

LEISHMANIASIS EAST AFRICA PLATFORM: FACILITATING INNOVATION AND ACCESS TO NEW TOOLS

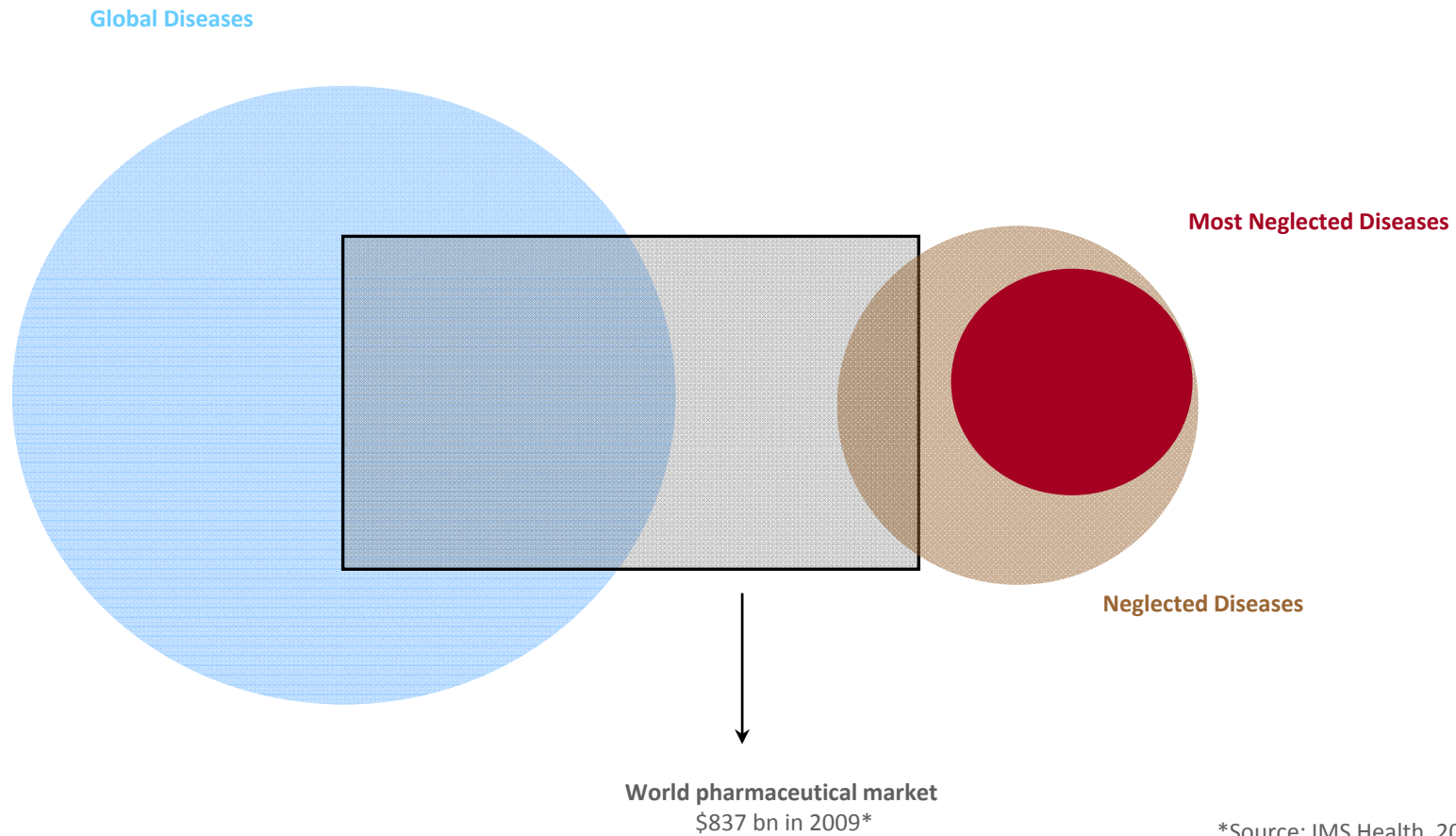


ASTMH meeting
December 2011
Philadelphia, USA

