  - Early involvement of EDCTP
  - Positive recommendation of the EDCTP Strategic Advisory Committee
  - Inclusion in annual workplans
  - Involvement of EDCTP in the grant management (review, monitoring)





# Criteria for prioritisation of EDCTP activities



1. Disease prevalence, burden and need taking into account status of interventions landscape
2. Product opportunities and following the course set in the Strategic Business Plan vis-à-vis the expanded remit i.e. NIDs and post registration programmes including effectiveness studies and pharmacovigilance
3. Timing factor: balance between immediate and long-term priorities
4. Balance among clinical trial phases: major investment focus III depending on existing global product portfolio.



# Objectives of NIDs stakeholder meeting



1. Update on the global product portfolio for NIDs: post discovery translation and clinical development pipe and product development partners
2. Identify current research and capacity gaps in clinical development of the products in global portfolio for NIDs
3. Identify priority areas for future calls for proposals and alternative funding mechanisms
4. Identify interested and potential partners to collaborate with in the execution of future EDCTP activities
5. Collate views of EDCTP stakeholders to promote coordination and integration of national programmes of EDCTP European partner states, and to strengthen partnership with African researchers and other global partners.

# Thank you



<http://www.edctp.org>