

DNDi
Drugs for Neglected Diseases *initiative*

LEAP
LEISHMANIASIS
EAST AFRICA PLATFORM



LEAP

AT WORLD LEISH 6

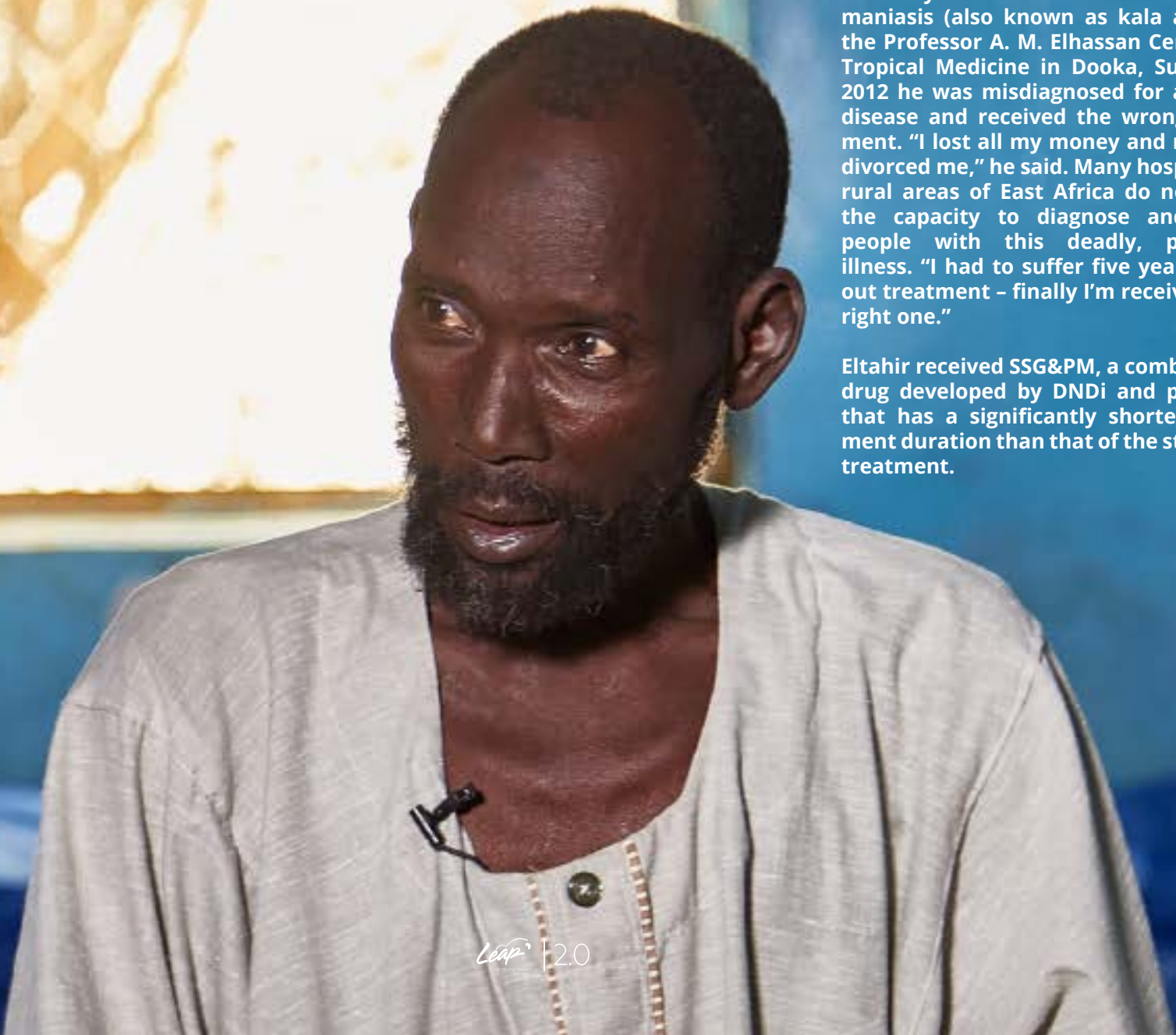
MAY 15-21 2017

**WORLD
6 LEISH**

TOLEDO, SPAIN

Toledo Congress Centre El Greco

Leap | 2.0
Keep moving forward



“This disease has destroyed my life,” said an emotional Eltahir Eissa on his third day of treatment for visceral leishmaniasis (also known as kala azar) at the Professor A. M. Elhassan Centre for Tropical Medicine in Dooka, Sudan. In 2012 he was misdiagnosed for another disease and received the wrong treatment. “I lost all my money and my wife divorced me,” he said. Many hospitals in rural areas of East Africa do not have the capacity to diagnose and treat people with this deadly, parasitic illness. “I had to suffer five years without treatment - finally I’m receiving the right one.”

