



LEAP LEISHMANIASIS EAST AFRICA PLATFORM

Building sustainable clinical research capacity
to deliver new treatments for patients in need



Inauguration of Gondar Leishmania Research and Treatment Centre, May 2008

About the platform

Launched in 2003 with the support of DNDi, LEAP brings together scientists and institutions in East Africa to develop clinical trial capacity to bring new treatment options to neglected Visceral Leishmaniasis (VL) patients in the region. LEAP is coordinated by the DNDi Africa office based in Nairobi, Kenya, at the Kenya Medical Research Institute (KEMRI).

Why focus on VL in East Africa?

- If untreated, VL is fatal
- Field-relevant treatments are scarce and far from optimal
- VL in Africa primarily affects children (over 60%)
- VL is a poverty-related disease
- East Africa is one of the most important foci for VL in the world
- Population displacements have exacerbated the spread of VL

Objectives

The LEAP mandate is to

- Study, validate, and facilitate registration of improved treatment options for VL in the East African region (Ethiopia, Kenya, Sudan, and Uganda)
- Provide capacity strengthening for treatment, evaluation, and clinical studies in the region

Approach and added value

A good example of South-South collaboration, LEAP joins regional efforts to address the high burden of VL by engaging the research community with regional health and regulatory authorities. The platform, giving priority to addressing first and foremost the **needs of patients**, develops joint proposals and seeks joint funding for its activities.

Added value and challenges addressed by LEAP

- Strengthening existing capacities for conducting clinical trials in East Africa – infrastructure and training
- Eliminating duplication of effort – time taken to get meaningful results is minimized
- Accelerating registration and adoption of much needed new VL treatments in member countries
- Facilitating the sourcing of research funds by collaboration with partners

LEAP's composition and the engagement of its members allow the platform to maintain its position as a group of reference, trusted by the international scientific community. This is due to the fact that ownership of LEAP lies with its members and that regulators and ministries of health participate in LEAP.

Taken together, these elements allow for efficient translation of research results into policy.



Uganda, South-South capacity building: Sudanese doctor and investigator train Ugandan colleagues on VL diagnosis and treatment, 2008.

Achievements

By focusing activities to responding to unmet needs, testing new treatments for VL in Africa, and strengthening capacity, LEAP has achieved the following since its inception:

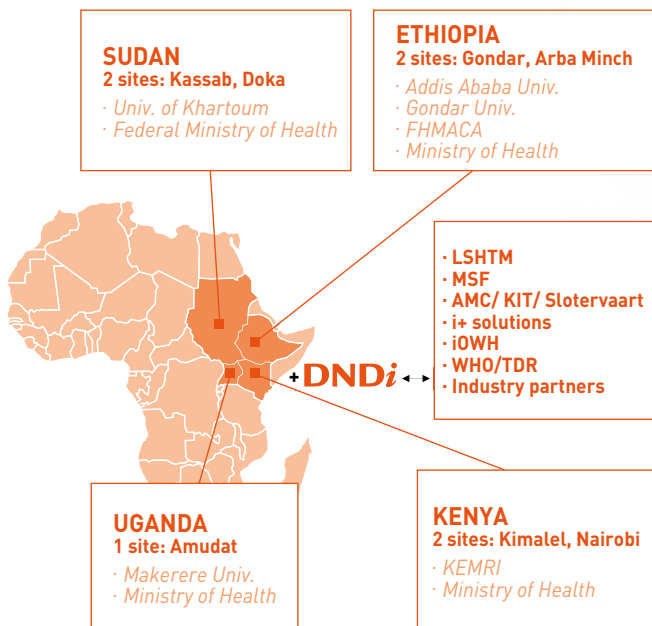
SSG&PM, a new, improved combination treatment for VL delivered in 2010

- World Health Organization (WHO) Expert Committee on the Control of Leishmaniases recommended SSG&PM as first-line treatment for VL in East Africa
- Integrated in the Sudanese National VL Guidelines

Clinical Trials

- Completion of LEAP 0104 paromomycin multi-country clinical trial (1100 patients)
- Ongoing liposomal amphotericin B (AmBisome®) combination trial for Africa
- Study of rapid diagnostic tests

LEAP - Leishmaniasis East Africa Platform



Sustainable capacity strengthening in Ethiopia, Kenya, Sudan, and Uganda

A few examples, in the following domains:

Training

- Good Clinical Practice (GCP)/Good Laboratory Practice (GLP) training for investigators, nursing staff, and laboratory technologists
- Establishment and training of Data and Safety Monitoring Board (DSMB); currently three sets of DSMB
- Training of clinical trial monitors
- Development of a regional data management centre

Infrastructure

- Building of two research and treatment centres in Ethiopia: Arba Minch and Gondar
- Site opened in Kimalael, Kenya
- Significant upgrading and opening of Professor El Hassan Centre for Tropical Medicine, Doka, Sudan

Communication and Advocacy

- Regular communications – biannual meetings, scientific conferences
- Important scientific publications

Before



After



The Professor El Hassan Centre for Tropical Medicine in Doka, Sudan, undergoes major renovation and expansion in 2010.



LEAP - DNDi Africa

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LEAP Partners

- University of Khartoum, Sudan
- Addis Ababa University, Ethiopia
- Gondar University, Ethiopia
- Makerere University, Uganda
- Kenya Medical Research Institute (KEMRI)
- Ministries of Health of Kenya, Uganda, Ethiopia, and Sudan
- Drug regulatory authorities in Kenya, Uganda, Ethiopia, and Sudan
- London School of Hygiene and Tropical Medicine (LSHTM)
- Médecins Sans Frontières (MSF)
- i+ solutions, The Netherlands
- ASK (AMC, Slotervaart Hospital, KIT), The Netherlands
- Institute for OneWorld Health (iOWH), USA
- UNICEF/UNDP/World Bank/WHO's Special Programme for Research and Training in Tropical Diseases (TDR)
- Drugs for Neglected Diseases *initiative* (DNDi)

Donors

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