LEAP @ 15: Our Journey Through the Years

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

1st DND Africa Meeting
7-9th May 2003, Nairobi
A desire to collaborate and resolve the many health problems
Creation of DNDi: as a Patient Needs-Driven & Innovative R&D Model

**DNDi commits to create disease specific platforms**

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

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

**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.

Oct 2004
Data Centre Created

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

Oct 2004
Our Journey

Uganda Joins LEAP

Uganda joins LEAP during the LEAP 0104b clinical trial

2006
Our Journey

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

2010
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 UPGRADEING
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
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 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
- **60 members** of LEAP
- **8 existing** study sites
- **One treatments delivered** (SSG&PM), others in the pipeline
- **Over 20 long-term** trainings conducted in the region
- **8 studies** completed with
- **13 publications** in peer reviewed journals
- **Over 11,000 VL patients** treated within and outside clinical studies (2010-2017)
- **Over 800 received short-term trainings** on GCP, GCLP and GFP
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
THANK YOU TO ALL OUR DONORS