Eltahir received SSG&PM, a combination drug developed by DNDi and partners that has a significantly shorter treatment duration than that of the standard treatment.



LEAP AT WORLD LEISH6 2017 *Leap* | 2.0

Keep moving forward.



The Leishmaniasis East Africa Platform (LEAP) will participate at the Worldleish-6 congress to be held in Toledo, Spain, the “City of Three Cultures”, from 16 to 20 May, 2017. This congress will bring together leishmaniacs from around the world to discuss the latest developments on leishmaniasis. In line with the congress objective of contributing to a better world by providing an international forum for sharing scientific values, knowledge and research for the benefit of patients around the world, LEAP will host the 24th LEAP meeting at the sidelines of the congress, present several abstracts and participate in a parallel session on platforms for research and control of leishmaniasis. For LEAP being part of this scientific discussion is another example of our commitment to encourage interaction, promote knowledge and learning of new best practices, and acquisition of a global perspective on the developments on leishmaniasis.



AUTHOR AND PRESENTER BIOS



PROF AHMED MUSA MUDAWI

Professor Musa is a professor of Immunology and Infectious Diseases and Director of the Institute of Endemic Diseases (IEND), at the University of Khartoum. He is a physician and infectious and Tropical Medicine expert, with an MSc in Tropical Medicine and International Health from the London School of Hygiene and Tropical Medicine, diploma of Tropical Medicine and Hygiene from the Royal College of Physicians in the UK and a membership of the Royal College of Physicians in Ireland. Prof Musa had his MBBS from the University of Khartoum and a Ph D in immunology in the same university. He is a qualified Clinical Trials Monitor by The WHO. Professor Musa sits in many committees setting guidelines for management of infectious diseases especially kala-azar. Prof Musa is the Principal Investigator, in Sudan, for LEAP clinical trials in the country. He is the immediate former Chair of the Leishmaniasis East Africa Platform.



PROF ASRAT HAILU MEKURIA

Prof Asrat Hailu Mekuria is a professor of Immunoparasitology in the School of Medicine, College of Health Sciences, Addis Ababa University. He holds a Ph.D degree from the University of Amsterdam, the Netherlands, and has over 30 years of research experience on leishmaniasis in Africa. Prof Asrat has published over 180 articles in peer reviewed journals, and has been leading several international projects on leishmaniasis. He is presently the Chair of the Leishmaniasis East Africa Platform.



ANKE KIP

Anke has a background in molecular biology and is currently finishing up her PhD on the clinical pharmacology of antileishmanial drugs. She has mainly focussed on the clinical pharmacokinetics of antileishmanial drugs in vulnerable patient populations such as pediatric and HIV co-infected patients.



FABIANA ALVES

Fabiana Piovesan Alves joined DNDi in 2008. She is the VL Leader of the Leishmaniasis Programme. Fabiana is a medical doctor, who graduated from the University of São Paulo, Brazil with residency in Pediatrics. Her PhD thesis on the molecular epidemiology of malaria in the Amazon region was followed by a post-doctoral position at TDR/WHO. She was a professor of parasitology at the University of São Paulo, coordinated projects at research institutes and has worked as a project manager for a clinical research organization. Fabiana has 15 years' experience in research on tropical diseases with the last 10 years principally in clinical research for the development of new treatments for neglected diseases, managing clinical trials from Phase I through to Phase III.



AUTHOR AND PRESENTER BIOS



GABRIEL OMWALO

Gabriel has over 10 years experience in clinical trials. He is a very passionate clinical trials quality expert with a strong experience in setting up, implementing and managing quality systems in clinical trials to support delivery of ethical studies and quality data.



