LEAP
LEISHMANIASIS
EAST AFRICA PLATFORM
NewsLETTER
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Drug Regulation in Kenya

By Dr Bibiana K. Njue

Drug registration in Kenya started in 1982; the process mainly involves an evaluation committee at the Kenya Pharmacy and Poisons Board (PPB) that aims to approve products based on quality, safety and efficacy. The committee reviews documents and product samples for quality analysis at three main labs (i.e. the National Control Laboratory (NCL), the Missions Essential Drugs Laboratory (MEDs Lab), and the Drug Analysis Research Unit (DARU)).

Further to that, PPB is recognized as a department of the Ministry of Health (MoH), and has grown from a single office to an entire building in 2003. In the longer term, plans are set to shift the status of the department from the MoH to a parastatal organization, such as the Kenya Medical Research Institute (KEMRI).

Since 2010, the PPB has adopted a new format for drug registration, called the 'Common Technical Document (CTD)', which is recognized internationally, notably by the WHO. This implies a more stringent approval process that has led to fewer drug registration applications, because of the amount of information that is required from applicants and in essence, has limited applications to those that are serious applicant submissions.

Drug Approval
The PPB has provisions for fast-track applications based on specific policy guidelines, which state that fast-track submissions have a product approval time of up to three months and regular applications can expect approvals between six months to one year. A fast-track submission is always accompanied by a written justification to the registrar. This request must only be submitted to the office of the registrar after the PPB's internal evaluation has been presented with the product sample and relevant documentation.

An example of a fast-track application submitted to the PPB was one by DNDi for the drug paromomycin (PM), for use as part of the treatment combination SSG&PM for visceral leishmaniasis. This drug was evaluated registered within a few months of submission.

Procurement
As a matter of policy, the budget allocation for medicines is proposed at the level of the Kenya MoH to the Ministry of Finance (Treasury Department). This is then presented to parliament for final decision. Based on parliament's funding allocation, at county level medicines are purchased from the MoH store, Kenya Medical Supplies Unit (KEMSA) and distributed to district hospitals depending on the need. These medicines can also be made available to Kenyans by international NGOs and multilaterals such as WHO, on a compassionate basis, as is the case with SSG&PM. Once a drug is registered with the PPB; the product is made available for sale at both public and private hospitals. KEMSA is solely responsible for public procurement and distribution of registered treatments to both public and private hospitals.

The MoH does not undertake any price control procedures. It is for that reason that product prices are often at the mercy of the market supply and demand. In this case, what the Kenya MoH advocates for is the increase of drug manufacturers in the marketplace, because this controls costs, influencing a downward trend in pricing.

Progress in Regulatory Harmonization
The process of harmonizing procedures within the East African Community has been ongoing for two years, notably in terms of product evaluation, Good Manufacturing Practices (GMP), and Market surveillance. This activity currently involves some members of the East African Community (EAC), with five countries currently involved: Kenya, Tanzania, Uganda, Rwanda, and Burundi. To date, a technical working group has been established and meets regularly. Currently, Kenya is steering the process through the use of its current CTD, which the other EAC countries are working to adopt.

Drug Registration Challenges
The PPB is responsible for ensuring that only registered medicines are available in the marketplace. It has been observed that some local manufacturers complain about the stringent registration process and in some cases go against procedure. For that reason, the PPB inspectorate has found unregistered drugs in the market. This predicament is observed when manufacturers submit applications to the PPB and simultaneously offer the same drug to the market for sale. This then causes the PPB post-market surveillance and inspectorate to be overstretched. In this case, the regulatory authority is sometimes found to be making the manufacturers withdraw their product from the marketplace. Secondly, is the need to improve GMP that will ensure manufacturers present quality products to the marketplace. This is a challenge, because some of the foreign and local manufacturers place their products in the marketplace without complying with GMP. The regulatory authority thus has to continue to follow up on the irregular practices of some manufacturers.

'The LEAP stakeholders should keep up the good work. Your efforts are admirable and the neglected patients are remembered in your R&D efforts, giving patients access to drugs that they, as neglected communities, would ordinarily never be able to afford themselves.'

