

Stakeholders' meeting on Malaria

19 September 2013

Austrian Ministry of Science and
Research

First district of Vienna, Freyung 3,
Vienna, Austria.

Michael Makanga, MD PhD.

EDCTP Director S-S 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

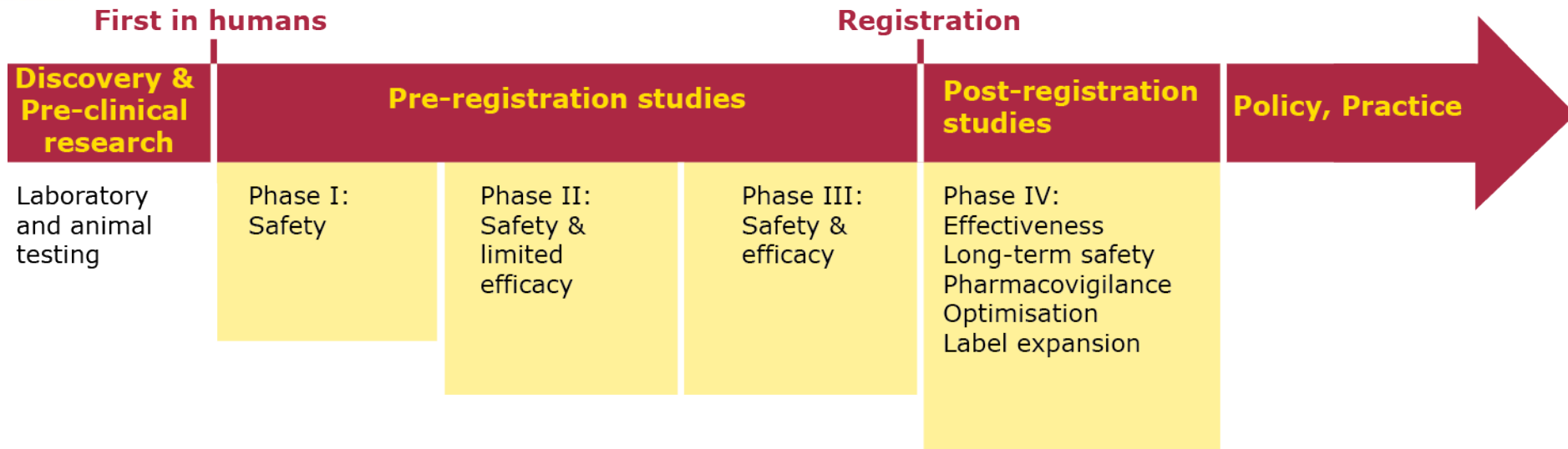
- Accelerate research and development of new or improved interventions against PRDs
- Coordination of the European member state national programmes working in **partnership** with sub-Saharan African countries
- Collaboration with the private sector and like-minded organisations.

