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*



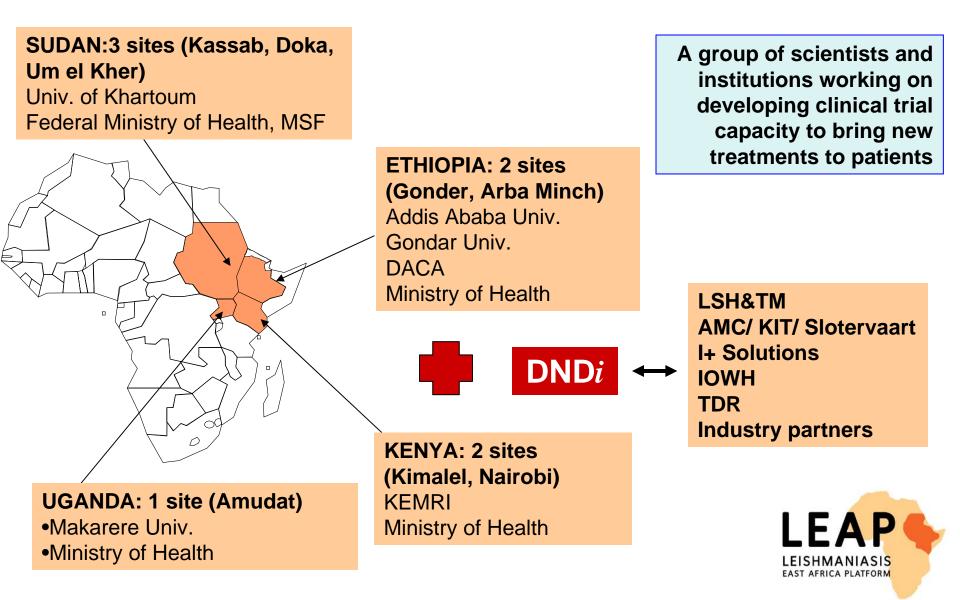
LEAP OBJECTIVES



- 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)



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

- 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





Prof Ahmed el Hassan Centre for Tropical Diseases SUDAN



Before



After

Amudat, Uganda





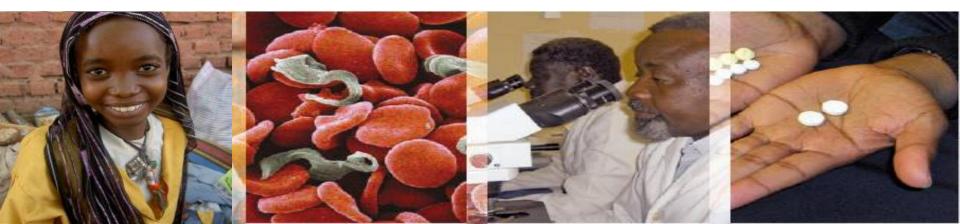
Advantages of LEAP Platform

- 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



ACKNOWLEDGEMENTS



- All our patients
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Asante Sana, Thank You, Merci

