

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

LEAP
Leishmaniasis East Africa Platform

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DNDi



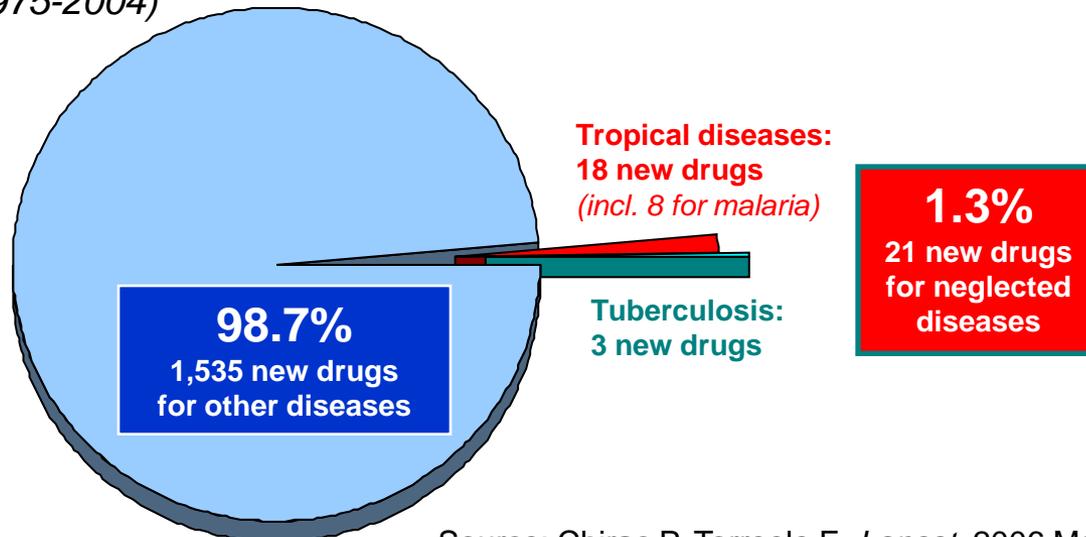
A Fatal Imbalance

Tropical diseases (including malaria) and tuberculosis account for:

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



(1975-2004)



Source: Chirac P, Torrele 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

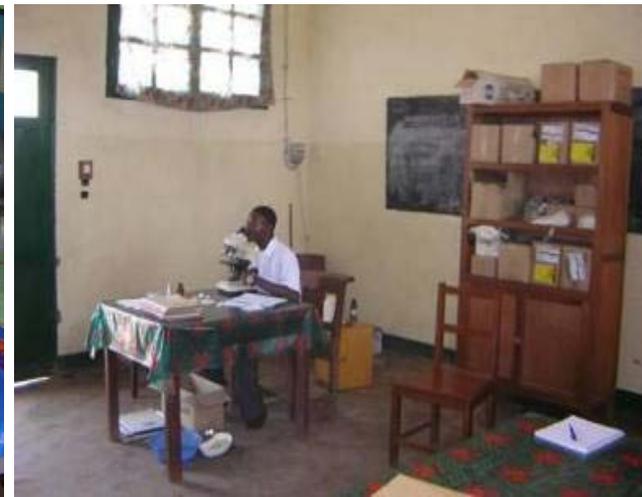
Combination Therapy



LEAP Platform

Challenges for Clinical R&D

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



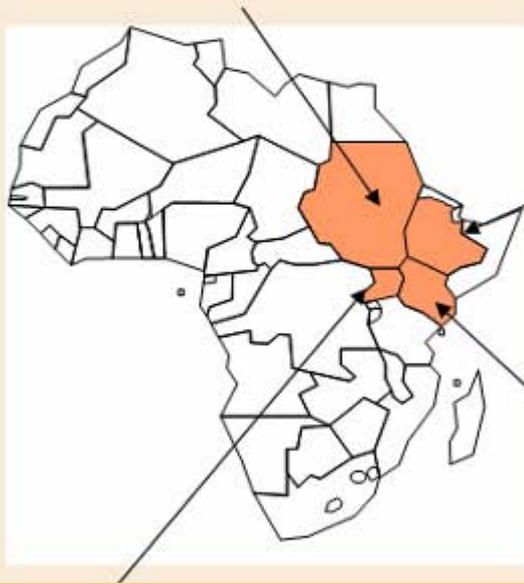
Idea for Platforms Started in 2003

- **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)

