Creating and sustaining an enabling R&D environment in Africa

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DNDi – A decade of R&D for neglected diseases in Africa
Nairobi Kenya

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“If you think research is expensive, try disease”

- Mary Lasker
Parallels with capacity development

Creating
Strengthening
Enabling R&D environment = Capacity development
Sustaining

Capacity development is the process of creating, strengthening and sustaining ability to solve own problems:

Individual
Institutional
National/Regional (societal)
The full cycle of R&D: capacity and gaps

Discovery & Pre-clinical research
- Laboratory and animal testing

Pre-registration studies
- Phase I: Safety
- Phase II: Safety & limited efficacy
- Phase III: Safety & efficacy

Post-registration studies
- Phase IV: Effectiveness
  - Long-term safety
  - Pharmacovigilance
  - Optimisation
  - Label expansion

Policy, Practice

Good Clinical Practice
Good Clinical Laboratory Practice
Research Projects Management (contract, financial, IPR management, etc.)
Research Ethics Review
Regulatory oversight
Good Manufacturing Practice
Strengthening of clinical trials capacity and the enabling environment
Accountability, ownership and partnership

• Beneficiaries (Abuja Declaration)
  • Proactive involvement – gap analysis
  • Commitment
  • Utilisation and provision of supporting framework
  • Proliferation and sustainability plans

• External Development Partners (Paris Declaration, Cotonou Agreement)
  • Alignment and harmonisation
  • Relevancy
  • Long-term plans and commitment
  • Monitoring and evaluation
Capacity development

First in humans

Discovery & Pre-clinical research
Laboratory and animal testing

Pre-registration studies
Phase I: Safety
Phase II: Safety & limited efficacy
Phase III: Safety & efficacy

Registration
Post-registration studies
Phase IV: Effectiveness
Long-term safety
Pharmacovigilance
Optimisation
Label expansion

Policy, Practice

Research Ethics Committees: Institutional and National

African Vaccine Regulatory Forum (AVAREF)

African Medicines Regulatory Harmonization (AMRH) Programme

Pan-African Clinical Trials Registry (PACTR)
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.tesafrica.org](http://www.tesafrica.org)
Project Coordinator: Dr Alexander Pym
- Botswana
- Malawi
- Mozambique
- South Africa
- Zambia
- Zimbabwe
- France
- Germany
- Netherlands
- United Kingdom
Good clinical laboratory practice accreditation

Source: ASLM
Thank you