Presenter: Dr Monique Wasunna
Head of DNDi Africa
Assistant Director, Research
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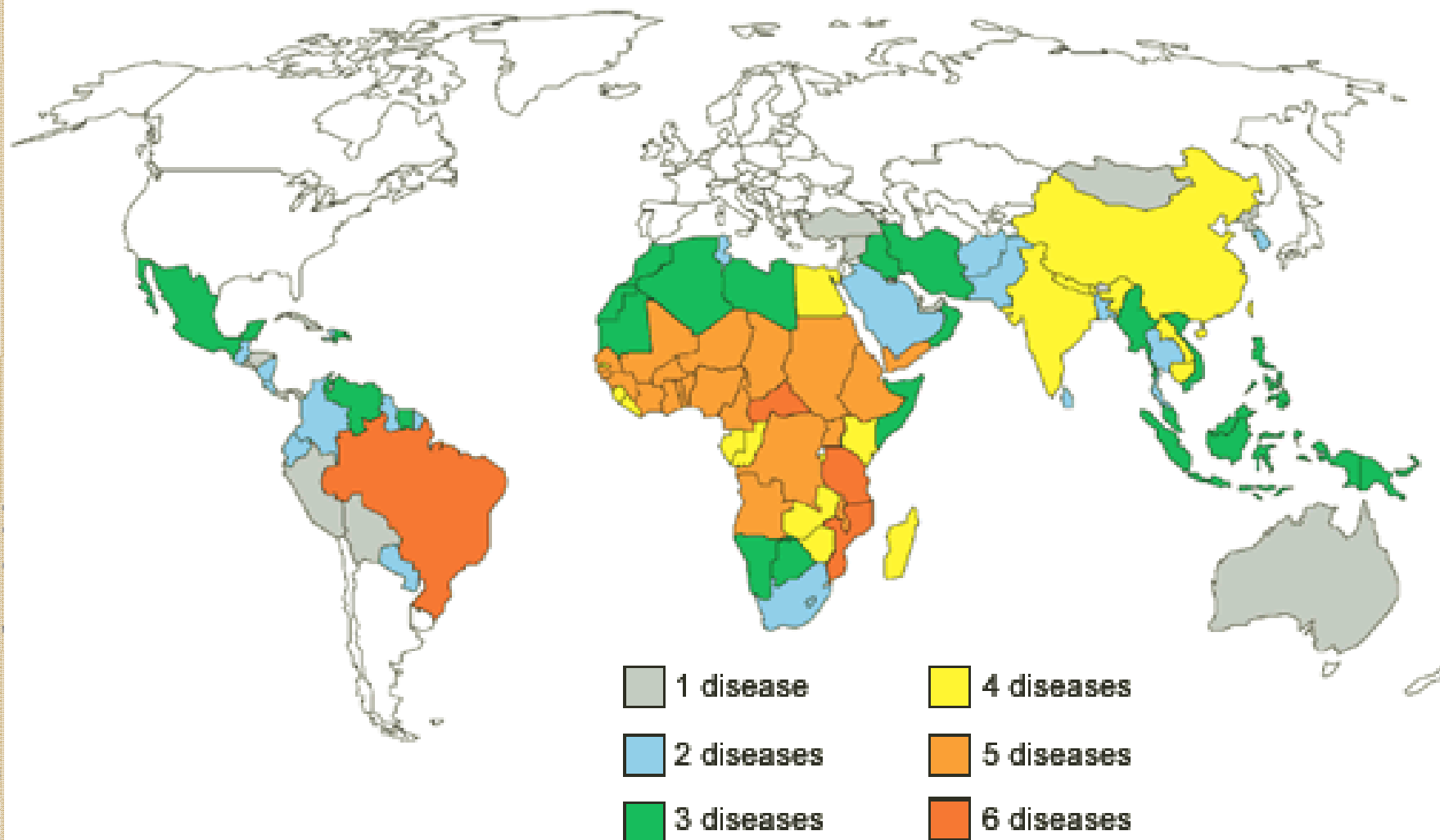