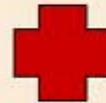
SUDAN: 2 sites (Kassab, Dooka)

Univ. of Khartoum
Federal Ministry of Health



ETHIOPIA: 2 sites (Gondar, Arba Minch)

Addis Ababa Univ.
Gondar Univ.
Ministry of Health



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KENYA: 2 sites (Nairobi, Kimalel)

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

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

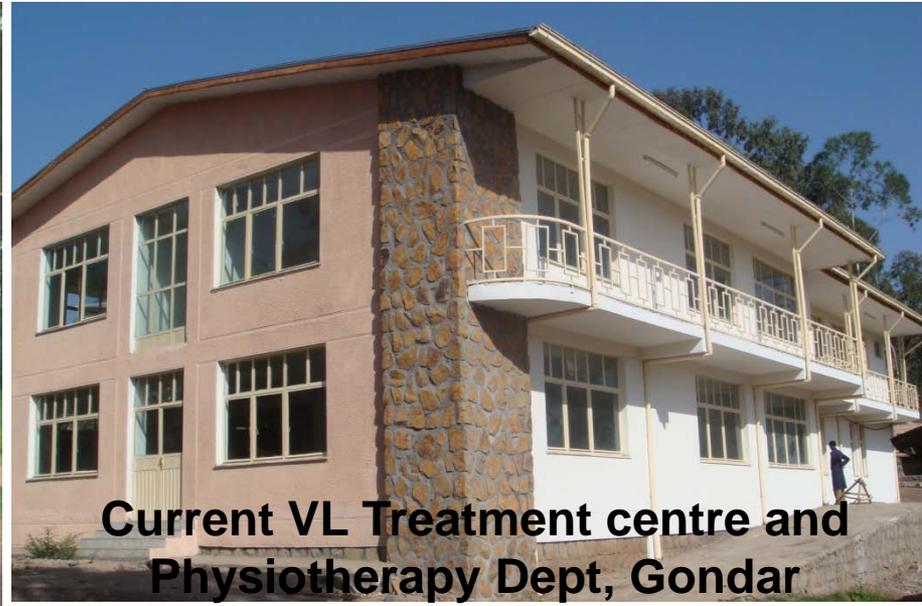
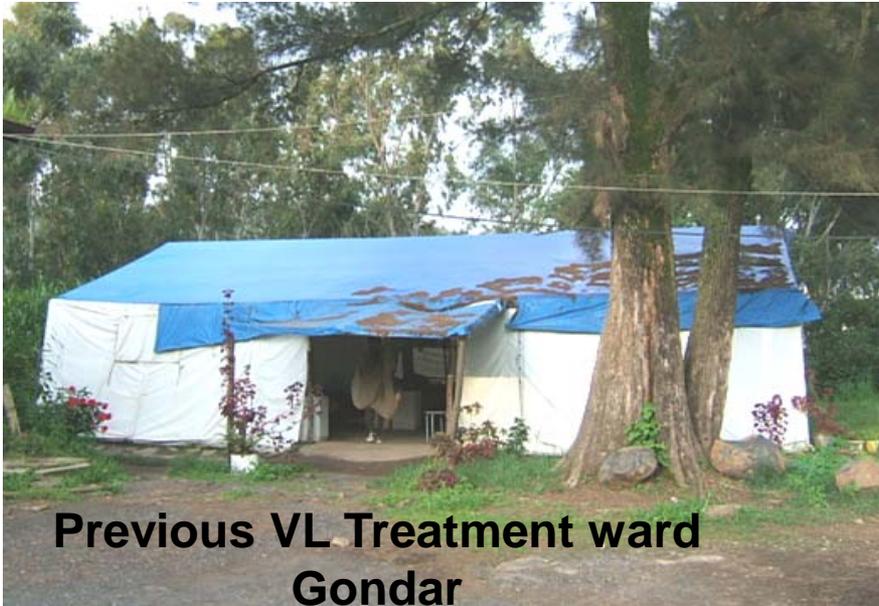
- A needs-driven approach, adapted per region
- Training of investigators to conduct research to international standards: Good Clinical Practice
 - Training of trial staff (needs, level, methods)
 - Ethics concepts (GCP, informed consent etc)
 - Standard operating procedures (SOPs)
 - Documentation &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



