



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



HIV/AIDS Stakeholders' Meeting

03-04 September 2013

ISCTE-IUL, Lisbon, Portugal

Charles S Mgone MD, MMed, FRCP, PhD
EDCTP Executive Director





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

General Assembly

Representatives and Deputies:

- Policy making body
- 16 European countries
- 4 African representatives:
 - Regional Economic Communities
 - African Union
 - WHO/AFRO Regional Health Ministries
 - Ministries of Finance/S&T

Strategic Advisory Committee

Scientific and strategic advisory body with membership from Africa, Europe and elsewhere

Executive Secretariat

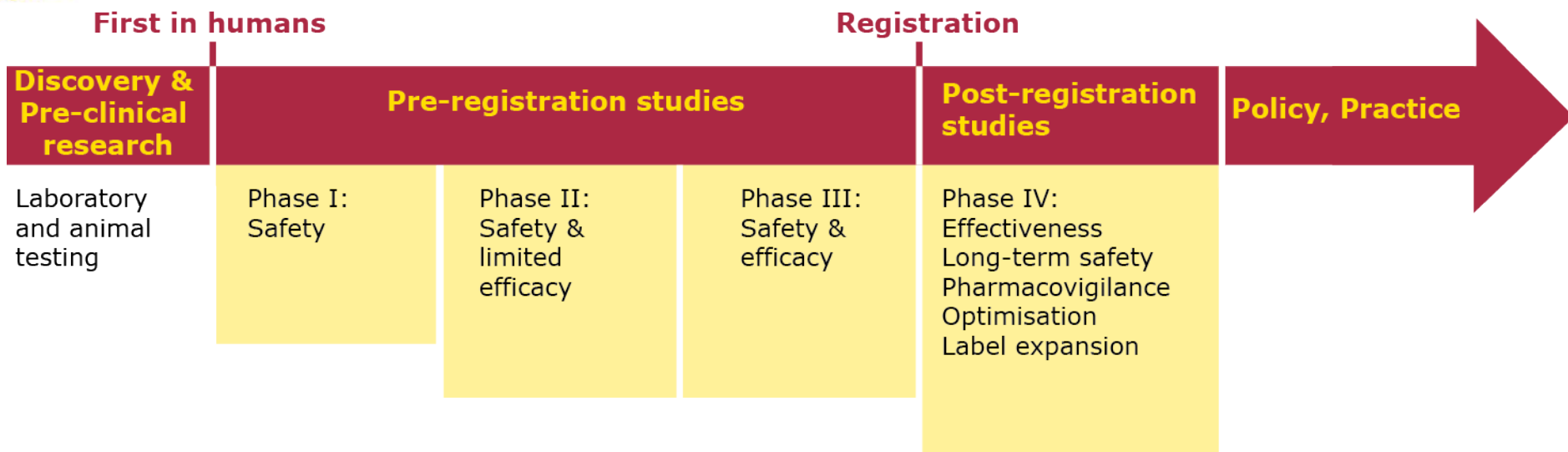
- Europe Office
- Africa Office

Working in partnerships

- Coordination of national programmes
- Partnerships with sub-Saharan Africa
- Synergy among R&D international partners
- Accelerated development of tools to fight poverty-related and neglected infectious diseases
- Support to capacity development



