



# The European & Developing Countries Clinical Trial Partnership

**Fourth EDCTP Forum  
Burkina Faso 2007**

**Linking European and African programmes: role of  
European member states**

**Dr Diana Dunstan**  
*EEIG-Assembly Chair*



# EDCTP

Mission: “To accelerate the development of new clinical interventions to fight HIV/AIDS, malaria and tuberculosis in developing countries, particularly sub-Saharan Africa, and to improve generally the quality of research in relation to these diseases”

*Through the integration of Member States’ National Programmes*

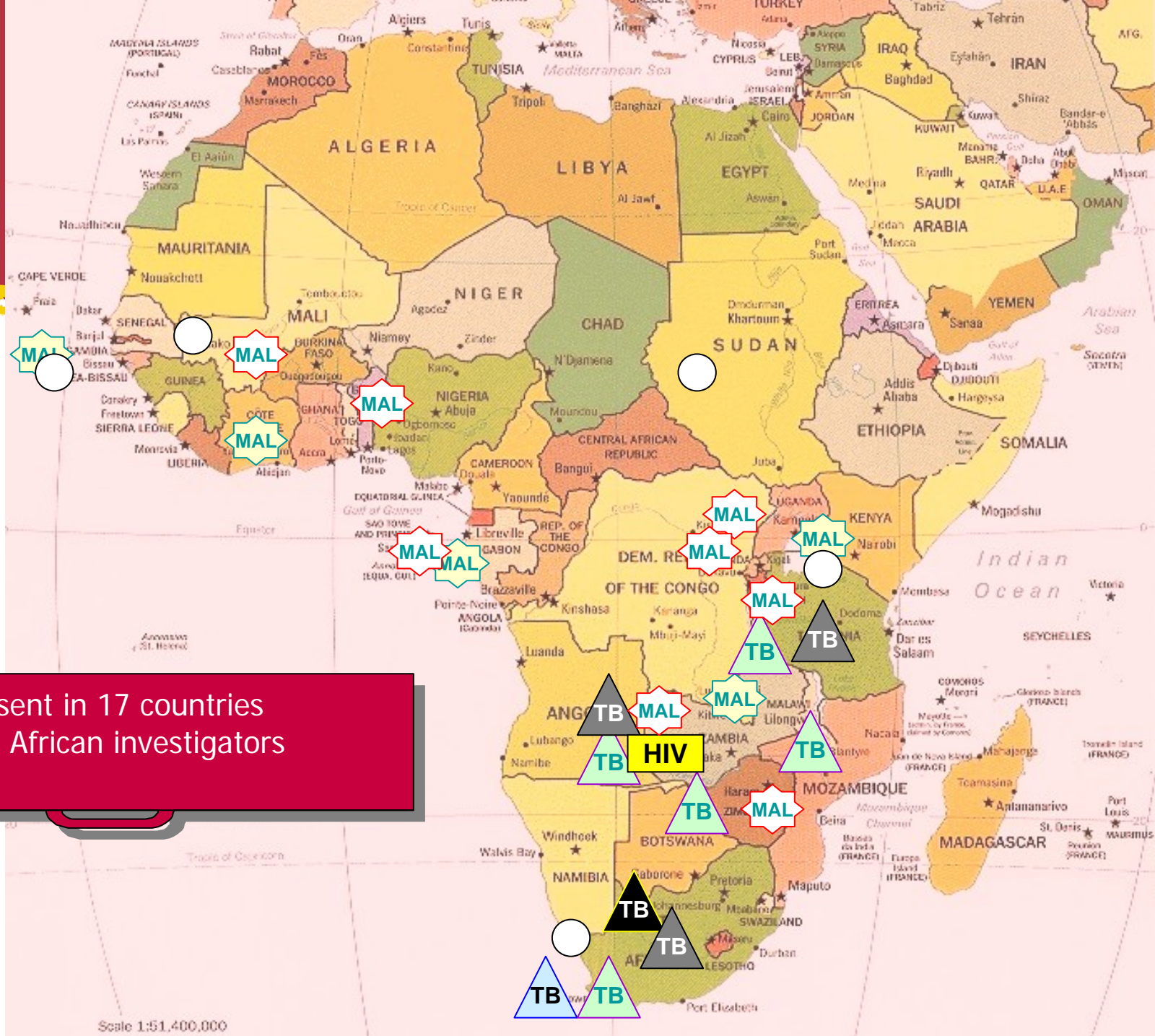
*And through equal and effective partnership with Africa and African researchers*





# Since last year's Forum

- Appointing a new Executive Director
- Making the 2006-2010 Roadmap a reality:
  - Better co-ordination and co-operation between MS National Programmes on PRDs.
  - More rapid and effective development of prevention and treatment of PRDs through clinical trial initiatives.
  - ✓ Stakeholder meetings
  - ✓ Joint call on capacity building and clinical trials for HIV with the Bill & Melinda Gates Foundation
  - ✓ 7 calls launched, 3 more due by end of year
- Real progress in understanding and implementation of the roles of all the components of EDCTP.



