LEISHMANIASIS EAST AFRICA
PLATFORM: Strengthening
Research Capacities in Disease-Endemic Countries

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DNDi
A Fatal Imbalance

Tropical diseases (including malaria) and tuberculosis account for:
• 12% of the global disease burden
• Only 1.3% of new drugs developed

(1975-2004)

Tropical diseases: 18 new drugs (incl. 8 for malaria)
1.3%
21 new drugs for neglected diseases

Tuberculosis: 3 new drugs

98.7%
1,535 new drugs for other diseases

Source: Chirac P, Torreele E. Lancet. 2006 May 12; 1560-1561.
A New Model for Drug Development:
DNDi created in 2003

- Non-profit drug research & development (R&D) organization founded in 2003
- Addressing the needs of the most neglected patients
- Harnessing resources from public institutions, private industry and philanthropic entities

7 Founding Partners

- Indian Council for Medical Research (ICMR)
- Kenya Medical Research Institute (KEMRI)
- Malaysian MOH
- Oswaldo Cruz Foundation Brazil
- Medecins Sans Frontieres (MSF)
- Institut Pasteur France
- WHO/TDR (permanent observer)

7 worldwide offices
DNDi’s Objectives

• Deliver **6 - 8 new treatments by 2014** for sleeping sickness, Chagas disease, leishmaniasis and malaria
• Establish a **robust pipeline** for future needs
• Use and strengthen existing **capacity in disease-endemic countries**
• Raise awareness and advocate for increased **public responsibility**
Challenges for Clinical R&D

- Research capacity
- Health system barriers
  - Infrastructure
  - Logistics
  - Communications
- Geography/climate
- Different regulatory environments
- Funding
Idea for Platforms Started in 2003

- 1st DNDi Africa meeting
  - 7-9 May 2003, Nairobi: 18 African countries, 71 participants
- Neglected, marginalized, forgotten, invisible diseases
- Consensus conclusion: more action, fewer words
- Desire to collaborate to solve many health crises plaguing Africa
  - For diseases urgently needing improvement of treatments: LEAP, HAT Platform
**Leishmaniasis East Africa Platform (LEAP)**

**SUDAN:** 2 sites (Kassab, Dooka)
- Univ. of Khartoum
- Federal Ministry of Health

**ETHIOPIA:** 2 sites (Gondar, Arba Minch)
- Addis Ababa Univ.
- Gondar Univ.
- Ministry of Health

**UGANDA:** 1 site (Amudat)
- Makerere Univ.
- Ministry of Health

**KENYA:** 2 sites (Nairobi, Kimalel)
- KEMRI
- Ministry of Health

A group of scientists and institutions working on developing clinical trial capacity to bring new treatments to patients

Industry partners:
- MSF
- I+ solutions
- LSH&TM
- AMC/SU/KIT (ASK)
- IOWH -India

**LEAP**

*Drugs for Neglected Diseases initiative*
LEAP Objectives

- Facilitate clinical testing and registration of new treatments for VL in the region (Ethiopia, Kenya, Sudan and Uganda)

- Evaluate, validate and register improved options that address regional needs for VL

- Provide capacity strengthening for drug evaluation and clinical studies in the region
Activities

Coordination

• DNDi Africa office at KEMRI established
  – Building and coordination of African LEAP network
  – Support implementation of DNDi research projects
  – Advocacy campaigns: African neglected diseases

• Biannual investigator meetings to coordinate
  – R&D activities
  – Share experiences
  – Conduct training
  – Liaise with clinical monitors and Data safety monitoring board
The LEAP Team

(Photo courtesy of Dr M Wasunna)
Activities
Training

• A needs-driven approach, adapted per region
• Training of investigators to conduct research to international standards: Good Clinical Practice
  • Training of trial staff (needs, level, methods)
  • Ethics concepts (GCP, informed consent etc)
  • Standard operating procedures (SOPs)
  • Documentation & Safety reporting
• Disease training: patient assessment and care, diagnosis & lab training, etc
• Training for Monitors and DSMB
Infrastructure upgrades

1. Ethiopia, Gondar University Hospital: LR&TC

2. Kenya, Kimalel Health centre – opened as a LEAP site in January 2009

3. Sudan, Dooka- development of a Laboratory Technologist & Clinical training centre, treatment centre & research site
Activities
LEAP clinical trial sites
Capacity strengthening

Renovation and re-equipping of clinical laboratories to high standards
April to June 2007: AMREF laboratory audits in Kenya, Sudan & Ethiopia

Positive and recommendations prioritized and gradually implemented
Activities
Research

• Facilitate multi-country, multi-centre studies
  – Paromomycin
  – AmBisome®
  – Miltefosine (in preparation)
  – Regional drug sensitivity testing
  – Others studies: cost effectiveness evaluations

• Regional pool of clinical trial expertise has been created
  – LEAP Platform serving as forum for members to share their clinical & research experience
Activities

Adapting national guidelines

• The platform supports the review and roll out of VL National Guidelines for member countries
  – National Diagnosis and Treatment Guidelines in Ethiopia are being rolled out.
  – National VL treatment guidelines are available for Sudan and Kenya.
  – The Uganda VL treatment guidelines are about to be finalized.
Communications

- Communicating work of DNDi & advocacy for NTDs
  - Platform meetings, newsletters, stakeholders’ meetings

- International dissemination of scientific results
  - Various presentations and symposia at key international meetings including RSTMH in 2007 and WorldLeish2009
Lesson learned

• Difference in cultural backgrounds appreciated in order to continue working as a team
• Communication and frequent consultations key to success of platform & in steering activities
• A wide membership of the platform: MoH and regulatory authorities of member countries that provide desired support towards achieving the platforms objectives
• Each member institution appreciated as an equal partner that plays an integral part towards the success of the platform
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By working together in a creative way, local partners, PDPs, private and public sector can bring innovation to neglected patients!