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
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
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](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.tesafirica.org](http://www.tesafirica.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.
• 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.
• 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

**HIV/AIDS**

**Treatment:**
- Paedriatic
- 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
Malaria Clinical Trials

- **Drugs**: 29,558,383 (59%)
- **Vaccines**: 15,689,618 (32%)
- **Other**: 3,919,256 (8%)
- **Diagnostics**: 414,613 (1%)
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
- Sytematic 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

<table>
<thead>
<tr>
<th>Translational projects</th>
<th>Vaccine candidates</th>
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<tbody>
<tr>
<td><strong>Phase 1a</strong></td>
<td><strong>Phase 2a</strong></td>
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<tr>
<td>ChAd63/MVA ME-TRAP + R21 + MF59</td>
<td><em>PfSPZ</em></td>
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<tr>
<td>P27 (multivalent MSP3 construct)</td>
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*P. falciparum* vaccines:  
- Red: Pre-erythrocytic  
- Blue: 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
Building on the current programme

- 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
• 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