Dr Bibiana Njue, Deputy Chief Pharmacist Product Evaluation Department

VIEWPOINT

ELISA to Determine the Level of Visceral Leishmaniasis in Urine

Participants at the VL ELISA training in KEMRI lab. Trainees represented all LEAP countries.

By Dr Neil Purcell

In September 2013, a new visceral leishmaniasis enzyme-linked immunosorbent assay (VL ELISA) for the detection of visceral leishmaniasis moved from the research lab in the UK to laboratories in East Africa for the start of detailed external product performance evaluation.

The VL ELISA was developed by Kalon Biological Ltd in partnership with Foundation for Innovative New Diagnostics (FIND), and with the collaboration of DNDi, to determine the level of leishmaniasis antigen found in human urine. The quantitative performance of the analysis enables users to measure the effectiveness of drug treatments in reducing parasite load.

During the UK product performance evaluation, the testing of patient samples from 120+ VL positive patients over different time courses has typically shown initially high levels of leishmaniasis antigen dropping by 90-99% in the first week of

medication. It was now deemed time to test the product in the field.

A training programme was arranged at the DNDi facilities at KEMRI, from 18 to 20 September 2013, to enable African scientists and laboratory staff to gain practical experience with the VL ELISA. This training was necessary, as this tool under development will be evaluated in DNDi sponsored VL clinical trials in East Africa.

The training was performed by Dr Neil Purcell from Kalon Biological Ltd, who has managed the VL ELISA development in the UK. Present in the training programme were scientists from Kenya, Uganda, Ethiopia, and Sudan (12 trainees in total).

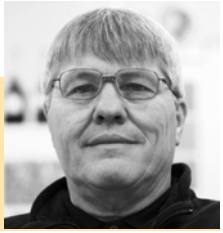
The training started with an introductory talk on the background and development history of ELISA, in general, and this VL ELISA, in particular. This allowed all the scientists present to ask questions related to the role, range and sensitivity of the product. The scientists then performed the VL ELISA on two separate occasions, with each participant performing all stages of the test from sample dilution, following the full assay protocol, then performing data reduction with curve fitting, and finally determination of the urine antigen levels.

All the scientists who attended the training were able to perform the test and became aware of its potential as well as some of the limitations (e.g. the test is not designed to screen patients, and has thus far only been used to monitor confirmed VL positive patients).

The practical sessions did not benefit from the advantages of using automated data capture by PC, followed by simple software-based curve fitting and unknown sample values being calculated. Instead, trainees had to perform manual curve fitting and then the individual sample values had to be the determination from the hand-drawn curve.

If routine testing is to be performed, automated data reduction and curve fitting is highly recommended.

Dr Purcell is the Director of Kalon Biological Limited



A Doctor's Voice – Kacheliba, Kenya

Medical Officer at Kacheliba District Hospital & Medical Officer in Pokot North Sub-District.

By Dr Martin Namuya

'In 1991, I lost my brother. At that time, he was eighteen years of age. His demise was as a result of kala-azar. This was very sad time for my family as we could not get treatment, because there was no kala-azar treatment programme running in Kacheliba, unlike what is available today. During this period, the government of Kenya was not offering subsidized treatment for the disease and kala-azar patients had to buy the drug sodium stibogluconate (pentostam), which was very expensive, costing as much as thirty thousand Kenyan shillings for a full treatment. Unfortunately, when we sought treatment at the Kacheliba District Hospital, my brother had to be referred to Kapenguria District Hospital, and that is where he passed away.

That period was also challenging for my community, because we were not aware of kala-azar. It was assumed that it was an abdominal tumour. It is for that reason the community used traditional medicine by cutting the site where the spleen is and applying herbal medication from leaves and roots. This is exactly what my brother experienced; he was sick for 6 months, by the time he was referred to Kapenguria his nose was bleeding as a result of low platelets, due to kala-azar.

Since 1991, the community has come a long way in its understanding of kala-azar. Today the people of Kacheliba are more informed and they know the disease has available treatments. As a result, many lives have been saved. They are aware of the symptoms, so when they see a patient with abdominal swelling, the first thing that comes to mind is kala-azar. Patients travel 180 kilometres to Kacheliba from as far as Baringo to get treatment at the Kacheliba District Hospital, where there is free treatment available to patients. The positive outcome is that to date the use of herbal medicines has reduced.