PROF JOSEPH OLOBO

Joseph Olobo is a professor of Immunology and Microbiology, College of Health Sciences, Makerere University, Kampala, Uganda. A veterinarian by basic training with a master's and PhD degrees in Immunoparasitology and Immunobiology respectively, his interest in Tropical Diseases spans back when he studied: the epidemiology of Trypanosomiasis and Leishmaniasis at the ICIPE, Kenya; Immunology of leishmaniasis in mice at WEHI Australia and later embarked on a pioneer bold study to produce bovine monoclonal antibodies against trypanosomes at ILRAD, Kenya. Furthermore he established the non-human primate model for preclinical leishmania vaccine trials at IPR, Kenya and had a stint at AHRI in Ethiopia working on TB. Prof Olobo has trained many young scientists from eastern Africa and Uganda. He sits on a number of international and local scientific committees. His current interests are on Immunology of Infectious Diseases particularly leishmaniasis and clinical trials.



JOY MALONGO

Joy Malongo is the LEAP Coordinator at the DNDi Africa Regional Office Nairobi where she has worked for 11 years. She is the focal point for the LEAP Platform, a network that brings together partners, experts, researchers, government representatives, NGOs, international organizations, policy makers and other stakeholders, mainly from the eastern Africa region, working in leishmaniasis. She holds a Bachelor's degree in Communication from Daystar University, and is pursuing an MBA in Strategic Management at the same university.



LILIAN WERE

Lilian is an experienced Clinical Research Associate with over 12 years work experience in clinical trials. She has experience in neglected tropical diseases and infectious diseases. Her passion is mentoring of trial teams and overseeing the implementation of clinical trials in NTDs and Infectious Diseases and to ensure CTs are compliant to GCP and adhere to international standards with the hope of securing safe medications for the neglected patients.



AUTHOR AND PRESENTER BIOS



DR. MONIQUE WASUNNA

Dr Wasunna is the Director of the DNDi Africa Regional Office in Nairobi. She holds a Bachelor of Medicine and Bachelor of Surgery degree from the University of Nairobi, a Masters degree in Clinical Tropical Medicine and a PhD in Medicine from the University of London. Monique is a founding member and former Chair of the Leishmaniasis East Africa Platform.



SETH OKEYO

Seth joined DNDi in 2010. He is a Data Management Officer, and focuses his interest in the application of different computer systems and technologies in management of clinical trials data. Seth holds a Bachelor's of Science degree in Computer Information Systems from The Kenya Methodist University, and currently pursuing his Masters of Science degree in Information Technology from Strathmore University, Kenya.



DR. THADDAEUS WANDERA EGONDI

Thaddaeus is a statistician with DNDi involved in data management and analysis for different trials. He has a PhD in Epidemiology and global health from Umea University, Sweden. He also has masters in Biostatistics from Hasselt University, Belgium and Bachelors in Statistics from University of Nairobi. He has previous experience in both clinical trials and population studies.



DR. ROBERT KIMUTAI

Dr Robert Kimutai joined DNDi as Clinical Trial Manager in 2010. He has 14 years experience in clinical drug trials of Leishmaniasis, HIV and Malaria, and has worked in different research roles. Robert has a Bachelor of Medicine/ Bachelor of Surgery and Master of Medicine (Paediatrics) from Nairobi University. He also has a Master of Public Health from the Institute of Tropical Medicine in Antwerp, Belgium. Robert is a Certified Physician Investigator with the Association of Clinical Research Professionals (ACRP).



SIMON BOLO

has been with DNDi for the last 12 years and is currently the Regional Operations Manager for DNDi Africa Regional Office in charge of operations, finance, human resource & administration and logistics functions of the Nairobi office. Simon is an MBA and CPA (K) qualified finance and operations management professional with over 20 years' hands-on experience in offering operations and programme support for the efficient delivery of multi-country projects in health and poverty reduction in Africa



DR. THOMAS DORLO

is a pharmacometrician and clinical pharmacologist with more than 10 years experience in the field of leishmaniasis. His group works on novel biomarkers, bioanalysis, and modelling & simulation of pharmacokinetics and pharmacodynamics of antileishmanial drugs with the aim to optimize current and future drug regimens for visceral and cutaneous leishmaniasis.



