



Plans and progress towards EDCTP2



Stakeholders' meeting on Tuberculosis and mycobacterial infections

28 October 2013

Fondation del Duca

Paris, France

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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

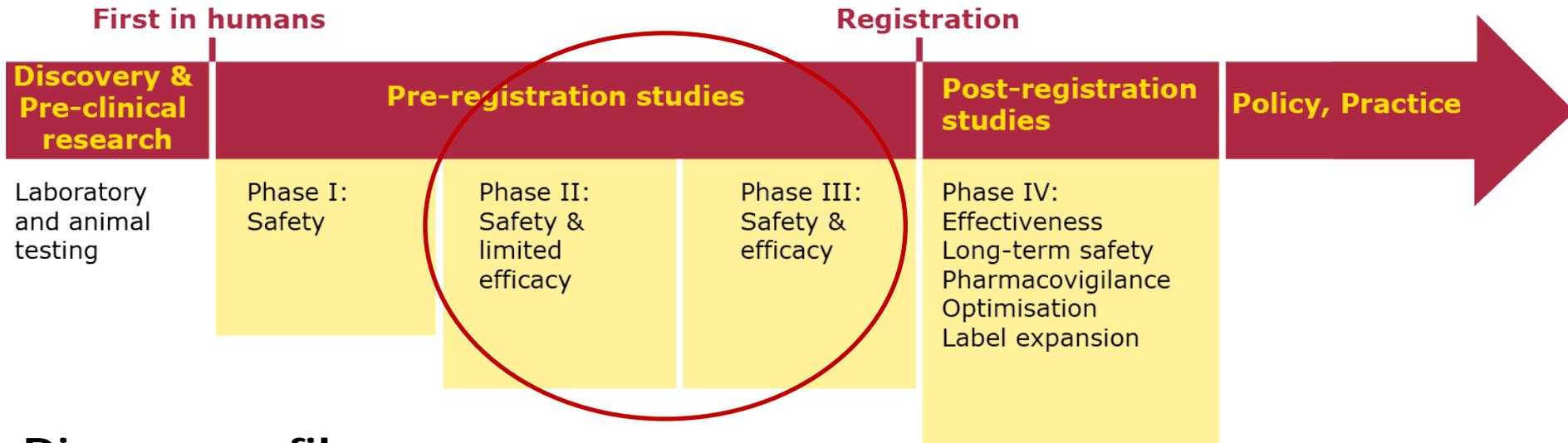


16 European Countries

- **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, 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)