Kala-azar is prevalent in Kacheliba and West Pokot due to different environment challenges. We cannot eradicate the sandfly. In addition, people in my community are nomadic by nature and are often exposed and prone to being bitten by sandflies and getting kala-azar. We do need continued support for vulnerable communities, like mine, since kala-azar is still a neglected disease.

'My Inspiration? Coming back to Kacheliba and getting a medical degree was inspired by the loss of my brother. I decided I must become a doctor. So I endeavoured to come back to Kacheliba and serve my people.'

- Dr Martin Namuya

VIEWPOINT

Improved Diagnostics for VL in Sub-Sahara Africa Are Direly Needed

By Prof Asrat Hailu

Availability of rapid diagnostic tests of visceral leishmaniasis (VL) is crucial for control programmes. The development of k39- based tests has undoubtedly created an enabling environment for the VL elimination programmes, especially in the Indian sub-continent. However, VL control programmes in Africa have suffered due to the lack of a sensitive rapid test. Efforts to improve the performance of k-39 based rapid tests in the East African VL endemic areas are continuing. A case in point is the development of k28 based rapid tests. This is a test in which a cocktail of antigens, which includes k39, k9 and k26, are assembled in rapid test formats so that sensitivity of the k39 rapid tests can be improved.

By Prof. Asrat Hailu, Professor of Immunoparasitology at the Addis Ababa University – Ethiopia.

The quest for improved diagnostics of VL is not limited to rapid diagnostic tests. There is still a dearth of tests that can be used in the evaluation of patients' clinical and parasitological response to treatment. To date, tests of cure are still based on splenic or bone marrow aspirates that involve the counting of parasites in the smears. Simple and non-invasive techniques are needed, for use in routine settings or clinical trials. There have been many discussions about availability of urine-based antigen detection tests that may be available for evaluation.

Recently, Loop-mediated isothermal Amplification (LAMP) was proposed as a molecular diagnostic for VL. This is a nucleic acid amplification technique, which utilizes only one enzyme and amplifies large amounts of DNA within 30-60 minutes by an isothermal assay. The test utilizes lyophilized reagents and is expected to be simple to use in a field setting.

LEAP clinical trial sites are representative of the two well-demarcated VL ecotypes in sub-Saharan Africa. These ecotypes of VL have shown distinctness in the treatment outcomes of DNDi-sponsored clinical trials, especially with respect to efficacy. To date, clinical trials have not taken note of this in their planning for drugs or diagnostics trials. For this reason, progress towards the development of effective treatments or diagnostics of VL has been slow. It is also likely that developers of tests have not taken this into consideration.

LEAP needs to engage itself with drug or diagnostics developers at the outset so that the tools can appropriately address unmet patient needs. This will also save us time in the conduct of multi-centre (multi-country) phase III studies.

K39 – rapid test

LEAP STATUS UPDATE

LEAP Meeting in June 2013

The 19th LEAP meeting was held in Nairobi at the Panafric Hotel, from 6 to 7 June 2013. Participants were largely from the LEAP countries (Sudan, Uganda, Ethiopia, and Kenya). A record 80 participants attended the meeting. In addition to the general LEAP meeting, a side meeting was convened on the 5 June 2013 for a final LEAP 0208 data safety monitoring board (DSMB) consultation, held at the Heron Portico Hotel.

The Current Clinical Trials (Information on Fexinidazole study forthcoming)

LEAP STUDIES	OBJECTIVE	STATUS	COUNTRY
SSG & PM PV	To monitor SSG/PM benefits and risks and provide evidence to incorporate these in VL management guidelines	Recruitment ended – 30 Nov. 2013. Data cleaning and analysis ongoing. Final report to regulatory authorities to be done 3Q 2014	Ethiopia, Kenya, Sudan, Uganda
LEAP 0511	To develop treatment for HIV/VL patients that have acceptable efficacy	Study approved to start and will recruit from 2Q 2014	Ethiopia
LEAP 0208	To develop short-course combination regimen for treatment of primary VL	Study completed. Final Clinical Study Report in preparation	Sudan and Kenya

Meet the LEAP Clinical Trial Principle Investigators (PIs)

The Leishmaniasis East Africa Platform (LEAP) has benefited from the scientific expertise in the region. The platform has principle investigators (PIs), who are among the few scientists in Eastern Africa with an interest in research and development (R&D) for the treatment of VL. The PIs have come together through LEAP to collaborate on research of VL as a neglected disease in the region. They are individually accomplished in their countries and work for institutions that have a national focus, which is integral for LEAP's R&D work and the accomplishment of health goals in their countries.