Leap | 20

LEAP
AT WORLD
LEISH6 *Leap* | 20

LEAP Abstracts

Poster sessions run from 1630hrs to 1930hrs

NO.	TITLE	AUTHOR	DAY/TIME
C1676	Reasons for screen failures in clinical trials carried out in the leishmaniasis East Africa platform trial sites	Lilian Were	Oral: Tuesday, May 16, 2017 15:00-16:00 MIRADERO ROOM
C1552	Phase II randomized clinical trial of the efficacy and safety of ambisome® in combination with sodium stibogluconate or miltefosine versus miltefosine monotherapy for African visceral leishmaniasis	Dr Monique Wasunna	Oral: Tuesday, May 16, 2017 15:00-16:30 GRECO ROOM C1-C2
C1671	Visceral leishmaniasis (VL) baseline clinical presentations and association with initial treatment outcome among eastern African patients	Dr Thaddaeus Egondi	Poster Wednesday, May 17, 2017
C1679	Safety and Efficacy of Miltefosine Allometric Dose for the Treatment of Children with Primary Visceral Leishmaniasis in Eastern Africa	Dr Jane Mbui	Poster: Wednesday, May 17, 2017
C1727	Treatment of visceral leishmaniasis outside clinical trials; the case of LEAP	Joy Malongo	Poster: Thursday, May 18, 2017
C1542	Aggregation of patient level data for routine reporting using DHIS2 tracker module for VL surveillance and control	Seth Okeyo	Poster: Friday, May 19, 2017
C1385	Safety and effectiveness of sodium stibogluconate and paromomycin combination for the treatment of visceral leishmaniasis in Eastern Africa: Results from a pharmacovigilance program	Dr Robert Kimutai	Poster: Friday, May 19, 2017
C1550	The economic impact of visceral leishmaniasis in Baringo, Kenya	Simon Bolo	Poster: Friday, May 19, 2017
C1678	Treatment relapse at baseline: Impact on unplanned visits in a randomized clinical trial of HIV/VL coinfection treatment for patients in Ethiopia	Gabriel Omwalo	Poster: Friday, May 19, 2017
C1254	Epidemiology of Visceral Leishmaniasis in Karamoja Sub-Region, North Eastern Uganda	Prof Joseph Olobo	Poster: Friday, May 19, 2017



Leap | 2.0

LEAP
AT WORLD
LEISH6  | 2.0



AT A GLANCE

LEAP SPEAKERS AT THE CONGRESS

PARALLEL SESSIONS

TUESDAY, MAY 16, 2017 11:30-13:00

Parallel session (2): PKDL
TOLEDO ROOM

PKDL an overview of clinical aspects
Ahmed Musa

TUESDAY, MAY 16, 2017 14:00-15:30

Parallel session (5): The present and future of VL Treatment
TOLEDO ROOM

Treatment of VL: The African case (C
Robert Kimutai

New insights into the exposure-response relationships for miltefosine
in the treatment for VL
Thomas Dorlo

Perspectives for improved treatments on VL
Fabiana Alves

ORAL COMMUNICATIONS SESSIONS

TUESDAY, MAY 16, 2017 15:00-16:00

Session 4: Mucocutaneous leishmaniasis, diffuse cutaneous
leishmaniasis, post kala azar leishmaniasis
MIRADERO ROOM

Reasons for screen failures in Clinical trials carried out in the
leishmaniasis East Africa Platform sites (c1676)
Robert Kimutai

TUESDAY, MAY 16, 2017 15:00-16:30

SESSION 5: Drug Development: Conventional and alternative.
Clinical and experimental therapy in cutaneous and visceral
leishmaniasis greco room c1-c2

Phase II randomized clinical trial of the efficacy and safety of
ambisome® in combination with sodium stibogluconate or
miltefosine versus miltefosine monotherapy for African
visceral leishmaniasis (C1552)
Monique Wasunna

Modeling Miltefosine exposure after allometric dosing in pediatric
Visceral Leishmaniasis Patients in Kenya and Uganda (C0640)
Anke Kip

WEDNESDAY, MAY 17, 2017 09:30-11:00

SESSION 7: Drug Development: Conventional and alternative.
Clinical and experimental therapy in cutaneous and visceral
leishmaniasis MIRADERO ROOM

