

LEISHMANIASIS EAST AFRICA PLATFORM (LEAP): A model for a Clinical Research platform in Africa

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PRESENTATION OUTLINE

- Impact of VL in East Africa
- LEAP: Who we are
- LEAP objectives
- Why regional approach
- LEAP activities
- LEAP achievements
- Advantages of LEAP Platform
- Challenges
- Conclusion
- Acknowledgements



Impact of VL in Eastern Africa

- Mainly disease of children (over 60%)
- Malnutrition common
- Prevalent among the poor
- Population displacements have exacerbated the spread of the disease
- Population mortality of VL can be up to 36%
- Low economic and agricultural activity = poor social economic activity
- Scarce or non-existent treatment options



(Photo courtesy of Prof. A Hailu)

LEAP – Where We Started

- A group of scientists and institutions working on developing clinical trial capacity to bring new treatment options to neglected VL patients
- Formed in August 2003 in Khartoum, Sudan
- Facilitated by DND*i* Africa office based in KEMRI
- Funded by DND*i*



LEAP OBJECTIVES



- Evaluate, validate and register 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



Leishmaniasis East Africa Platform (LEAP)

SUDAN: 3 sites (Kassab, Doka, Um el Kher)

Univ. of Khartoum

Federal Ministry of Health, MSF

ETHIOPIA: 2 sites (Gonder, Arba Minch)

Addis Ababa Univ.

Gondar Univ.

DACA

Ministry of Health

KENYA: 2 sites (Kimalael, Nairobi)

KEMRI

Ministry of Health

UGANDA: 1 site (Amudat)

•Makarere Univ.

•Ministry of Health

A group of scientists and institutions working on developing clinical trial capacity to bring new treatments to patients

LSH&TM
AMC/ KIT/ Slotervaart
I+ Solutions
IOWH
TDR
Industry partners



DNDi



LEAP TEAM



WHY A REGIONAL APPROACH

- **Burden of disease:** Sudan 20,000; Ethiopia and Kenya 4,000 cases each; Uganda 200 VL cases. Epidemics common
- Open to pursue **regional approach:** clinical trial network involving health and regulatory authorities
- Consensus to **prioritise patient needs** (eg, focused clinical trials)
- Need to pursue antimony vs. paromomycin vs. combination therapy (eg. SSG + PM)
- Need to evaluate combination therapy with AmBisome
- Develop joint proposals
- Seek joint funding
- South-South collaboration

LEAP ACTIVITIES

- **Unmet treatment needs**
 - o Safe
 - o Efficacious
 - o Short course
 - o Affordable
 - o Registered
 - o Field adapted
- **Testing new treatments for VL in East Africa**
 - o Paromomycin (PM) clinical trial for registration, PM + SSG combination
 - o Ambisome, miltefosine, combination therapy
 - o Rapid diagnostic tests evaluation
- **Capacity strengthening**
 - o Training
 - o Infrastructure

LEAP ACHIEVEMENTS

- Completion of LEAP 0104 paromomycin multi-centre clinical trial
- Ongoing AmBisome combination trial for Africa
- Study of rapid diagnostic tests
- PM + SSG incorporated into Sudan National VL Guidelines
- Strengthening clinical trial capacity in Ethiopia, Kenya, Sudan and Uganda
 - Personnel, e.g.
 - GCP/GLP training for investigators, nursing staff and laboratory technologists
 - Establishment and training of DSMB. Currently 3 sets of DSMB
 - Training of clinical trial monitors
 - Communications, e.g.
 - Regular communications – biannual meetings, scientific conferences
 - Important scientific publications
 - Infrastructure, e.g.
 - Building of 2 research and treatment centres in Ethiopia
 - Arba Minch in February 2006; Gondar in May 2008
 - Site opened in Kimalel, Kenya in June 2009
 - Upgrading and opening of Prof El Hassan Centre for Tropical Medicine Dooka Oct 2010

ETHIOPIA

**Gondar, Clinical Trial Center
before rehabilitation**



**Arba Minch,
before rehabilitation**



Gondar New Site, May08



Arba Minch new lab



Prof Ahmed el Hassan Centre for Tropical Diseases SUDAN



Before

After



Amudat, Uganda





Advantages of LEAP Platform

- Strengthen existing capacities for conducting clinical trials in Eastern Africa: infrastructure, personnel
- No duplication of effort – time taken to get meaningful results minimised
- Registration of much needed VL new drugs in all member countries
- Sourcing of research funds easier
- Owned by members, hence trusted by community
 - Governments will readily give support because they are members of LEAP
- Translation of research results into policy easier

Challenges to build innovation and clinical research capacities in Africa

- Public African leadership needed
- Strengthen Sustainable Research capacities
- Stimulate transfer of technologies to Africa
- Strong partnerships and South-South collaborations
- Strengthen Regulatory environment
- Governments to take more responsibility for health of citizens
- Translation of clinical research results into policy
- Collaboration between PDPs and MOH to facilitate access to new tools



CONCLUDING REMARKS

- Solid gains have been made in the last 7 years
- Clinical trials capacity strengthened
- Regional partnership: LEAP a success story
- Many patient needs still unmet

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Asante Sana, Thank You, Merci

