

1. Name of the project

The LEAP Platform (Leishmaniasis in East Africa Platform) for Leishmaniasis

2. Description of the approach

The LEAP Platform (Leishmaniasis in East Africa Platform) is a regional clinical research network that brings together experts from leishmaniasis-endemic countries in East Africa.

Founded in Khartoum, Sudan, in 2003, by the non profit R&D organisation Drugs for neglected Diseases *Initiative* (DNDI), the LEAP Platform incorporates partner institutions from across the spectrum of clinical research and disease control organizations working in leishmaniasis.

Visceral leishmaniasis (VL) is the most severe form of tropical diseases which are transmitted by the sandfly. VL is characterized by prolonged fever, enlarged spleen and liver, substantial weight loss, progressive anaemia, and is complicated by co-infection with other infectious diseases, such as malaria, pneumonia, and HIV. Of the 200 million people in 62 countries who are threatened by VL, approximately 500,000 new cases and 60,000 deaths occur each year.

VL is a fatal disease that kills almost all untreated patients, mostly affects patients who live in areas where access to health care is minimal and is a disease embedded in poverty and neglect. If the number of treatments has increased in past decade, there are numerous drawbacks for each of them such as difficulty to administer, length to treat, toxicity, cost and increasing resistance

3. Implementation methodologies;

Developing drugs is a difficult process, especially when clinical trials are carried out in remote settings. The aim is to strengthen clinical research capacity, which is lacking in part due to the remoteness and the geographical spread of the patients (most of whom live in the most impoverished regions of Africa). The LEAP Platform gather a group of scientists and institutions working on developing clinical trial capacity to bring new Visceral leishmaniasis treatments to patients. It currently involves partner institutions in four countries: in Kenya, the Kenya Medical Research Institute (KEMRI) and the Ministry of Health; in Ethiopia, Addis Ababa University (AAU), the Drug Administration and Control Authority (DACA), and the Ministry of Health; in Sudan, the University of Khartoum, and the Federal Ministry of Health; and in Uganda, Makerere University and the Ministry of Health.

One of the critical issues for the platform is to develop clinical trials in remote settings complying with International standards for Good Clinical Practices (GCP) to register the drugs. To work towards efficient clinical trials, DNDi and its partners have identified critical steps and methodologies

- Building trust and partnerships with patients, local communities, and local healthcare workers..
- Improving the local infrastructure and ensuring that the entire logistical chain in place is in compliance with GCP.
- Recruiting relevant human resources and training. Quality healthcare workers at a local level must not It is vital to attract and maintain good human resources through the training of the healthcare workers – the doctors, and laboratory technicians, and nurses conducting the clinical trials, as well as the clinical monitors, and the data safety monitoring boards. Working with local/national governing and regulatory authorities is also necessary to conduct clinical trials; they play a crucial
- Ensuring prioritization and sustainability in the field of clinical trials, through increased public awareness.

4. What is innovative about this approach/tool/project;

The LEAP platform seeks to build an environment conducive to efficient clinical trials and to build effective scientific partnerships, in order to develop new drug candidates.

Aside conducting clinical trials, this platform also serves for ongoing educational cooperation between countries in the East African region and for standardization of procedures and practices as far as is possible within the confines of local regulations.

LEAP projects are carried out as collaborative efforts within member countries. This approach within the drug development process is innovative by

- Bringing together groups of researchers, academics, and clinicians working on most neglected diseases and providing them with the space and the time to work together to formulate their regional strategies, as they address the fundamental problems at the field level. This pillar is extremely important, as many local partners have long historical relationships with local populations, which are crucial in facilitating the process
- Enabling partners to share different experiences, knowledge and problem-solving techniques. Improving the local infrastructure. This part of the process demands a lot of planning and tedious work, but is an integral component for any clinical trial to take place.

5. Evidence of results and impact;

To date, some of the LEAP Platform's accomplishments since its inception include:

- Assessment of regional capacity of R&D in neglected diseases
- Strengthening clinical trial capacity through Six clinical trial centers established in Ethiopia (2), in Sudan (2), Kenya (1) and in Uganda
- More than 1000 patients enrolled into a multi center clinical trial
- Training for investigators, nursing staff and laboratory technologists Personnel, clinical trial monitors e.g.

Through the LEAP platform, DNDi and its partners aims to register in Africa 3 new treatments by 2011 to be used in combination therapy

In the long term, LEAP will facilitate the design and implementation of new trials needed to ultimately make available new tools for the diagnosis and treatment of VL.

6. Costs associated with the development of the approach/tool/project and/or its implementation;

The development costs for the period 2009/2011 including training, capacities building, equipments and data management is expected to be 1,5 Million Euros

7. Contact information.

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