Pharmacokinetics of Simultaneously Administered Antileishmanial
and Antiretroviral Drugs in HIV/VL co-infected patients in Ethiopia (C0622)
Anke Kip

THURSDAY, MAY 18, 2017 11:30-13:00

SESSION 16: Clinical and Experimental Immunopathology and
Pathogenesis MIRADERO ROOM

Macrophage Activation Marker Neopterin as a Pharmacodynamic
Biomarker in Visceral Leishmaniasis (C0140)
Anke Kip

FRIDAY, MAY 19, 2017 15:00-16:00

SESSION 25: Leishmania-HIV Co-infection MIRADERO ROOM

Efficacy and safety of AmBisome monotherapy and ambisome plus
miltefosine for patients coinfecting with hiv and visceral leishmaniasis
in ethiopia – the hiv/vl 0511 trial (C1670)
Ermias Diro



24TH LEAP MEETING 2017 *Leap* | 2.0 Keep moving forward.



The 24th LEAP meeting will be a one day meeting of LEAP members and partners to interact, discuss and review planned activities, and agree on next steps to improve availability, adoption of, and access to treatments for leishmaniasis. Under the byword “KEEP MOVING FORWARD”, the meeting taking place at the Hotel Eurostars Toledo on May 15, 2017 will be the first after the launch of LEAP 2.0, a restructuring of the platform to enable it adjust to the expanding clinical trial needs of the region. **The Infectious Disease Data Observatory (IDDO) a VL data sharing platform, an initiative of a team from Oxford University will be launched at this meeting.**

PARALLEL SESSION **36** on Platforms for research and control of leishmaniasis

The role of partnerships as a modern approach to researching and developing treatments for neglected tropical diseases has been recognized and encouraged as a valuable step forward. To this end, the Drugs for Neglected Diseases (DNDi) and partners in VL and CL created disease specific platforms in disease endemic countries. The LEAP Platform, the RedLeish Network which brings together leishmaniasis experts in Latin America and other networks that are contributing to leishmaniasis research and control are Infectious Disease Data Observatory (IDDO) and Kala-Azar Consortium for Control and Elimination of VL (KalaCORE) will participate in parallel session 36 on Platforms for research and control of leishmaniasis, on Saturday 20th May 2017. This session will discuss the roles of these platforms and their contribution to research and control of leishmaniasis globally. Prof. Asrat Hailu, the Chair of the LEAP Platform will speak on “LEAP: Contributing to strengthening clinical trial capacity, treatment and control of VL in East Africa”.

**CLOSED
MEETING**

**26TH LEAP PRINCIPAL INVESTIGATOR'S MEETING
AGENDA MONDAY, MAY 15, 2017, TOLEDO, SPAIN**

Hotel Eurostars, Paseo de San Eugenio, Toledo

TIME	AGENDA ITEM	FACILITATOR
Chair:	Prof Asrat Hailu, Chair LEAP Platform	
08:20 – 08:30	Welcome and Introduction	Dr Monique Wasunna, DNDi
08:30 – 09:00	New Chemical Entities (NCEs) for leishmaniasis and discussion	Dr Jorge Alvar, DNDi
09:00 – 09:30	LEAP 2.0 Update: Strategic Advisory Committee (SAC) and discussion	Dr Monique Wasunna, DNDi
09:30 – 10:00	Financial Management of LEAP Platform partners: Internal control and Assurance review	Laurence Vielfaure, Finance and Planning Director, DNDi
10:00 – 10:20	Publications	Dr Monique Wasunna & Dr Jorge Alvar, DNDi
10:20 – 10:30	Debrief on Ethiopia visit by Dr Bernard Pecoul, Dr Joanne Liu and Dr Monique Wasunna	Dr Monique Wasunna, DNDi
10:30 – 10:40	Debrief on the Amudat and Kacheliba LEAP 0714 and 0208 Dissemination exercise	Joy Malongo, DNDi
10:40 – 10:50	IDDO update	Prof Philippe Guérin, IDDO, Monique & Jorge, DNDi
10:50 – 11:00	TEA Break	

24TH LEAP MEETING AGENDA
MONDAY, MAY 15, 2017, TOLEDO, SPAIN
 Hotel Eurostars, Paseo de San Eugenio, Toledo