EDCTP present in 17 countries  
Support 64 African investigators



# Successes

## EDCTP Senior Fellows:

- Dr Alexis Nzila

Awarded a prestigious Royal Society prize for advancing discoveries into antifolate drugs for the treatment of malaria.

- Dr Abraham Alabi

One year extension recently approved for capacity building and multi-centre evaluation of a colorimetric HIV viral load assay developed by Dr Alabi. Long-term objective of wider use of a simple assay for monitoring HIV-infected patients on antiretroviral therapy

## Clinical Trials work:

- Professor Chifumbe Chintu

Information from this pharmacokinetic study contributed to the FDA granting tentative approval for a pill containing 3 anti-HIV drugs specifically formulated for children.



# *€20M joint call between the Bill & Melinda Gates Foundation & EDCTP – awards agreed*

## **Capacity Building In Preparation For The Conduct Of Preventive HIV Vaccine Trials**

*Six projects have been awarded with joint funding from many member states, EDCTP and Bill & Melinda Gates Foundation:*

### ***Deliverables include:***

- A capacity building plan, including training, upgrading of infrastructure and networking activities
  - Epidemiological baseline (cohort studies, retention, HIV incidence)
  - Virus isolation and characterisation
  - Immunological and virological characterisation of early infections
  - Population genetics
  - Studies in adolescent age groups
  - Studies on HIV exposed non-infected individuals (including discordant couples)
  - Social and behavioral studies relevant to HIV vaccine trials.
  - Other clinical research protocols (including other HIV interventions or non-HIV vaccines)
  - Phase II clinical trials of preventive HIV candidate vaccines.
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- Each consortium includes participants from at least **two** European countries which are members of the EDCTP, an Africa site with track record on HIV vaccine or related research (“**core**” site) and one or more additional sites in Africa, to develop and expand the number of “core” sites for future large scale trials.



# Build on progress: challenges for the Member States

- Researchers
- GA/ENNP
- Political commitment



# Member States

**Networking and Coordination of European national programmes on PRD and supporting activities in developing countries.**

**3 key Strategies:**

- **Project Integration**

- Linking existing projects and developing new ones

- **Institutional Collaboration**

- Forging alliances between national programmes

- **Coordination of National Funding**

- At the level of national ministries and funding agencies, development of joint research calls and promoting removal of barriers to cooperation



## Future work: ENNP

- EDCTP is carrying out a new analysis of Member States' research activities that lie within the remit of EDCTP, in order to identify where there may be scope for linking individual research efforts together into a Joint Programme.
- Where these activities can be validated as Joint Programme activities they may be eligible for additional EDCTP funding to enhance the research.
- MS co-funding to date is €60m, to match EDCTP/EU committed funds of €47m. MS commitment to co-funding for new current calls is encouraging.



## Future work: Political Commitment

- Much closer interaction by EDCTP, MS and EC with European development agencies and ministries of foreign affairs (as well as research agencies), particularly in order to facilitate capacity building and infrastructure for developing countries.
- Forging bridges internationally – e.g. Bill & Melinda Gates Foundation, Canadian International Development Agency.



## New Strategy 2007-2010: Joint funding of new projects

- 7 calls launched July & August 2007, 3 more to be launched December 2007 (World Aids Day)
- Focus on 9 topics:
  - TB vaccines
  - TB treatment
  - Malaria vaccines
  - Malaria treatment
  - Malaria and pregnancy
  - HIV vaccines
  - HIV treatment
  - HIV microbicides
  - Networks of Excellence
- A Stakeholder meeting held for each topic
- Large project approach with a focus on **products**
- Funding through open call or brokering



# Focus on the Future





# Independent Expert Review of EDCTP

## Key recommendations to Member States:

- Renewal of commitment by MS, including direct contribution to a common funding pot
- Greater African presence in relation to the General Assembly
- MS acceptance of single integrated scientific and ethical evaluation conducted by EDCTP
- MS that have made greater financial commitment should have greater decision-making power on the General Assembly.
- MS should enforce the Article 169 concepts in their own countries.