- ## Neglected Diseases:
- primarily affect developing countries
 - lie outside the world market



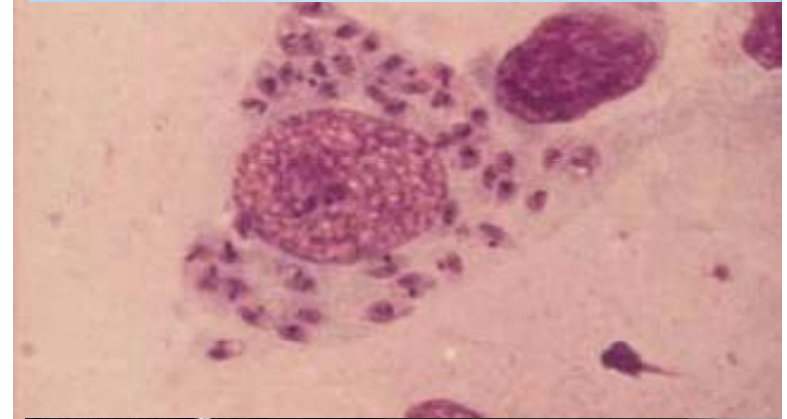
*Source: IMS Health, 20.04.2010

Countries Burdened with Neglected Tropical Diseases



Visceral Leishmaniasis (VL)

- **200 million at risk** worldwide (in 70 countries)
- 500 new cases/year
- Transmitted by the **sandflies**
- **Symptoms:** prolonged fever, enlarged spleen & liver, substantial weight of loss, progressive anemia
- **Fatal if untreated**
- **Current drugs:** antimonials, Amphotericin B, AmBisome®, miltefosine, paromomycin
- **Needs:** oral, safe, effective, low-cost and short-course treatment



Impact of VL in Eastern Africa

- At least 35,000 new cases/year
- Mainly disease of children (>60%)
- Malnutrition common
- Prevalent among the poor
- Population displacements exacerbate disease spread
- Low economic and agricultural activity = poor social economic activity
- Scarce or non-existent treatment options
- Epidemics occur - South Sudan



Challenges for Clinical R&D

- Research capacity
- Health system barriers
 - Infrastructure
 - Logistics
 - Communications
- Geography/climate
- Different regulatory environments
- Funding