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

- 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

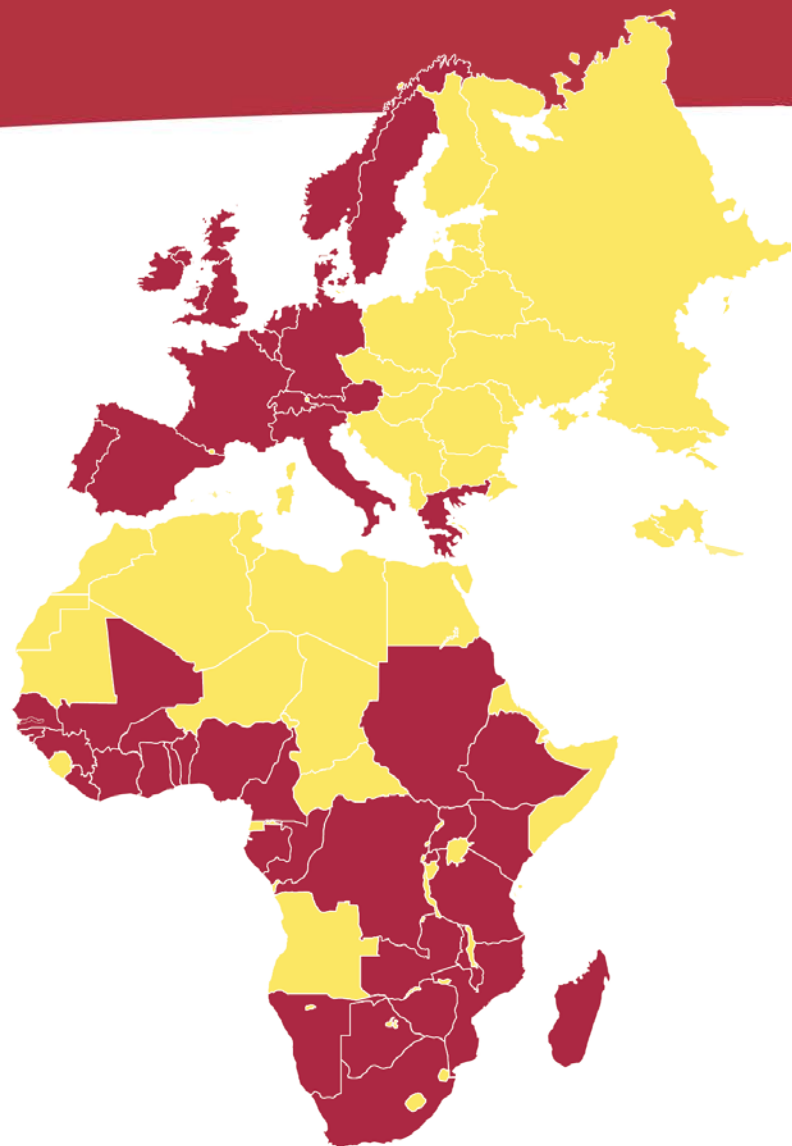
- Botswana
- Malawi
- Mozambique
- South Africa
- Zambia
- Zimbabwe
- France
- Germany
- Netherlands
- United Kingdom



Current EDCTP projects in a nutshell



• Number of projects	241
• Participating European countries	12
• Institutions	118
• Participating African countries	29
• Institutions	156
• Clinical trials	88
• Malaria	33
• HIV/AIDS	30
• Tuberculosis	25
• Capacity building in ethics	74
• Senior Fellowships	50
• Post docs	37
• PhD	143
• MSc	189



Previous Malaria Stakeholders' meetings (1)



- Malaria vaccines – January 2007, Copenhagen
 - Phase II candidate vaccines, including age de-escalating trials in infants and children
 - Artificial challenge IIa studies in non endemic countries of pre-erythrocytic vaccines were considered valuable but not a prerequisite
 - Artificial challenge with insectary-bred mosquitoes in endemic countries was not recommended
 - Capacity building.

Previous Malaria Stakeholders' meetings (2)



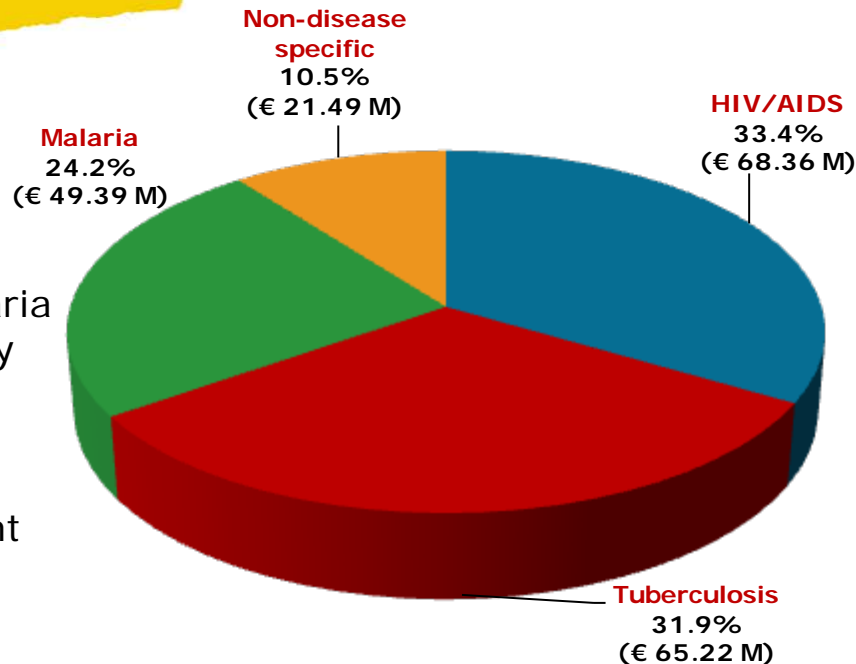
- Malaria treatment – June 2007, Vienna
 - Phase IIIb clinical trials: efficacy and safety assessment in special patients populations such as infants, HIV/AIDS and tuberculosis co-infected individuals; DDI studies on antimalarials with ARVs
 - Development of new antimalarials (phase II and III studies) both ACTs and non-ACTs
 - Systematic PK studies on available combination antimalarials especially ACTs in development and those already registered
 - Phase IV longitudinal studies in view of the long half lives of many of the partner drugs in the available ACTs.

