

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

**LEAP**  
Leishmaniasis East Africa Platform

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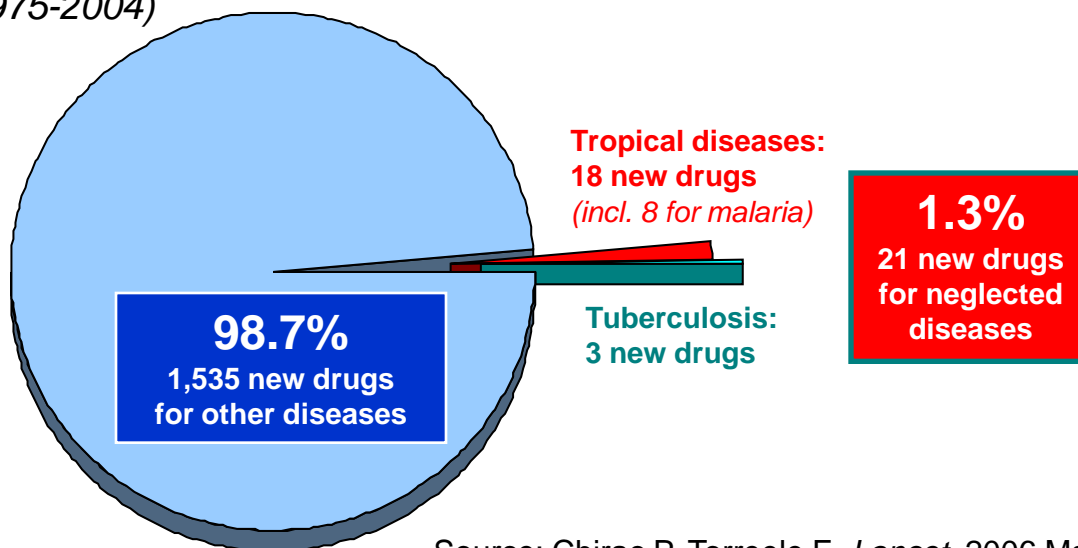
# A Fatal Imbalance

**Tropical diseases (including malaria) and tuberculosis account for:**

- 12% of the global disease burden
- Only 1.3% of new drugs developed



(1975-2004)



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)



# 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**

Discovery

Preclinical

Clinical

Available to patients

High-Troughput  
Screening at IPK



Lead Opt. Consortium:  
Advinus, CDRI, IRD, Anacor

Combination Therapy



LEAP Platform

# 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

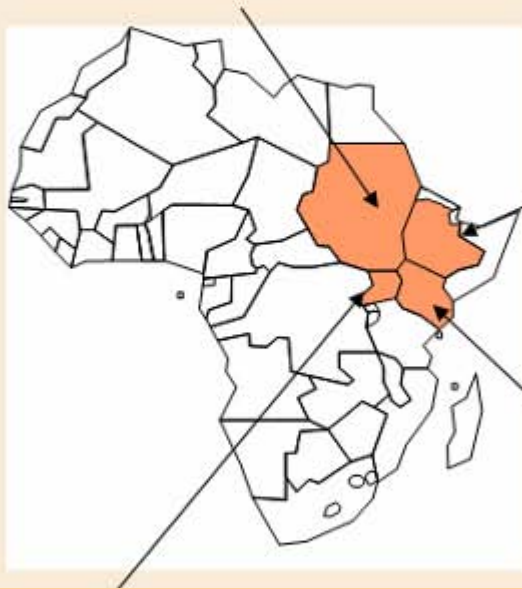
- **1<sup>st</sup> DNDi Africa meeting**
  - 7-9 May 2003, Nairobi: 18 African countries, 71 participants
- **Neglected, marginalized, forgotten, invisible diseases**
- **Consensus conclusion: more action, fewer words**
- **Desire to collaborate to solve many health crises plaguing Africa**
  - For diseases 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