SUDAN
Prof. Ahmed Musa
Director, Institute of Endemic Diseases, University of Khartoum

KENYA
Dr Monique Wasunna
Chief Research Officer and Assistant Director Research, KEMRI
Director, Drugs for Neglected Diseases Initiative (DNDi), Africa Office

SUDAN
Prof. Eltahir Khalil
Federal Ministry of Health (FMoH)

UGANDA
Prof. Joseph Olobo (PhD)
Professor - College of Health Sciences Makerere Universi

ETHIOPIA
Dr Asrat Hailu (PhD)
Professor of Immunoparasitology, Addis Ababa University

KENYA
Dr Juma Rashid
Director, Centre for Clinical Research, KEMRI

LEAP Welcomes Our New Colleagues on Board!

Fabiana Alves, Clinical Manager, DNDi

Dr Fabiana Piovesan Alves is a medical doctor, who graduated from the University of São Paulo, Brazil, with residency in Paediatrics. Following her PhD thesis on the molecular epidemiology of malaria in the Amazon region, Dr Alves took on a post-doctoral position at TDR/WHO. She was a professor of parasitology at the University of São Paulo, coordinated projects at various research institutes, and also worked as a project manager at a clinical research organization. Dr Alves has 15 years of experience in research on tropical diseases, including malaria, leishmaniasis, Chagas disease and schistosomiasis.

Jorge Alvar, PhD, Head of Leishmaniasis Clinical Program, DNDi

Dr Jorge Alvar was the Medical Officer in charge of the Leishmaniasis Control Programme in the Department of Neglected Tropical Diseases at the World Health Organization (WHO) between November 2004 and November 2012. In this position, Dr Alvar launched an ambitious strategic plan and specific control programmes for leishmaniasis in different regions and countries.

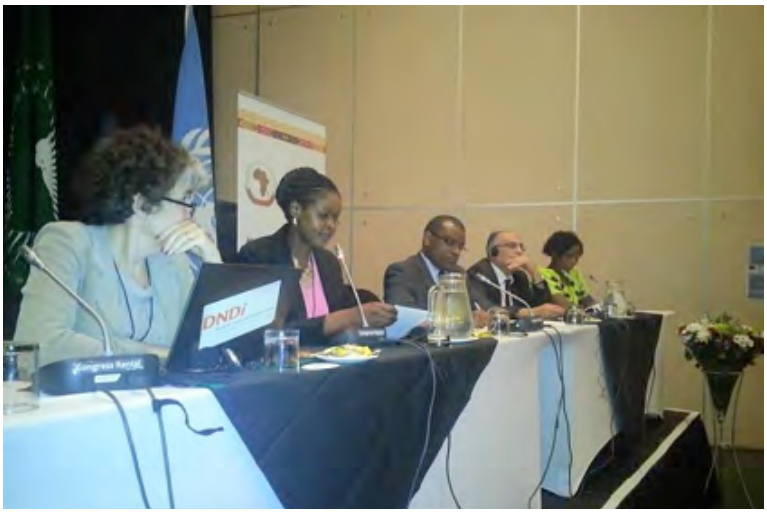
Prior to this position, he was the director of the National Centre of Tropical Medicine at the Institute of Health Carlos III, Madrid, Spain.

Pharmacovigilance and Basic GCP Training - Abdurafi, Ethiopia

From 18 to 20 March 2013, a Pharmacovigilance and Basic GCP training course was given in Ethiopia at the MSF Abdurafi project. In attendance were 14 clinical officers. The objective of the course was to enable the efficient implementation of the SSG&PM Pharmacovigilence study and to equip with basic GCP knowledge. The two-and-a-half day course consisted of interactive lectures, open discussions and practical exercises.