EDCTP scope



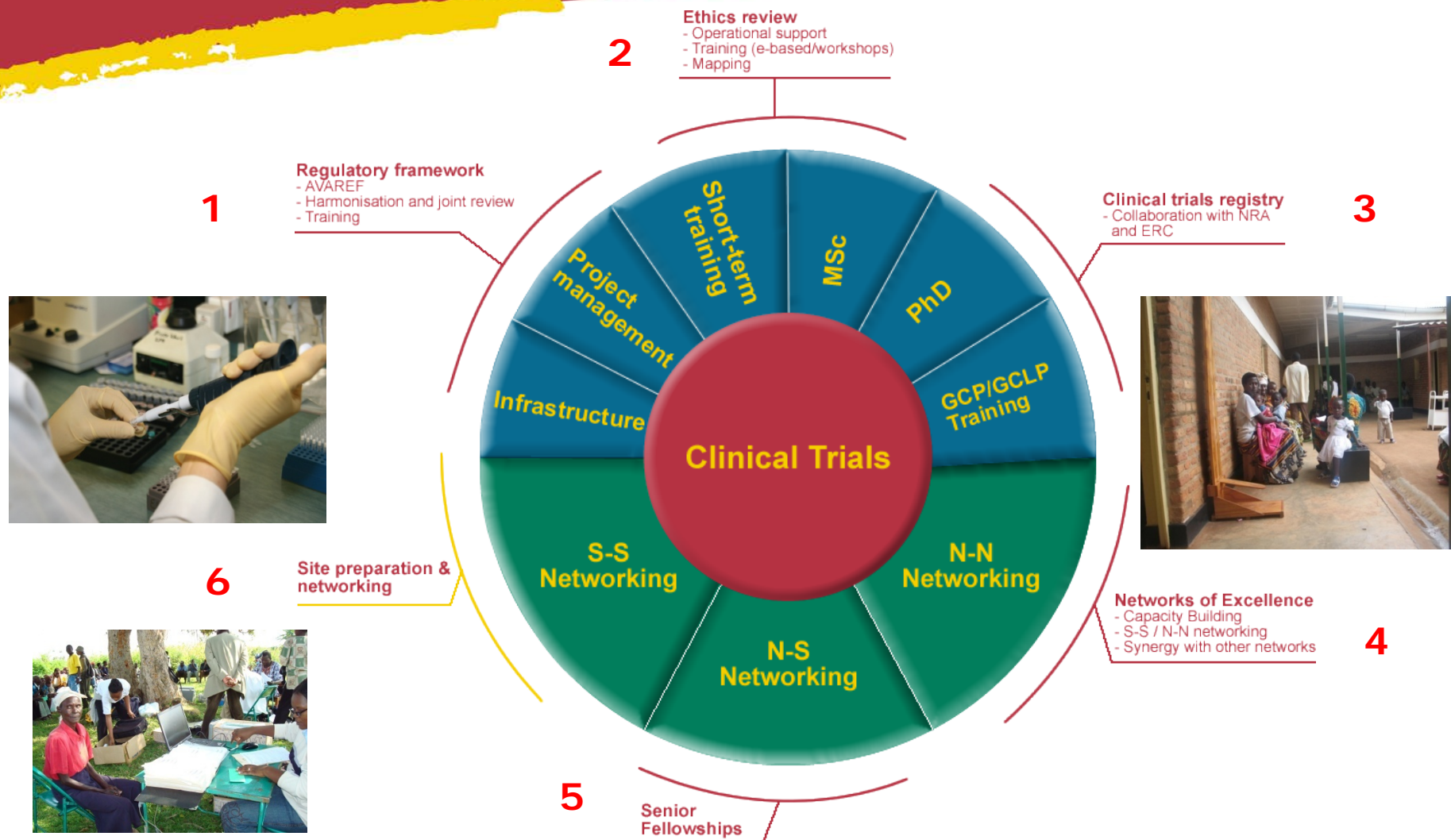
Disease profile:

HIV/AIDS, TB, Malaria and NIDs

Interventions:

Drugs, Vaccines, Microbicides and Diagnostics

Strengthening of clinical trials capacity and the enabling environment



- 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: Dr Alexander Pym

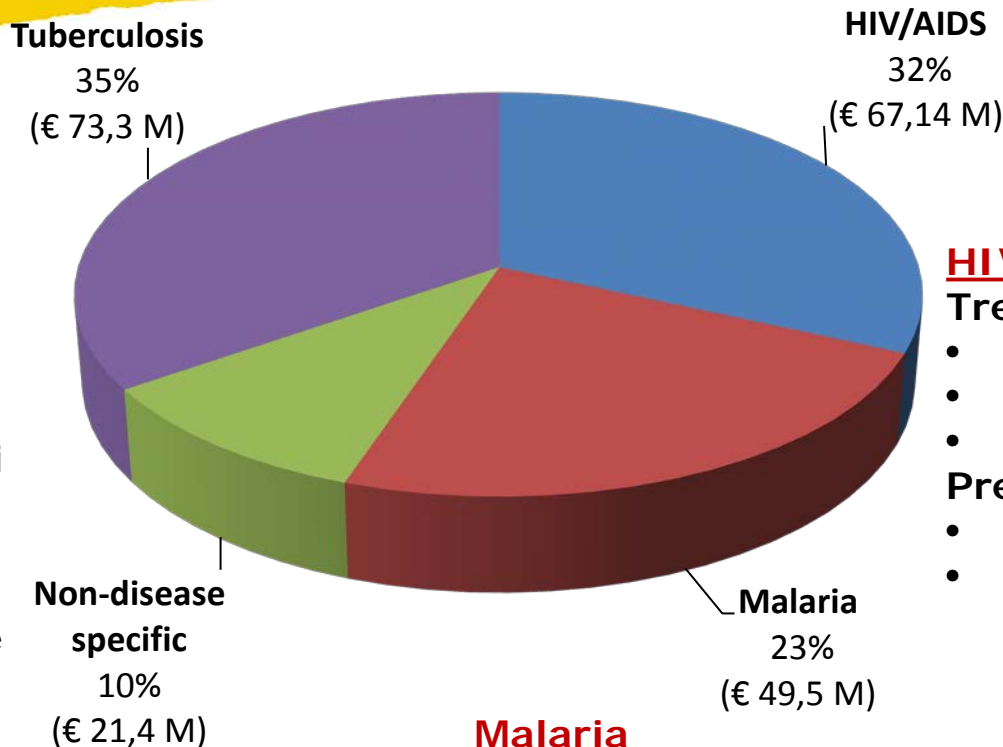
- Botswana
- Malawi
- Mozambique
- South Africa
- Zambia
- Zimbabwe
- France
- Germany
- Netherlands
- United Kingdom