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 Gerhard Walzl

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

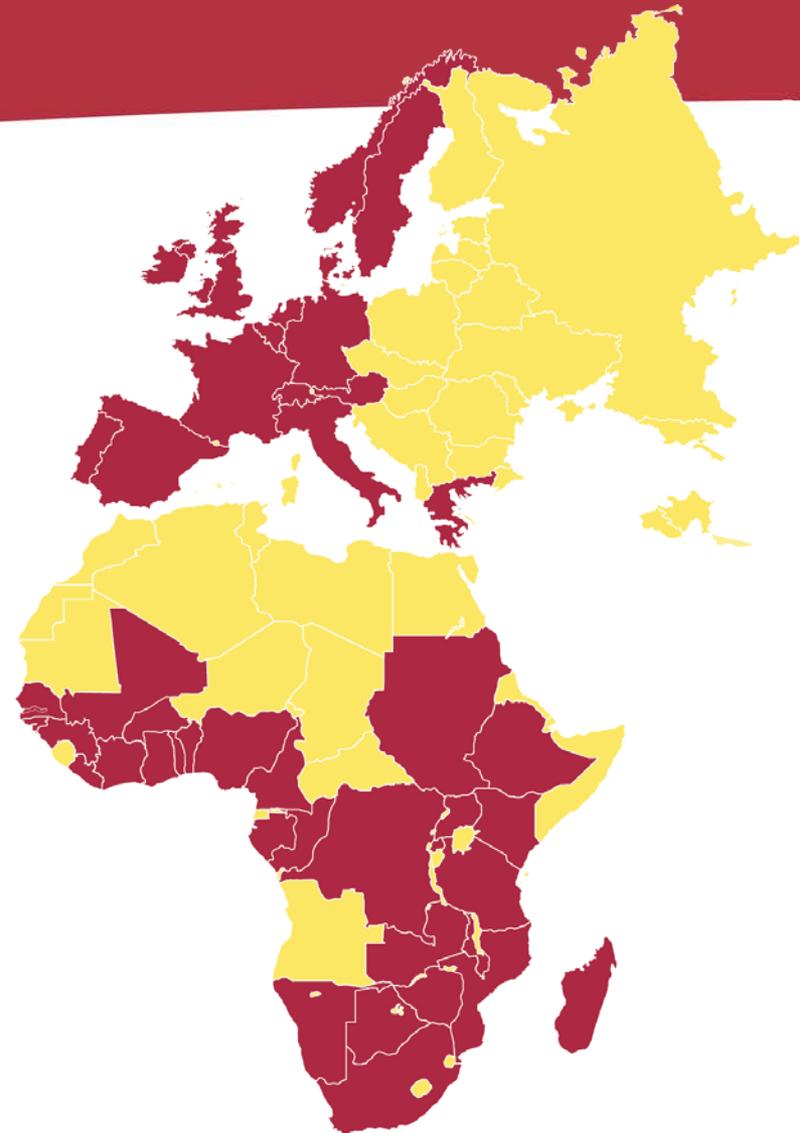




Current EDCTP projects in a nutshell



- 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





Previous TB Stakeholders' meetings - Vaccines



- TB vaccines – April 2007, The Hague
 - Open call to support phase II candidate vaccines
 - Support as many candidates as possible and identify most promising ones
 - Include capacity building and networking elements
 - Open call to support proof of principle studies
 - Focus on new upcoming TB vaccine candidates upstream in pipeline



Previous TB Stakeholders' meetings - Treatment



- TB Treatment – May 2007, Dublin
 - Brokered call for a drug programme to shorten and simplify treatment in drug sensitive adult tuberculosis
 - Clinical development programme to optimise the use of moxifloxacin and high dose rifampicin to shorten the duration of therapy < 4 months
 - Consortium to conduct Phase II RCTs and culminate in pivotal Phase III RCTs



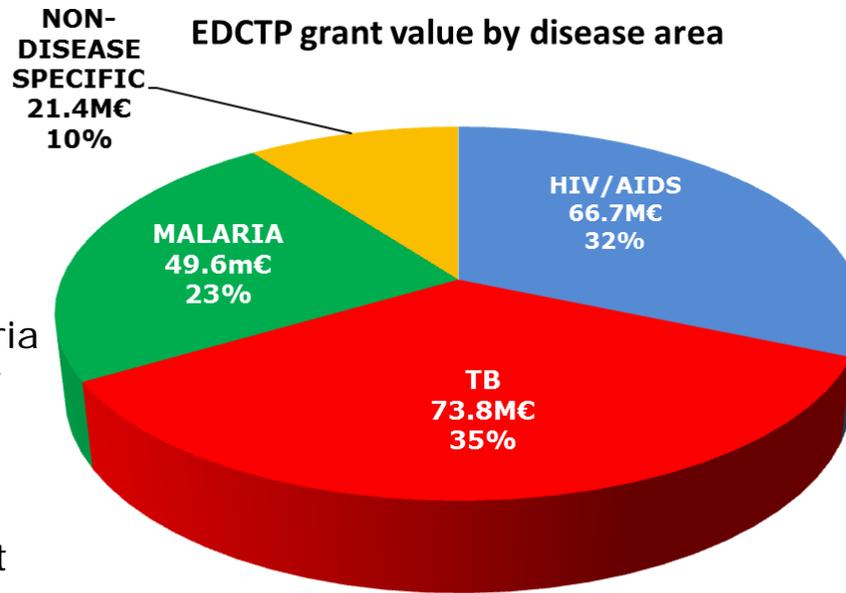
Previous TB Stakeholders' meetings - Diagnostics



- TB Diagnostics – October 2008, Paris
 - Focus on diagnostic tools in late development stage
 - Priority should be given to products that can be deployed at point of care (POC)
 - Maximum impact on TB control
 - Open call for projects that address issues of childhood TB, harmonised bio-bank and cost effectiveness

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:

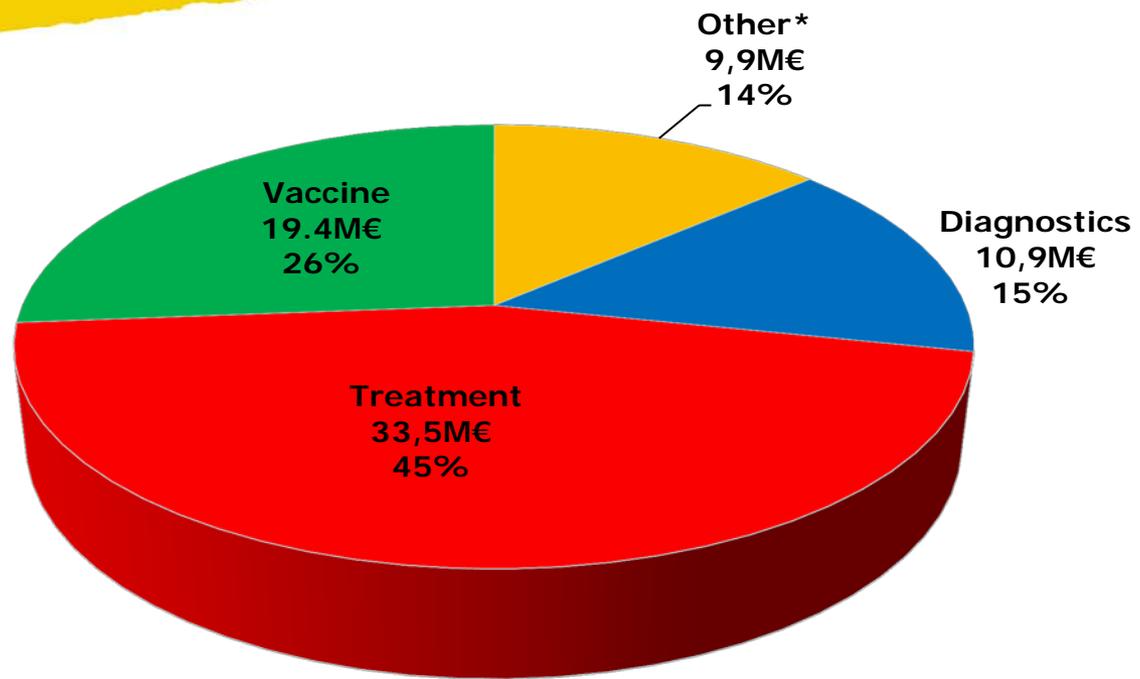
- Paediatric
- Second line ARVs
- HIV/TB coinfection

Prevention:

- PMTCT
- Preparatory studies for microbicides and vaccine development



TB Clinical Trials



Total funding TB research EDCTP: 73,800,973€

* Other include clinical research baseline studies, capacity building (i.e., fellowships)

- Shortening duration of TB treatment, uncomplicated TB
 - PanACEA: phase II/III evaluating moxifloxacin, rifampicin, SQ109
 - Rifaquin: phase III evaluating high dose rifapentine & quinolone
 - PK/PD studies
- Co-infections
 - Optimisation and drug-drug interactions studies of TB and HIV/malaria co-treatment
 - Lopinavir exposure is insufficient in children given double doses of lopinavir/ritonavir during rifampicin-based treatment for TB
 - Pharmacokinetic studies: rifampicin & efavirenz, rifampicin & isoniazid, rifabutin & lopinavir/ritonavir, rifampicin&artemisinin-based Rx
 - Impact of deworming on host immunity and clinical outcome in pulmonary TB
 - RCTs to prevent TB-Immune reconstitution inflammatory syndrome

Three subconsortia:

REMox: bring moxifloxacin beyond phase III

- Chief Investigator: Prof Stephen Gillespie, St Andrews, UK

HIGHRIF: bring high-dose rifampicin beyond phase II

- Chief Investigator: Prof Martin Boeree, RUNMC, the Netherlands

SQ109: bring SQ109 beyond phase II

- Chief Investigator: Prof Michael Hoelscher, LMU, Germany

Network

- 6 European research organisations
- 12 sub-Saharan clinical trial sites
- 3 pharma companies (Bayer, Sequella and Sanofi)