Events – Pictorial

A Decade of R&D for Neglected Disease in Africa – Nairobi



On 2 and 3 December 2013, NEPAD and partners held the First Scientific Conference on Medicines Regulation in Africa, at the Birchwood Hotel in Johannesburg, South Africa. The forum was themed 'Building Partnerships for Sustainable Capacity Development on Medicines Regulation in Africa'. The conference was informed by the need for African regulatory authorities, scientists and the industry to work together in addressing some of the challenges affecting the delivery of medical products and technologies to the public. Harmonizing medicines regulation was observed as an important but neglected challenge. LEAP and DNDi representatives who made presentations were Dr Christine Wasunna and Dr Nathalie Strub-Wourgaft.

VL Guidelines Training For Health Workers – Kacheliba, Kenya

In November 2013, the Kenya Ministry of Health, in partnership with DNDi and KEMRI, facilitated a VL guidelines training. The 30 participants who attended the event represented the following areas: Kacheliba, Kabarnet, Kerio Valley, Marigat, Chomolingot and West Pokot .The aim of this workshop was to educate health workers on Kenya's newly-revised VL guidelines, which were launched in 2012. This activity was aimed at enabling health workers to effectively implement the combination treatment SSG&PM as first-line treatment and to standardize diagnosis and treatment procedures.

Q&A – Good Financial Practices (GFP)

What is GFP?
When I joined DNDi in 2005, part of my role was to work with partners on financial reporting. The clinical trials (CTs) were being run by principal investigators (PIs), who were scientists that also doubled as accounting officers. Therefore, because we needed to have well-documented income and expenditure for financial reporting purposes, we developed a simple tool that would be standardized across all trial and treatment sites.

Since the PIs were already comfortable with good clinical practices (GCP) as a standard for the conduct of clinical trials, the development of Good Financial Practice (GFP) was influenced by GCP, which is how we coined the name. It was an easy terminology to use and was picked up relatively fast.

GFP provides a set of guidelines for financial reporting meant to standardize the reporting across LEAP partners and is accompanied by templates to facilitate accurate, complete and timely reporting, the three main pillars of GFP.

What methods have been used to inculcate GFP into LEAP financial practice?
Implementation has been carried out through specific GFP training off-site as well as continuously on-site during financial monitoring visits. The latter is a key activity that ensures that accountants working at the partner institutions are GFP compliant. Such off-site group training provides the accountants a solid understanding of the nature of current and planned studies, and thus helps them to provide the necessary finance support from their back offices in their various institutions. The training is planned to counteract the premise that accountants are generally not in sync with the actual project activities and therefore not very supportive to the researchers/project team.

The benefits of this training have been rewarding: financial reports are prepared by the accountants and reviewed by country PIs, who now, through GFP, have a better understanding of what they are signing off, because of the simple templates provide. Most importantly, the finance function at various partner institutions has improved in supporting the implementation of the clinical trial activities, which really is the end game!

By Mr Simon Bolo, Regional Operations Manager – DNDi Africa

What are some of the templates that are used in GFP?
First and foremost, we have the guidelines written down and revised periodically to reflect the realities of the day. The standard tool is a financial reporting template that compares the budget versus the actual expenses at a given point in time. The template also shows inflow of funds to the partner; calculates the cost per patient treated; and includes a section for explaining any variances.
In addition, to this standard reporting template, a more elaborate tool has been developed for some of the partners to help capture the expenses on a daily basis and automatically generate financial reports periodically. This is, therefore, linked to the financial reporting template above. Currently, in Amudat in Uganda and at the University of Addis Ababa in Ethiopia, this extended tool, which acts as an accounting system, is in use.

What have been some of the challenges experienced in the implementation of GFP?
Partner finance staff turnover is a prevalent challenge. In most cases we don't have control of government staff, so if there is a change of guard with officers moving to other positions within or outside government. GFP may suffer because of these gaps. To mitigate this, we carry out training on a needs basis on-site for the newly appointed officers.

In 2012, DNDi Board Treasurer, Mr Derrick Wong, together with Laurence Vielfaure, Finance Director-DNDi Geneva, both attended the most recent GFP training workshop held in Nairobi. Ideas were exchanged, and overall we learned a lot from the workshop interactions. The lessons learnt have now been introduced into our current GFP practices.

GFP is a system that can easily be replicated in other regions and projects to help improve and standardize partner financial reporting. We have proposed this system to the HAT Platform team based in Kinshasa, DRC, and we shall be working with them to see how best to implement.