Activities

Infrastructure upgrades

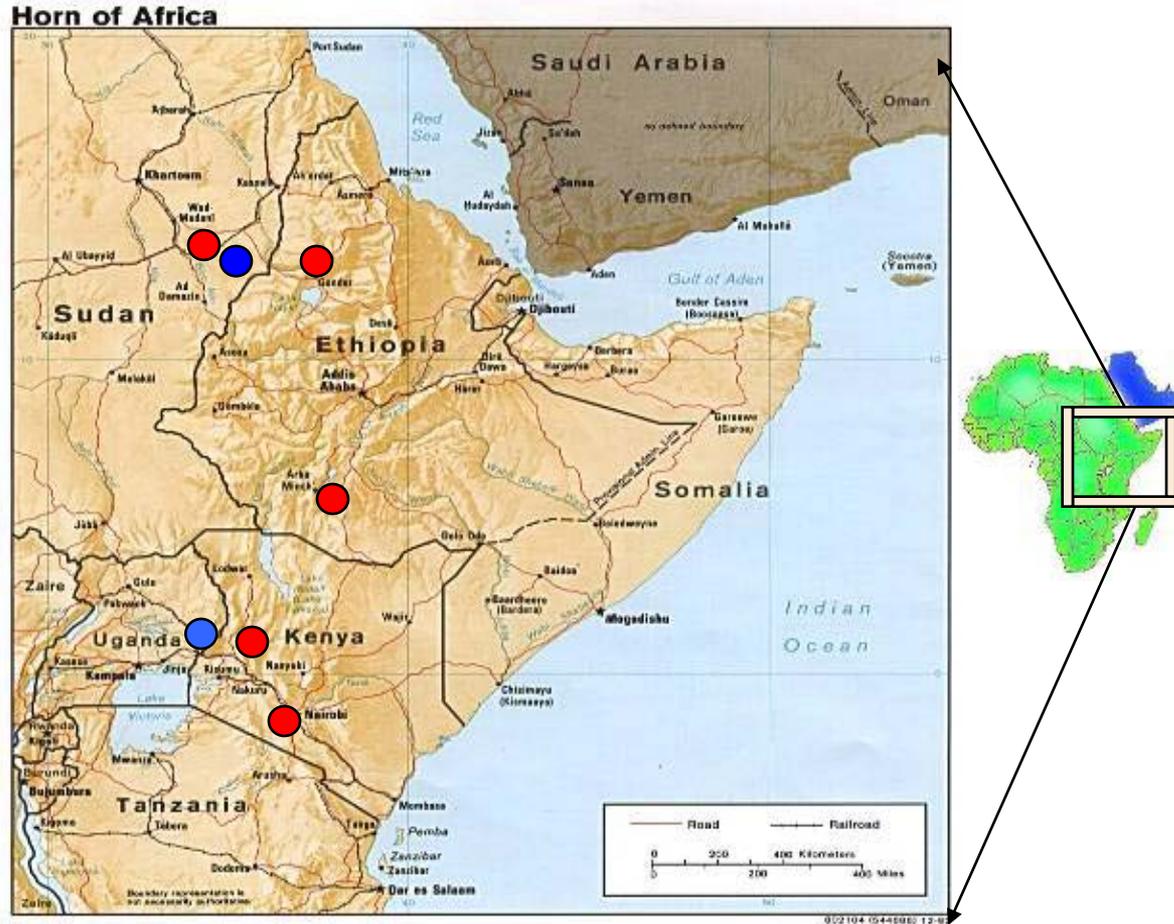
1. Ethiopia, Gondar University Hospital: LR&TC



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



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 findings 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 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

A STEP TOGETHER IN THE RIGHT DIRECTION



TheLancet.com

Ongoing neglect of leishmaniasis



...of the world's most neglected diseases, leishmaniasis, is a chronic infection that causes disfigurement and death. It is caused by a parasite that is transmitted by sandflies. The disease is most common in poor, rural areas of Latin America, the Mediterranean basin, and sub-Saharan Africa. It is a major cause of blindness and disfigurement in these regions. The Lancet is calling for more research and funding to address this neglected disease.

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

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

DNDi

Drugs for Neglected Diseases *initiative*

DNDi

Drugs for Neglected Diseases *initiative*