**DNDi**



## **KENYA: 2 sites (Nairobi, Kimalale)**

KEMRI  
Ministry of Health

## **UGANDA: 1 site (Amudat)**

- Makerere Univ.
- Ministry of Health

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

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

**DNDi**

Drugs for Neglected Diseases initiative

**LEAP**  
Leishmaniasis East Africa Platform

# 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





## Activities

# Infrastructure upgrades

### 1. Ethiopia, Gondar University Hospital: LR&TC



**Previous VL Treatment ward  
Gondar**



**Current VL Treatment centre and  
Physiotherapy Dept, Gondar**

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

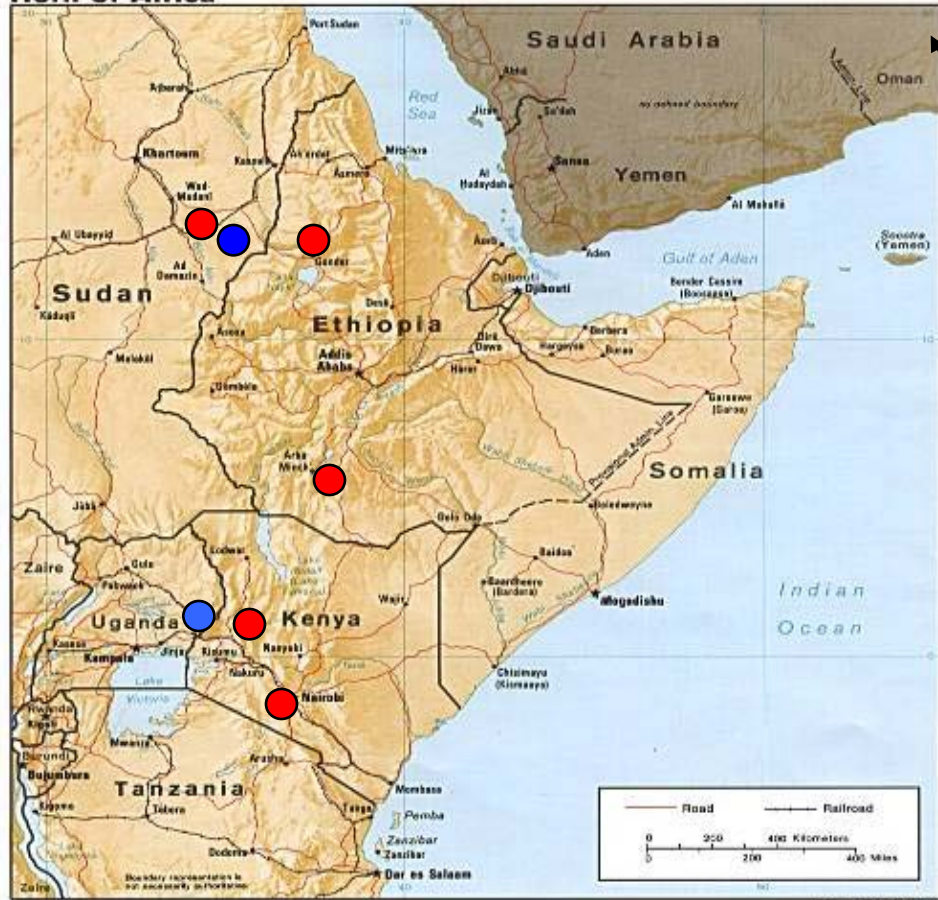
3. Sudan, Dooka- development of a Laboratory Technologist & Clinical training centre, treatment centre & research site



## Activities

# LEAP clinical trial sites

Horn of Africa





## 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

# LEAP would not be possible without funding from...

- Department for International Development (DFID), United Kingdom
- International Solidarity, Republic and Canton of Geneva, Switzerland
- Médecins Sans Frontières, International
- Medicor Foundation, Liechtenstein
- Ministry of Foreign and European Affairs (MAEE), France
- Region of Tuscany, Italy
- Spanish Agency of International Cooperation for Development (AECID), and
- Other private foundations and individual donors who wish to remain anonymous.



By working together in a creative way, local partners, PDPs, private and public sector can bring innovation to neglected patients!



[www.dndi.org](http://www.dndi.org)

**DNDi**

Drugs for Neglected Diseases *initiative*

**DNDi**

Drugs for Neglected Diseases *initiative*