Events – Upcoming

16th International Congress on Infectious Diseases (ICID), 2-5 April 2014 in Capetown, South Africa

20th Bi-annual LEAP Meeting, 10 -11 April 2014 in Kampala, Uganda

VL Demo Project (Stakeholders meeting), 7 May 2014 in Geneva, Switzerland

The 4th Africa Health Exhibition and Congress (AHC),6-8 May 2014 in Johannesburg, South Africa

IST Africa Conference, 6-9 May 2014 in Mauritius

7th European & Developing Countries Clinical Trials Partnership (EDCTP), June 30- July 2 2014 in Berlin, Germany

ICOPA –XIII International Conference on Parasitology, 10 -15 August 2014 in Brazil
World Health Day (WHD), 7 April 2014

LEAP Meeting, September 2014 (date and venue TBC)

Publications Concerning VL

2014

Safety and Efficacy of Single Dose Versus Multiple Doses of AmBisome® for the Treatment of Visceral Leishmaniasis in Eastern Africa: A Randomised Trial, by E. A. G. Khalil, T. Weldegebreal, B. M. Younis, et al., PLoS Negl Trop Dis., January 2014

Development of an Ex Vivo Lymph Node Explant Model for Identification of Novel Molecules Active against Leishmania major, by Alex G. Peniche, Yaneth Osorio, Adam R. Renslo, et.al.,, Antimicrobial Agents and Chemotherapy:, 14 October 2013

Kazal-type serine proteinase inhibitors in the midgut of Phlebotomus papatasi, by Leah Theresa Sigle, Marcelo Ramalho-Ortigão. Mémorias do Instituto Oswaldo Cruz, 15 August 2013

Visceral leishmaniasis after kidney transplantation: report of a new case and a review of the literature, by Bouchekoua M, Trabelsi S, Ben Abdallah T, Khaled S. Transplant Rev, 2014 Jan

Strong Association between Serological Status and Probability of Progression to Clinical Visceral Leishmaniasis in Prospective Cohort Studies in India and Nepal by Epco Hasker mail, Paritosh Malaviya, et al., PLoS NTDs, 23 January 2014

First detection of Leishmania infantum kinetoplast DNA in hair of wild mammals: Application of qPCR method to determine potential parasite reservoirs, by Rubén Mu˜noz-Madrid, Silvia Belinchón-Lorenzo et al., Acta Tropica, 20 August 2013

Clinical epidemiology, diagnosis and treatment of visceral leishmaniasis in the pokot endemic area of Uganda and Kenya, by Yolanda K. Mueller, Jan H. Kolaczinski, Timothy Koech et al., AJTMH, 8 January 2014

Rapid Healing of Cutaneous Leishmaniasis by High-Frequency Electrocauterization and Hydrogel Wound Care with or without DAC N-055: A Randomized Controlled Phase IIa Trial in Kabul, by Ahmad Fawad Jebran, Ulrike Schleicher, Reto Steiner et al., PLoS Negl Trop Dis., 13 February 2014

Simultaneous Occurrence of Ocular, Disseminated Mucocutaneous, and Multivisceral Involvement of Leishmaniasis, Hindawi Publishing Corporation- Case Reports in Infectious Diseases, by Cyriac Abby Philips, Chetan Ramesh Kalal, K. N. Chandan Kumar et al., 18 February 2014

Five-Year Field Results and Long-Term Effectiveness of 20 mg/kg Liposomal Amphotericin B (Ambisome) for Visceral Leishmaniasis in Bihar, India, Plos NTDs, by Sakib Burza mail, Prabhat K. Sinha, Manica Balasegaram

2013

Design, synthesis and biological evaluation of 2-substituted quinolines as potential antileishmanial agents, by Vadiraj S. Gopinath, Jakir Pinjari, et al., Eur J Med Chem., November 2013.

The drug and vaccine landscape for neglected diseases (2000—11): a systematic assessment, by B. Pedrique, N. Strub-Wourgaft, B. Pécoul, et al., The Lancet Global Health, October 2013.