Previous Malaria Stakeholders' meetings (3)



- Pregnancy associated malaria – June 2007, Vienna
 - Phase IIIb clinical trials on case management of malaria in pregnancy using alternatives to CQ and S-P with focus on efficacy and safety of antimalarials and systematic PK studies
 - Intermittent preventive treatment of malaria in pregnancy (IPTp) using alternatives to the standard S-P regimen (alternative drugs and dosing regimens to the 2 or 3 doses S-P regimen)
 - IPTp studies including HIV–infected pregnant women
 - Consortia approach instead of individual researchers were recommended for PAM studies.

Details on EDCTP grants



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

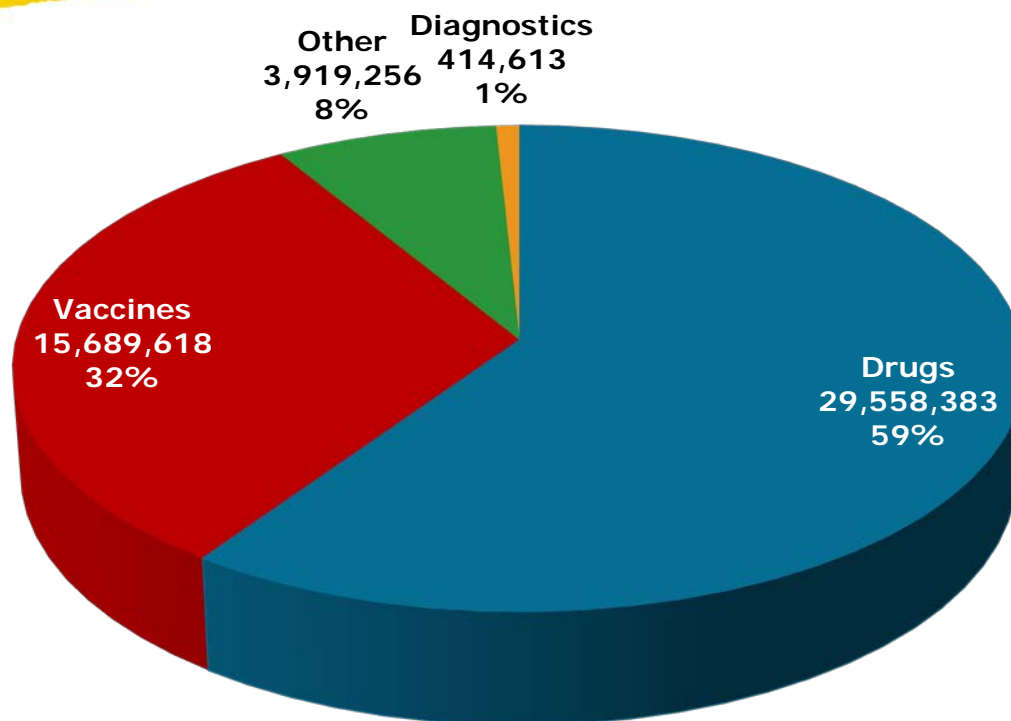
Treatment:

- Paediatric
- Second line ARVs
- HIV/TB coinfection

Prevention:

- PMTCT
- Preparatory studies for microbicides and vaccine development

Malaria Clinical Trials

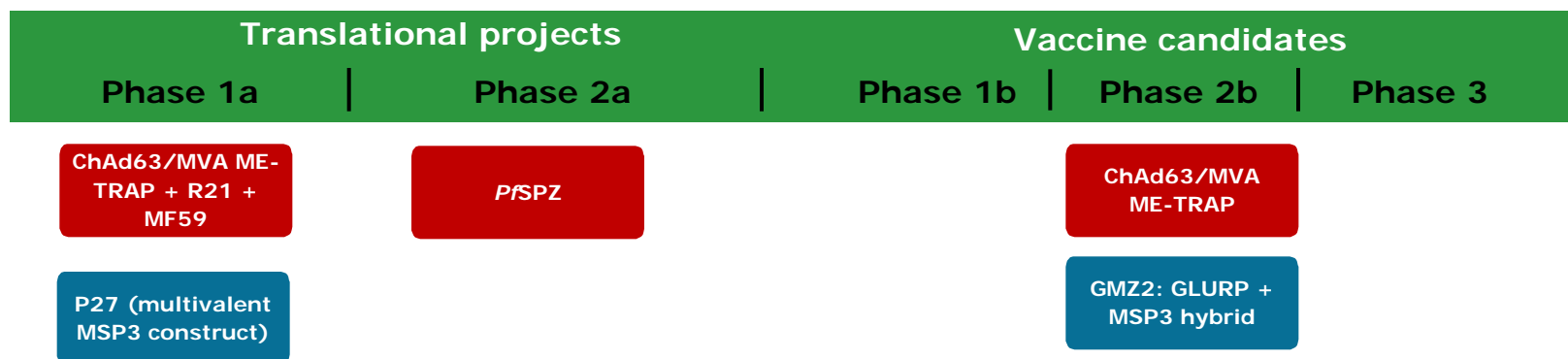


EDCTP funded Malaria clinical trials



- Uncomplicated malaria: Phase III/IV on all existing ACTs (AS-AQ, AS-MQ, DHA-PPQ and (AS-PRD) and non ACTs CL/QN: 11 trials
- Severe malaria: phase II/II evaluating IV/IM artesunate: 2 trials
- Pregnancy associated malaria
 - Case management (AS-AQ, DHA-PPQ, AS-MQ and AL): 1 trial
 - IPTp SP alternatives (MQ versus SP, screening and treatment with AL and DHA PPQ): 3 trials
 - IPTp in HIV infected individuals (MQ, SP and CTX): 2 trial
- Systematic PK and DDI studies in HIV infected individuals: AS-AQ, DHA-PPQ and AL: 2 trials.
- Malaria vaccine: 8 trials plus 4 in preparatory phase.

EDCTP funded clinical malaria vaccine studies



P. falciparum vaccines: ■ Pre-erythrocytic ■ Blood-stage

Transition to EDCTP2

- End of no-cost extension for EDCTP – 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, workplans**
 - Establishment of the Scientific Advisory Committee
 - Expansion of the Secretariat
 - Call on Epidemiological studies and capacity development
 - Inviting new EU Member States and Associated Countries

- Expanded scope of EDCTP2 under Horizon 2020
 - Involve all phases of clinical trials
 - Implementation research on health services optimisation
 - Partnering in phase III clinical trials
- Closer collaboration with partners
 - Acknowledgment of sub-Saharan contribution
 - Closer working relationship with the private sector
 - Closer ties with other international development partners
 - Potential collaborative research with other developing countries outside sub-Saharan Africa
- Improved governance
 - Implementation structure
 - Scientific Advisory Committee

Types of projects under EDCTP2

- Integrated Activities
 - Clinical trials; networking; project management; capacity strengthening
 - Ethics/Regulatory
 - Networks of Excellency
- 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
 - Simplified cofunding rules
- 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)
- Requires to be included and approved as part of EDCTP workplans

Joint Activities



- Undertaken by EDCTP-IS or any EDCTP Participating State with other countries or third parties
- Consortium model of funding
- Included and approved in EDCTP workplans
- 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 and evaluation)

Expected outcomes of the malaria stakeholders' meeting



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



www.edctp.org