Idea for Platforms Started in 2003

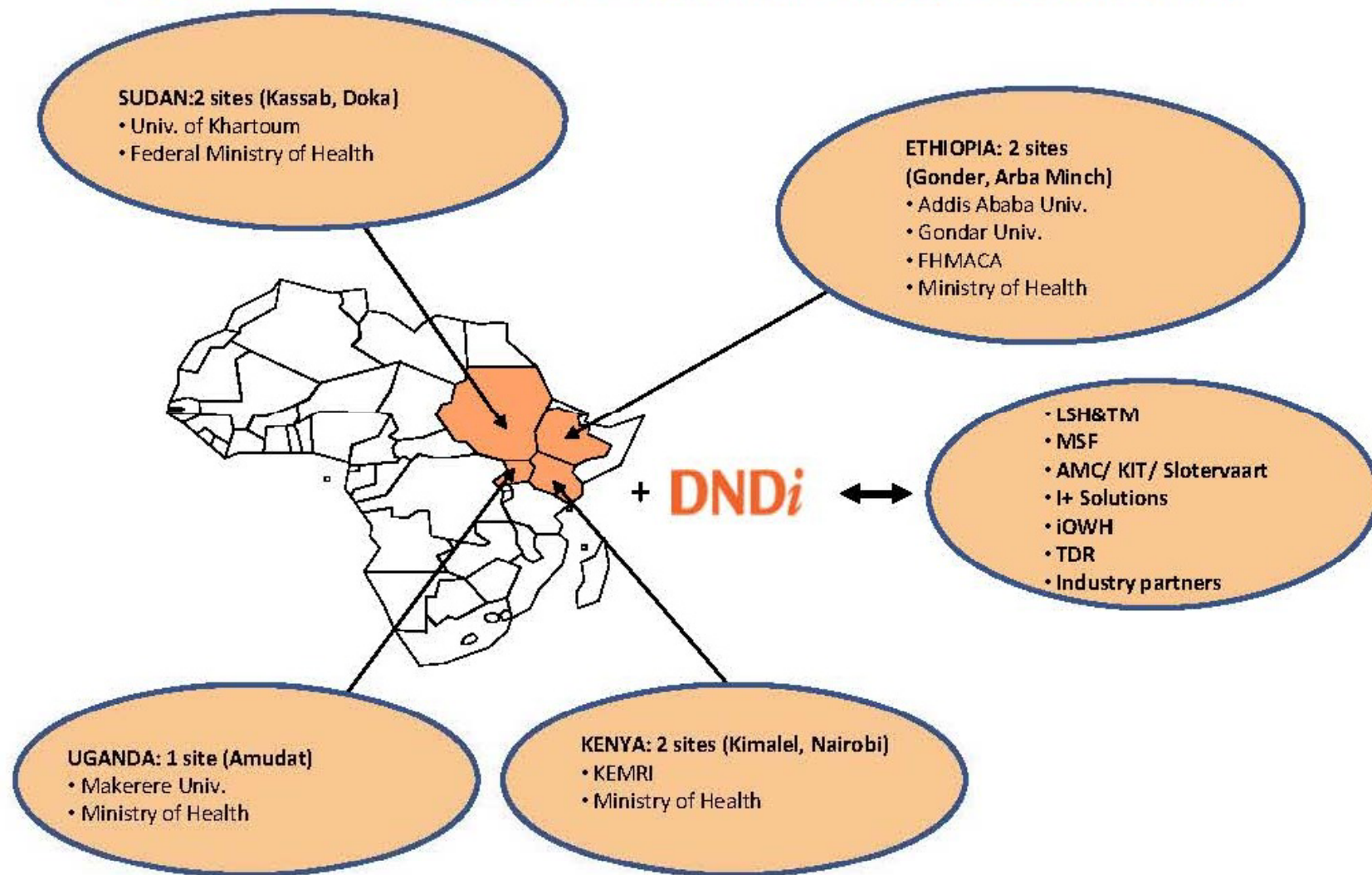
- **Disease-specific platforms: brainchild of DNDi**
- **Desire to collaborate to solve many health crises plaguing Africa**
 - For diseases urgently needing improvement of treatments: LEAP, HAT Platform
- **1st DNDi Africa meeting**
 - 7-9 May 2003, Nairobi: 18 African countries, 71 participants
- **Neglected, marginalized, forgotten, invisible diseases**
- **Consensus conclusion: more action, fewer words**

LEAP is born

- LEAP was formed in August 2003, Khartoum, Sudan
- Member countries: Ethiopia, Kenya, Sudan and Uganda
- A group of scientists and institutions working on developing clinical trial capacity to bring new VL treatments to patients
- Holds 2 meetings annually rotational basis

LEAP

Leishmaniasis East Africa Platform



LEAP Objectives

- Facilitate clinical testing and registration of new treatments for VL in the region (Ethiopia, Kenya, Sudan, Uganda)
- Evaluate, validate and register improved options that address regional needs for VL
- Provide capacity strengthening for drug evaluation and clinical studies in the region