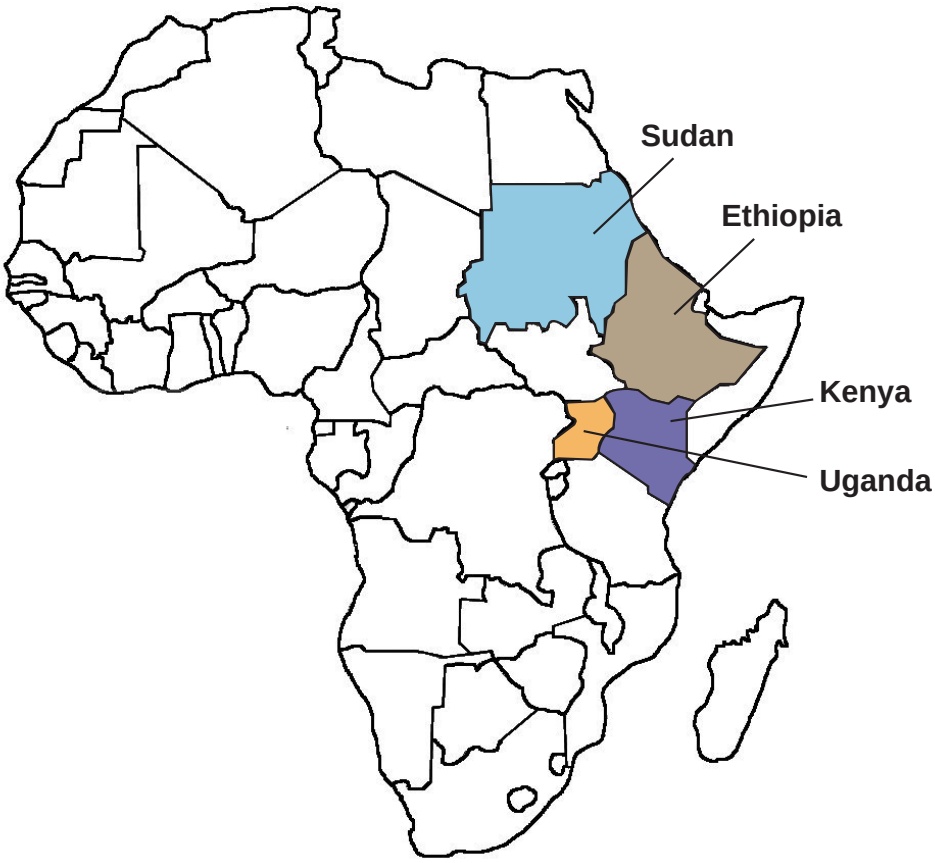
Validation of Two Rapid Diagnostic Tests for Visceral Leishmaniasis in Kenya, by J. Mbui, M. Wasunna, et al., PLoS Negl Trop Dis., September 2013.

Screening strategies to identify new chemical diversity for drug development to treat kinetoplastid infections, by R. Don and J-R Ioset. Parasitology, August 2013.

Report of the Post Kala-Azar Dermal Leishmaniasis (PKDL) consortium meeting, New Delhi, India, 27-29 June 2012, by P. Desjeux, R. Shankar Ghosh, P. Dhalaria et al., Parasites & Vectors, July 2013.

Methodology of Clinical Trials Aimed at Assessing Interventions for Cutaneous Leishmaniasis, by P Olliaro, M Vaillant, B Arana et al., PLoS Negl Trop Dis., March 2013

Successful Therapy of Visceral Leishmaniasis With Curdlan Involves T-Helper 17 Cytokines, by Kuntal Ghosh, Gunjan Sharma, Anindita Ukil, et. al., Journal of Infectious Diseases, 2013



LEAP
LEISHMANIASIS
EAST AFRICA PLATFORM

LEAP consists of a group of scientists and institutions working on developing clinical trial capacity to bring new treatments to patients.

LEAP SITES

- **Sudan: 3 sites**
  (Kassab, Dooka, and Um El Kher)
- **Ethiopia: 2 sites**
  (Gondar and Arba Minch)
- **Kenya: 2 sites**
  (Nairobi and Kimalel)
- **Uganda: 1 site**
  (Amudat)

LEAP collaborates with DNDi, MSF, IOWH - India, IDA, TDR and industry partners in visceral leishmaniansis (VL) R&D work in East Africa.

DNDi AFRICA
Drugs for Neglected Diseases *initiative*

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