



**LEAP**  
LEISHMANIASIS  
EAST AFRICA PLATFORM

# LEAP @ 15: Our Journey Through the Years

*Dr. Monique Wasunna, Director, DNDi Africa Regional Office  
LEAP Meeting, 3rd October 2018, Uganda*

# Our Beginnings

May  
2003

1

## 1<sup>st</sup> DND Africa Meeting

7-9<sup>th</sup> May 2003, Nairobi

*A desire to collaborate and resolve the many health problems*



# Our Beginnings

2

## Creation of DNDi: as a Patient Needs-Driven & Innovative R&D Model

July  
2003

*DNDi commits to create disease specific platforms*

**DNDi**

Drugs for Neglected Diseases *initiative*

Drugs for Neglected Diseases *initiative* (DNDi) is a collaborative, patients' needs-driven, non-profit drug research and development (R&D) organization that is **developing new treatments for neglected diseases**



# Our Beginnings

August  
2003

## 3 Follow up meeting in Khartoum Sudan

LEAP platform born (Ethiopia, Kenya Sudan)

*A desire to collaborate realized*



The Late  
Dr. Rashid  
Juma

# First Clinical trial

Oct  
2004

## LEAP 0104 Study begins

- Patients aged 4-60 years with VL enrolled
- Primary and secondary efficacy outcomes were parasite clearance at 6-months follow-up and end of treatment.



# Data Centre Created

Oct  
2004

**Data Centre established in  
Africa office** to carry out data  
management for LEAP studies



# Our Journey

2006

## Uganda Joins LEAP

Uganda joins LEAP  
during the LEAP  
0104b clinical trial



# Our Journey

2010

**SSG&PM**  
**Recommended**  
**first-line treatment**  
**for VL** in Eastern  
Africa by the WHO  
Expert Committee  
on Control of  
Leishmaniases





# Our Journey

2018

## Begun Miltefosine/PM study

**objective:** To compare the efficacy of two combination regimens of PM (14 days) and MF (14 or 28 days) with the standard 17-day course of SSG-PM for the treatment of primary VL patients in eastern Africa

**Secondary objectives:** safety, PK, PD, compliance to oral treatment



# Capacity Strengthening Activities



## LAB UPGRADING

Laboratories in very remote regions have been upgraded to support globally recognized clinical trials with GCP standards



## TRAINING

Over 30 long-term trainings conducted in the region

Over 800 received short-term trainings such as GCP, GCLP and GFP

# Capacity Strengthening Activities



**Before**



**After**

## INFRASTRUCTURE DEVELOPMENT AND UPGRADING

- New clinical trial sites and treatment centres built in Sudan, Ethiopia
- Renovations in Uganda and Kenya
- Infrastructures supports both clinical trials and treatment of leishmaniasis patients
- Over 11,000 VL patients treated within and outside clinical studies (2010-2017)

# Accountability to Stakeholders **Dissemination to Stakeholders**



Community stakeholders meeting



LEAP meetings



Study results dissemination to communities



Study results dissemination to Ministries of Health



# Awareness Creation



## Awareness creation through:

- Mass media
- Various websites
- Social Media
- Participating in local and global conferences



# Access to Treatments



Training of health workers on leishmaniasis guidelines



Supporting change of country policies to include up to date treatments and diagnostics

- SSG & PM registered in Sudan, Kenya and Uganda
- About 11000 patients have been treated within and outside VL clinical trials in LEAP sites

# The Future: LEAP 2.0



LEAP 2.0 is a restructuring of the platform in line with increasing clinical trial needs in the region and DNDi Business Plan 2015-2023

## Focus

- Sustained advocacy and communication
- Proactive engagement with stakeholders
- Focus on building stakeholder capacity to ensure access

# Changes: From LEAP to LEAP 2.0

- Portfolio includes **VL, PKDL and CL**
- **New areas of activity** (access, phase I studies, data sharing – IDDO)
- **Membership**
  - Geographical extension (Eritrea, South Sudan, Somalia)
  - Institutional and individual members
  - Formalize partnerships
    - Clear partner roles, specific goals and responsibilities, including agreements with precise R&D deliverables
    - Encourage visibility of LEAP in partner institutions
  - Formalize membership
    - Active, updated, consistent and readily available database.