TIME	AGENDA ITEM	FACILITATOR
11 : 00 – 19 : 00	OPEN SESSION	
Chair:	Prof Asrat Hailu, Chair LEAP Platform	
11:00 – 11:10	Welcome and Introduction	Prof Asrat Hailu, Addis Ababa University, Ethiopia & Dr Jorge Alvar, DNDi Geneva
11:10 – 11:30	Perspectives of new treatments for VL in eastern Africa: The present and the future	Dr Fabiana Alves, DNDi Geneva
11:30 – 11:50	PM + Miltefosine Communications plan	Linnet Otieno, DNDi Africa
11:50 – 12:10	LEAP 0511 results and way forward	Dr Séverine Blesson, DNDi Geneva
12:10 – 12:30	PKDL clinical trial update	Dr Brima Musa, IEND, University of Khartoum, Sudan
12:30 – 13:00	Discussion	All
13:00 – 14:00	LUNCH Break	
Chair:	Prof Yalemtehay Mekonnen	
14:00 – 14:20	Leishmaniasis in Africa: Is elimination possible? the WHO approach	Dr José Antonio Ruiz Postigo, World Health Organization (WHO), Geneva
14:20 – 14:30	Discussion	All

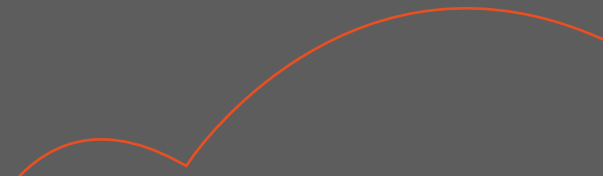


TIME	AGENDA ITEM	FACILITATOR
14:30 – 14:50	DHIS 2 implementation plans (VL Surveillance Data)	Dr Raymond Omollo & Michael Ochieng, DNDi Africa
14:50 – 15:00	Discussion	All
15:00 – 15:20	Joint Reviews and way forward for LEAP	Dr Nathalie Strub-Wourgaft, DNDi Geneva
15:20 – 15:40	EDCTP Proposal WP2 Improving VL diagnosis and treatment monitoring in eastern Africa by evaluating less-invasive tools	Isra Cruz, FIND, Geneva
15:40 – 16:00	Discussion	All
Chair: Prof Asrat Hailu		
16:00 – 17:00	VL Data Sharing Platform Launch	Prof Philippe Guérin, IDDO
17:00 - 19:00	Cocktail	

VL DATA SHARING PLATFORM UPDATE

Prof Philippe Guérin from the Infectious Diseases Data Observatory (IDDO) will present an update on the new VL data platform. The platform will enable researchers to maximise the use of data generated from VL trials that have been conducted globally by providing a global database of individual patient data that will enable meta-analysis exploring various factors that affect treatment efficacy. You will also be able to hear more about the project in a symposium on 'Platforms for research and control' on Saturday 20 May at 9.30, chaired by Jorge Alvar Monique Wasunna and from DNDi, and drawing upon the experience of the Leishmaniasis East Africa Platform, the Leishmaniasis Research Network (redeLeish), IDDO and KalaCORE.

The Infectious Diseases Data Observatory (IDDO) assembles clinical, laboratory and epidemiological data on a collaborative platform to be shared with the research and humanitarian communities. The data is analysed to generate reliable evidence and innovative resources that enable research-driven responses to the major challenges of emerging and neglected infections.





Leap | 2.0

LEAP
AT WORLD
LEISH6 Leap | 2.0
Keep moving forward



24TH LEAP MEETING

2017

Leap | 2.0
Keep moving forward.

About LEAP :

Launched in 2003, with the support of DNDi, LEAP is a research capacity strengthening network of scientists, local and international experts and health authorities from Ethiopia, Kenya, Sudan and Uganda, to strengthen clinical research capacity, facilitate knowledge sharing and training, as well as infrastructural upgrade of research centres for clinical trials in the region.



LEAP Secretariat

DNDi Africa Regional Office, Nairobi | Tetezi Towers, 3rd Floor, George Padmore Road Kilimani
P.O. Box 21936 – 00505 Nairobi, Kenya | Tel: +254 020 3995000 | Email: leap@dndi.org | Website: www.dndi.org