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

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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)

98.7%
1,535 new drugs for other diseases

100% 100%
Tropical diseases: 18 new drugs (incl. 8 for malaria)
Tuberculosis: 3 new drugs
1.3%
21 new drugs for neglected diseases

Source: Chirac P, Torreele E. Lancet. 2006 May 12; 1560-1561.
Presented by Manica Balasegaram, DNDi
ECOSOC Innovation Fair, July 7, 2009 – Geneva, Switzerland

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
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**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

## LEAP clinical trial sites
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Activities

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.

Activities

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!

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