# Changes: From LEAP to LEAP 2.0

## Governance

- Adopting the LEAP Advisory Committee to be launched in October in Uganda
  - Include all stakeholders (current country PIs, reps from partner institutions, individuals (based on desired expertise), Ministries of Health
    - **Increased stakeholder engagement in developing a common agenda**
  - New and young scientists to engage at a higher level within the platform (new ideas).
  - Transition planning strategy (mentorship caucus)
  - PI per project not per country to promote increased participation of young scientists in the research process

## Develop Code of Practice for use of DNDi supported sites

- To enable donors, have greater transparency into resources attributed to DNDi activities in relation to LEAP partner activities

# Challenges of LEAP



- 1 **Overcoming regulatory barriers** - Different regulatory processes in the countries make it difficult to conduct studies
- 2 **Access to treatments** - Transforming regulatory approval to country adoption and implementation
- 3 **Policy environment** - Securing an enabling policy environment including clear global norms on IP management
- 4 Ensuring **sustainable financing** for R&D towards NTDs
- 5 **Research capacity** - Lack of/different levels of capacity
- 6 **Tough terrain** - Endemic regions are often **difficult to work in**



# Summary: LEAP achievements in numbers



**2 Studies** – currently ongoing



**8 studies** completed with



**60 members** of LEAP



**13 publications** in peer reviewed journals



**8 existing** study sites



**Over 11,000 VL patients** treated within and outside clinical studies (2010-2017)



**One treatments delivered** (SSG&PM), others in the pipeline



**Over 800 received short-term trainings** on GCP, GCLP and GFP



**Over 20 long-term** trainings conducted in the region

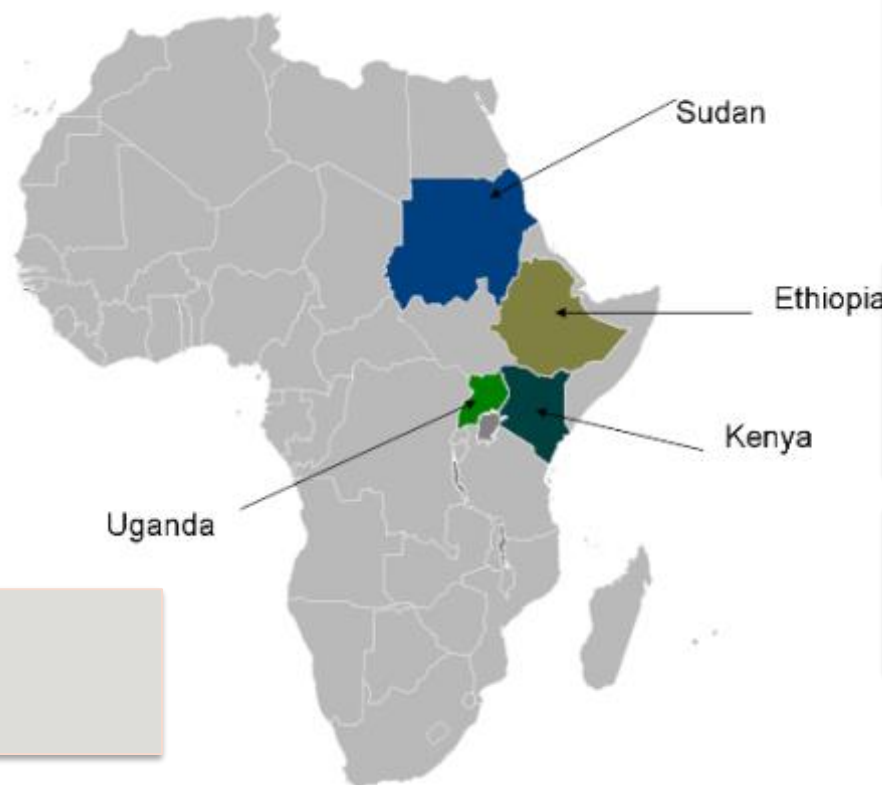
# Leishmaniasis East Africa Platform (LEAP)



**LEAP** - is a clinical research network that brings together experts from leishmaniasis endemic eastern African countries to facilitate clinical testing and improved access to better treatments for leishmaniasis in the region.

## Study sites:

Gondar (Eth)  
Abdurafi (Eth)  
Dooka (Sudan)  
Um el kher (Sudan)  
Amudat (Uganda)  
Kimalel (Kenya)  
Kacheliba (Kenya)



## SUDAN:

- Univ. of Khartoum
- Federal Ministry of Health

## ETHIOPIA:

- Addis Ababa Univ.
- Gondar Univ.
- Ministry of Health

## KENYA:

- KEMRI
- Ministry of Health

## UGANDA:

- Makerere Univ.
- Ministry of Health



# THANK YOU

TO ALL OUR

## PATIENTS AND COMMUNITIES







# THANK YOU

TO ALL OUR  
PARTNERS IN THE REGION

**DNDi**  
Drugs for Neglected Diseases initiative

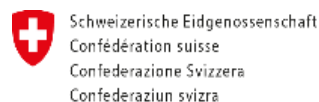




# THANK YOU

TO ALL OUR  
DONORS

**DNDi**  
Drugs for Neglected Diseases initiative



medicorfoundation



Global Health Innovative Technology Fund



wellcome trust