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

LEAP
Leishmaniasis East Africa Platform

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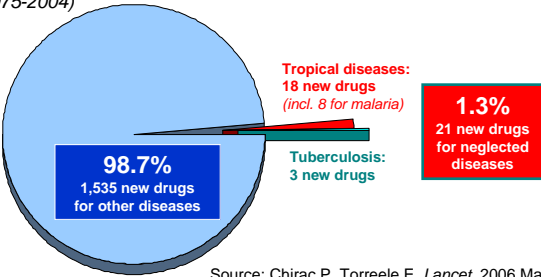
A Fatal Imbalance

Tropical diseases (including malaria) and tuberculosis account for:

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



(1975-2004)



Category	Percentage	Number of New Drugs
Other diseases	98.7%	1,535
Tropical diseases (incl. malaria)	1.3%	18
Tuberculosis	1.3%	3
Total for neglected diseases	1.3%	21

Source: Chirac P, Torreale E. *Lancet*. 2006 May 12; 1560-1561.

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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

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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

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Challenges for Clinical R&D

- Research capacity
- Health system barriers
 - Infrastructure
 - Logistics
 - Communications
- Geography/climate
- Different regulatory environments
- Funding



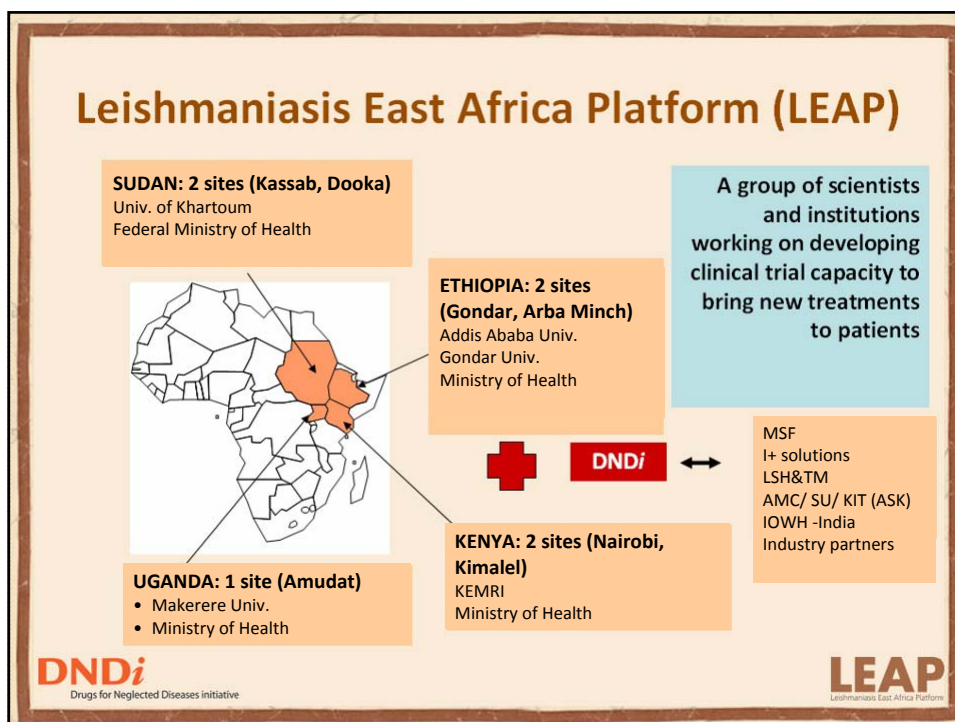
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Idea for Platforms Started in 2003

- **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

DNDi Drugs for Neglected Diseases initiative

LEAP Leishmaniasis East Africa Platform

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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

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The LEAP Team



(Photo courtesy of Dr M Wasunna)

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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

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Activities Infrastructure upgrades

1. Ethiopia, Gondar University Hospital: LR&TC



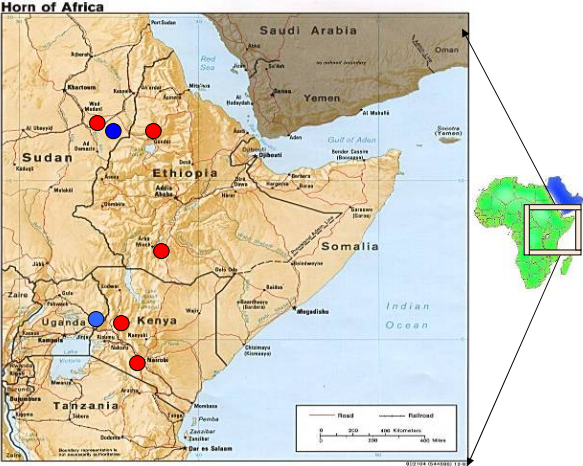
Previous VL Treatment ward
Gondar

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

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Activities LEAP clinical trial sites



Horn of Africa

Saudi Arabia
Yemen
Ethiopia
Sudan
Kenya
Uganda
Tanzania
Somalia

Road
Railroad


0 250 500 Kilometers
0 250 500 Miles

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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



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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

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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.

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Activities
Communications

- Communicating work of DNDi & advocacy for NTD s
 - Platform meetings, newsletters, stakeholders' meetings
- International dissemination of scientific results
 - Various presentations and symposia at key international meetings including RSTMH in 2007 and WorldLeish2009



TheLancet.com

LEAP and DNDi step up to the challenge of developing better treatments for visceral leishmaniasis in Africa

DNDi LEAP

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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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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

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