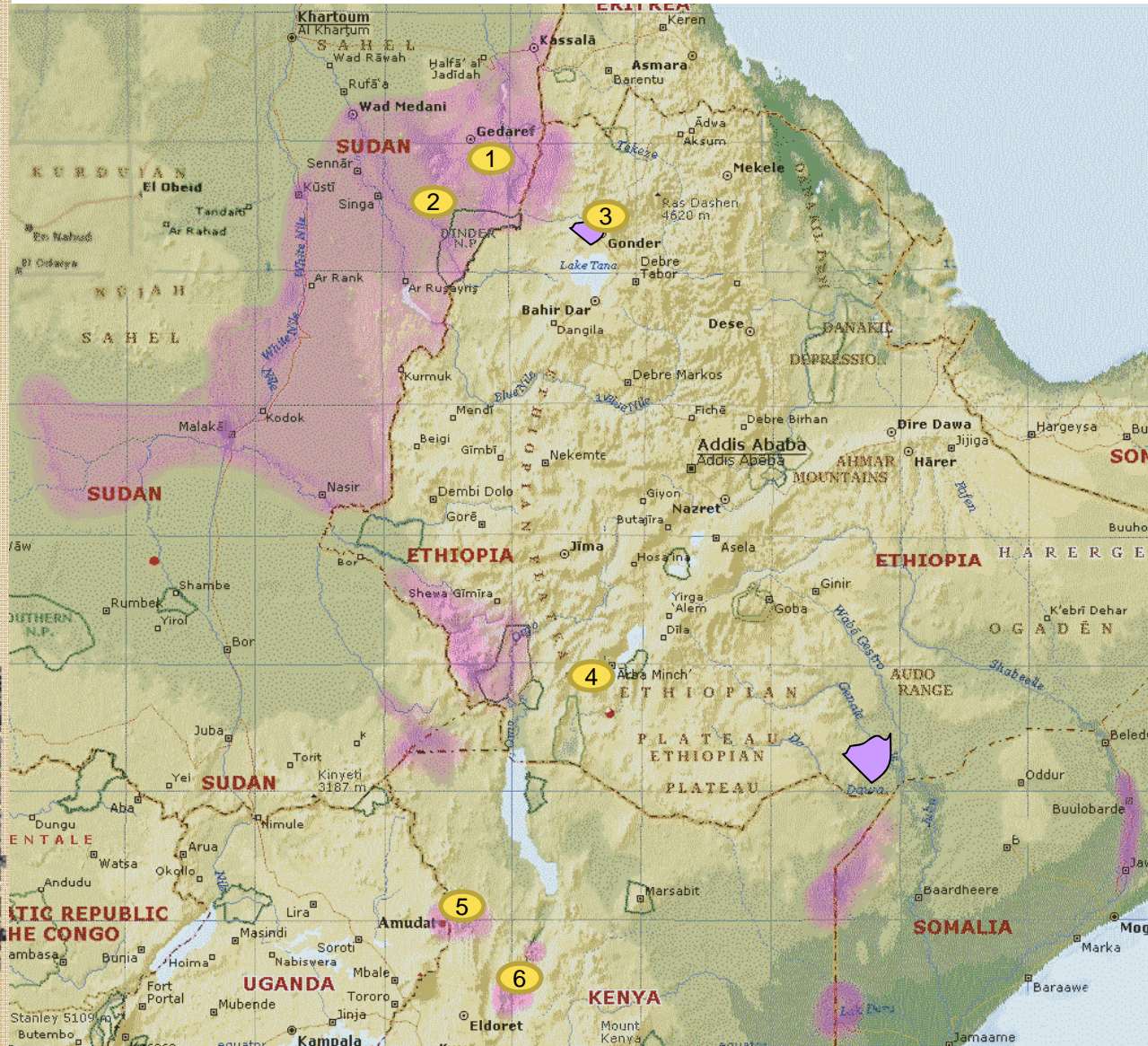
Advantages of LEAP

- True South-South collaboration
- Strengthen existing capacities for conducting trials in Eastern Africa: infrastructure, personnel
- Eliminate duplication of effort
- Accelerate registration of new VL drugs in member countries
- Facilitate research funding
- Act as a trusted reference group: owned by its members, hence trusted by the community and governments
- Efficiently translate research results into policy