- Central Africa: CANTAM
 - Establishing reference values of CD4+ cell counts in HIV-negative pregnant women in Cameroon
 - Assessment of the impact of ARV on glycaemia and transaminase levels in HIV patients in Cameroon. Data will be used in monitoring patients on ARV in Central Africa
 - Comparison of automated versus manual method for quantification of HIV-1 RNA in plasma samples
 - Investigating the impact of malaria on haematological parameters in HIV-positive patients

- Eastern Africa: EACCR
 - Mentorship visits on paediatric HIV-malaria coinfection
- Southern Africa: TESA
 - Finalisation of an HIV incidence study protocol in Malawi
- Western Africa: WANETAM
 - Study on building research infrastructure and capacity to implement an HIV/STD prevention trial in post-conflict Liberia

Details on EDCTP grants



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

Malaria

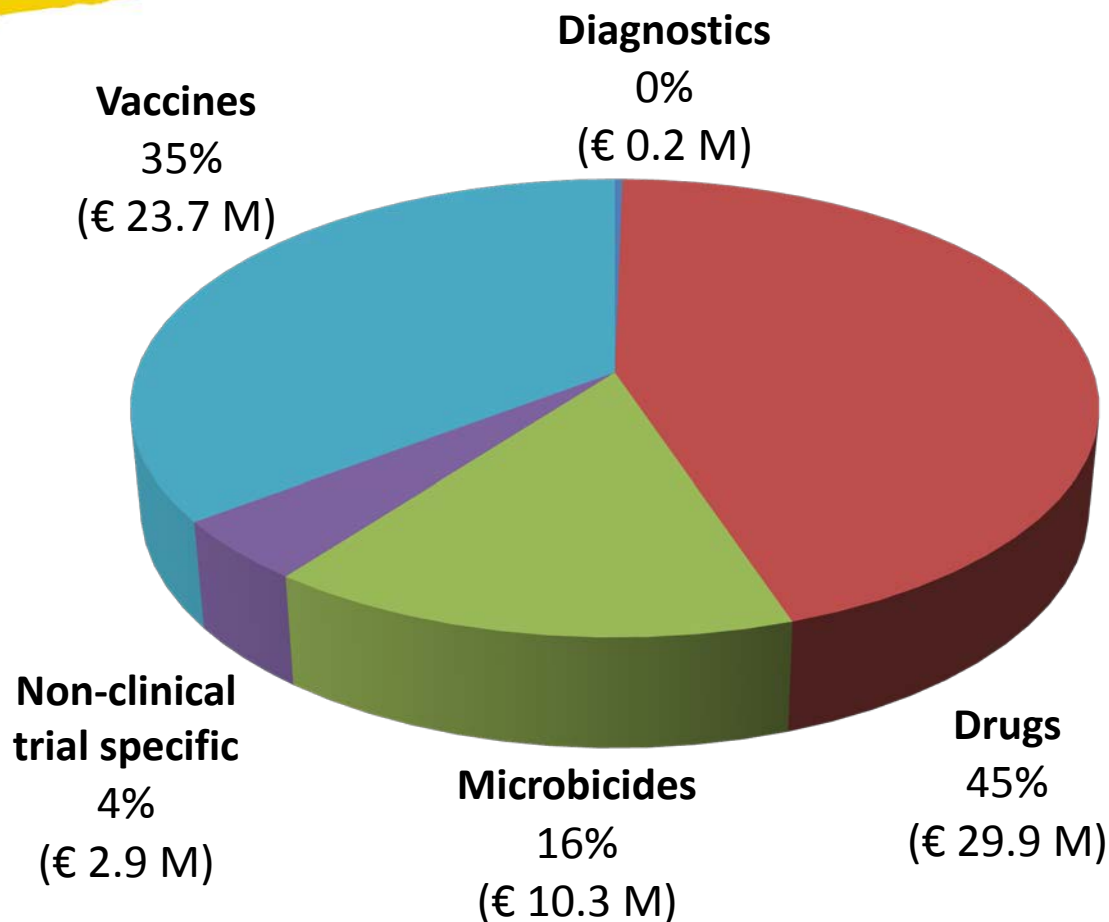
Treatment:

- Malaria in pregnancy
- Severe malaria in children

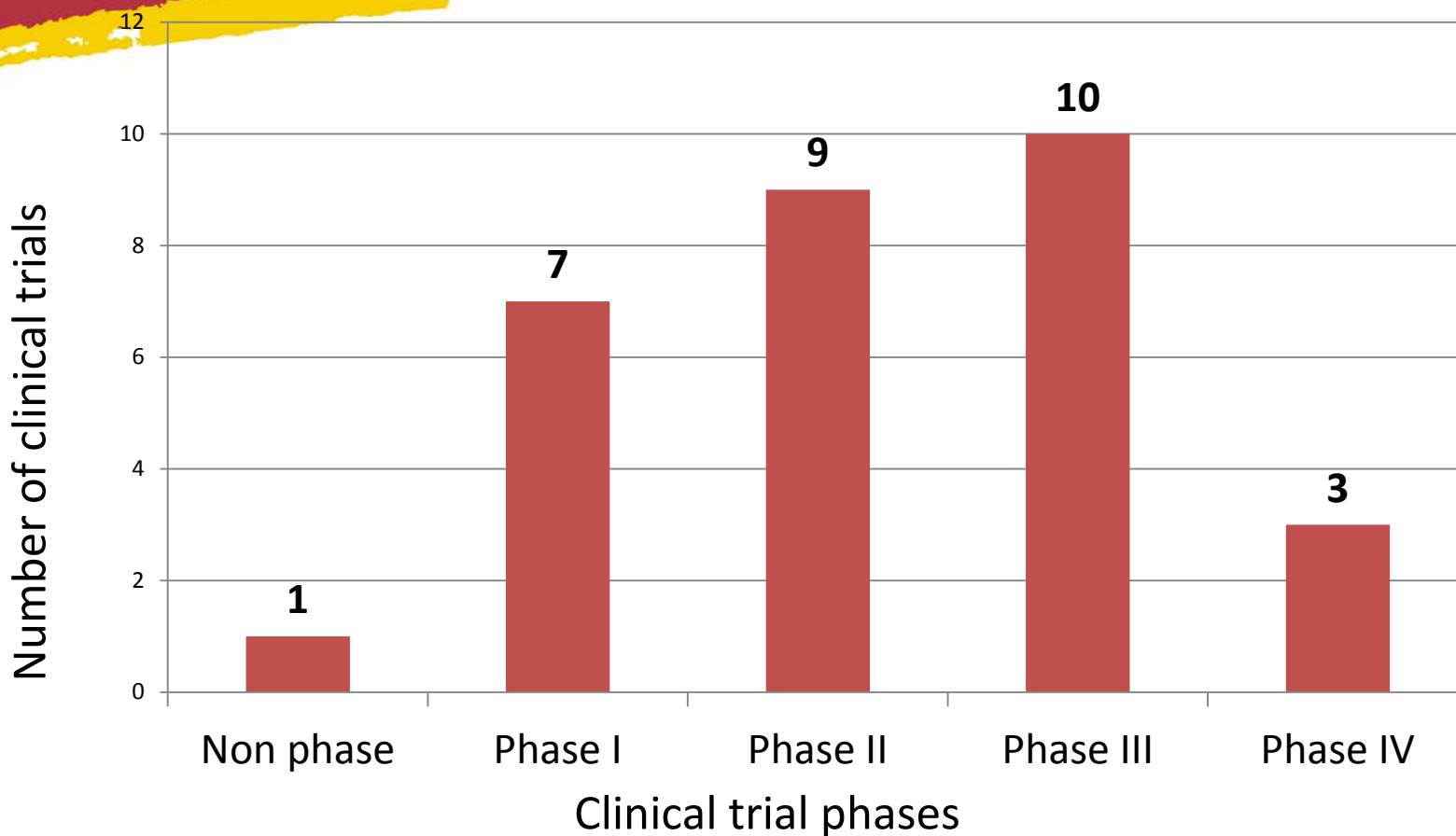
Prevention:

- Vaccine development

HIV/AIDS Clinical Trials supported on EDCTP grants



HIV/AIDS Clinical Trials supported on EDCTP grants



30 clinical trials/ 11 completed



Achievements of EDCTP funded grants



- Contributed to the evidence base that led FDA approval and WHO prequalification of a fixed-drug combination formulation for the treatment of HIV in children (CHAPAS trial)
- Influenced revision of 2010 WHO guidelines on PMTCT: 43% reduction in HIV infections in infants and >50% reduction of PMTCT (Kesho Bora)
- Demonstrated that the prime/boost HIV-1 DNA multigene/multiclade-MVA/CMDR vaccine is safe and highly immunogenic when administered intradermally (TaMoVac)
- Contributed to results on efficacy of a treatment strategy to prevent mother-child transmission of HIV1 during 12 months of breastfeeding (PROMISE-PEP)
- Demonstrated results on TB/HIV co-treatment. A study completed in 2012 found that there is no need to increase efavirenz dose during concomitant rifampicin based anti-TB therapy (HIV-TB Pharmagene)



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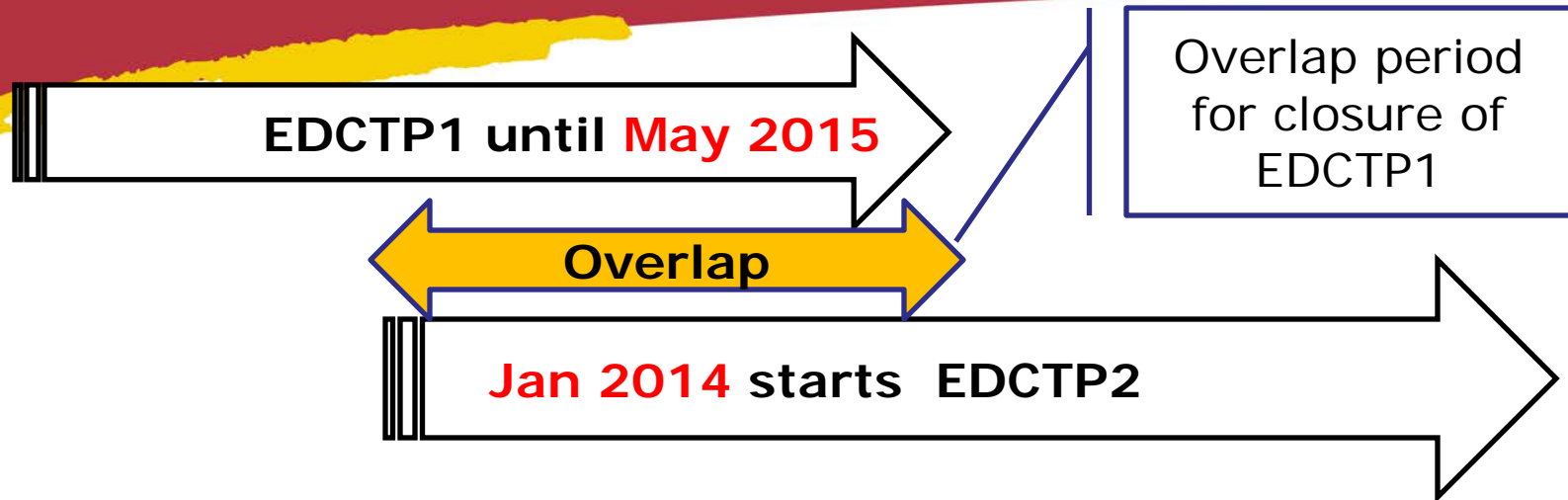
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Towards EDCTP2

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

- Activities that are selected and funded by EDCTP from EU contributions and unrestricted contributions from Participating States and third parties
- EDCTP 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
- 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 (for the funds provided by EDCTP from the EU contribution the Participating States will be bound by M&E rules of Horizon 2020)
- Included in EDCTP annual workplan

Joint Activities

- Undertaken by EDCTP-IS or any EDCTP Participating State with other countries or third parties
- Consortium model of funding
- Included in EDCTP annual workplan
- 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 focus on phase III clinical trials depending on existing global product portfolio.

Objectives of HIV/AIDS stakeholder meeting



- Review the current status in the field of HIV/AIDS
- Identify the key research areas, current opportunities and barriers to progress
- Develop recommendations that will contribute towards the EDCTP strategy for supporting HIV/AIDS research on:
 - Priority research topics for Calls for Proposals
 - Proposals for development of cooperative projects
 - Products in the pipeline for evaluation by EDCTP
 - Focused capacity building initiatives
 - Proposals for funding partnerships

Thank you



<http://www.edctp.org>