Objectives PanACEA

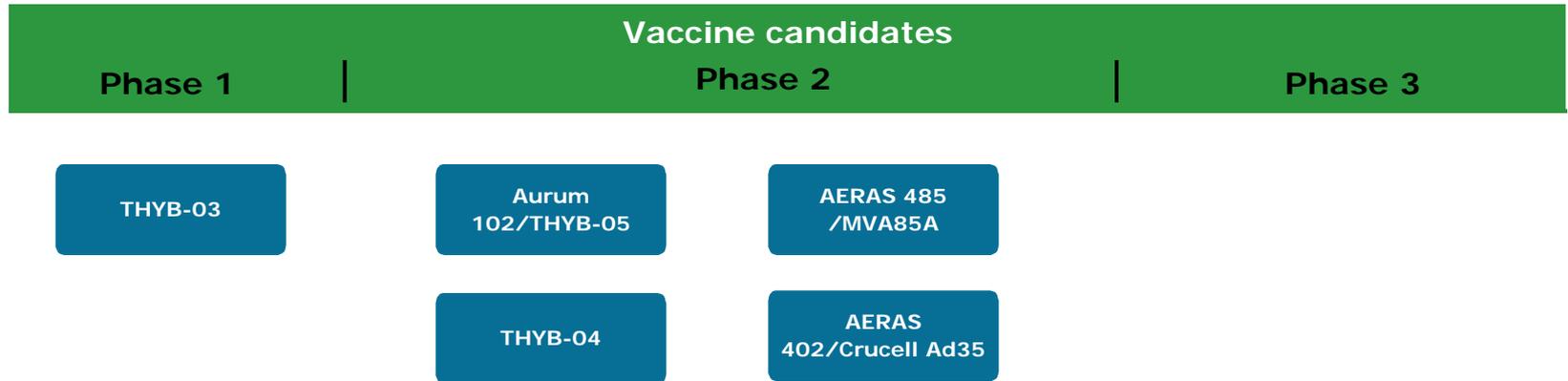
- Shorten and simplify treatment of uncomplicated pulmonary TB
- Increase TB clinical trial capacity in Africa
- Develop sustainable TB clinical trials network in Africa



EDCTP funded TB diagnostic trials



- Point of care diagnostics:
 - GeneXPERT/MTB/RIF assay – RCT (TB-NEAT Expert)
 - LAM lateral flow strip test – RCT (TB-NEAT LAM)
 - Evaluation of new and emerging diagnostics (TB-CHILD)
- Biomarkers:
 - Microbiological and immunological strategies in HIV-/HIV+ children (PROMISE-TB)
 - Host cytokine signatures in active TB (AE TBC)





Expanded scope under EDCTP2



- 10-year programme 2014-2023
- All phases of clinical trials (I-IV) including implementation research on the optimisation of health services
- Inclusion of neglected infectious diseases such as sleeping sickness, elephantiasis, buruli ulcer, leprosy, river blindness etc.
- Increased budget
 - EC proposal for funding: € 683 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



Calls for Proposals include 2 categories of activities:

1. Clinical research projects

- Integrated projects
 - Large scale collaborative projects to undertake full clinical trials in SSA. The projects must 2 EU partners & 1 partner from SSA.
 - 3-5 years, EDCTP contribution of EUR 5-15M.
- Strategic primer grants
 - Small scale collaborative projects addressing specific clinical research area, supporting a larger clinical study or undertaking a full, small-scale clinical trial, typically a phase I or IIa clinical trial in SSA.
 - 2-4 years, EDCTP contribution of EUR 1-3M.

2. Capacity Building

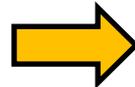
- Fellowships
- Networks of Excellence
- Ethics and Regulatory



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 to EDCTP
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 – TBD

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)

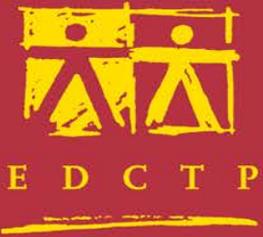


Expected outcomes of the TB and mycobacterial infections stakeholders' meeting



- Review of the current status in the field of TB and mycobacterial infections
- Identification of key research areas, current opportunities and barriers to progress
- Recommendations that will contribute towards the EDCTP strategy for supporting TB and mycobacterial infections 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



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