LEAP 0104: A multi-country clinical trial (I)

- Phase III clinical trial of safety and efficacy of short-course combination of PM (15mg/kg/d; 11mg/kg/d base) and SSG (20mg/kg/d) for 17 days vs SSG standard therapy for 30 days
- Over 1100 VL patients involved
- Started 2004
- 6 clinical trial sites in Eastern Africa

LEAP 0104 Clinical Trial Sites



- 1 Kassab Hospital,
University of Khartoum,
Sudan
- 2 Um el Kehr centre, MSF-
Holland, *Sudan*
- 3 Gonder Hospital, Gonder
University, *Ethiopia*
- 4 Arba Minch Hospital, Addis
Ababa University, *Ethiopia*
- 5 Amudat Hospital,
Makerere University,
Uganda
- 6 Kimalel Hospital, KEMRI,
Kenya



LEAP 0104: A multi-country clinical trial (II)

- Results: SSG&PM combo 17 days was as efficacious as standard SSG treatment 30 days (>90% at 6 months follow-up)
- WHO Expert Committee in 2010 recommended use of SSG&PM as first-line regimen for treatment of VL in Eastern Africa
- MOHs of Sudan and Kenya have recommended SSG&PM for VL

Achievements (I)

Innovation

- Completion of LEAP 0104 PM trial
- Ongoing AmBisome combination trial for Africa
- Completed study of VL rapid diagnostic tests
- SSG&PM: a new improved combination first-line treatment for VL

National protocols

- SSG&PM incorporated into national VL guidelines of Sudan and Kenya
- Support review of national VL guidelines in Ethiopia and Uganda

Access

- Support for new treatment registration
- SSG&PM field implementation and pharmacovigilance

Achievements (II)

Sustainable Capacity Strengthening in Ethiopia, Kenya, Sudan and Uganda:

- **Training:** Clinical trial GCP/GCLP, monitors, DSMB
- **Communications**
- **Infrastructure**



Strengthening Capacity and Infrastructure

**Previous VL treatment ward,
Gondar, Ethiopia**



**Current VL treatment centre,
Gondar, Ethiopia**





Achievements (III)

Publications

- Hailu A, Musa A, Wasunna M, Balasegaram M, Yifru S, et al. (2010) **Geographical Variation in the Response of Visceral Leishmaniasis to Paromomycin in East Africa: A Multicentre, Open-Label, Randomized Trial.** *PLoS Negl Trop Dis* 4(10): e709.
- Musa AM, Younis B, Fadlalla A, Royce C, Balasegaram M, et al. (2010) **Paromomycin for the Treatment of Visceral Leishmaniasis in Sudan: A Randomized, Open-Label, Dose-Finding Study.** *PLoS Negl Trop Dis* 4(10): e855.

Barriers to Innovation and Access

- Challenges of availability and affordability of new treatments
- Inadequate political will and purchasing power of governments
- Infrastructure and extreme poverty of citizens
- Regulatory barriers

Moving ahead: Challenges to building innovation and clinical research capacities in Africa

- Public African leadership needed: govts must take more responsibility for health of citizens
- Strengthen sustainable research capacities
- Stimulate transfer of technologies to Africa
- Strong partnerships and South-South collaborations
- Strengthen regulatory environment
- Translation of research results into policy
- Collaboration between PDPs and MoHs to facilitate access to new tools

ACKNOWLEDGEMENTS



- **All our patients**
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THANK YOU, ASANTE SANA



Best Science for the Most Neglected

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