OCTOBER 2016 • ISSUE 5

LEAP Newsletter

LEISHMANIASIS EAST AFRICA PLATFORM

INSIDE THIS ISSUE

Dear Partners and Friends,
As another year passes and as we begin to look forward to the excitement of new opportunities and challenges, it is good to look back and recognize what has been accomplished. LEAP prides itself in strengthening local capacities in research. In this edition, we highlight the accomplishments of our members who have been awarded some very prestigious doctorates and fellowships. We share experiences from Umeå, Maseno, London, Oxford, and Antwerp and even hear from those who have benefited from the Africoleish supported GCLP initiative. You can read more about their experiences in this issue of the newsletter.

In this issue, we reflect on best practices in data management focusing on a recently completed study and celebrate partnerships highlighting the activities of the KalaCORE Consortium. We also have the Head of the Neglected Tropical Diseases Unit in Kenya share the vision for leishmaniasis in Kenya and highlight the activities initiated to improve and strengthen access to treatments for leishmaniasis patients. With the patient as the main focus, Tsadik, a Visceral Leishmaniasis (VL) patient from Abdurafi shares with us his journey in search of treatment.

We learn through our experiences. All of this reflects the tremendous progress we are making in improving access to better treatments for leishmaniasis in the region. Indeed, we have come a long way.

I do not believe that our successes would have been possible without the dedication and commitment of the LEAP members, partners and stakeholders; and the unwavering support from DNDi.

In 2017, we will continue to take the mission of LEAP forward into the future.

I would like to express my gratitude to members who have supported and contributed to this 5th issue as well as the past issues of the LEAP newsletters.

As the Chair of the LEAP Platform, I am proud of our achievements and I am looking forward to continuing success in the years to come.

Thank you all for your support.

Prof. Asrat Hailu

WORLDLEISH 6 in Toledo, Spain

Registration is now open for the next edition of WorldLeish, the premier congress for leishmaniasis expected to attract around 1500 participants including scientific experts and health decision-makers, WHO representatives, and governments representatives from endemic countries, and all major organizations involved in the fight against leishmaniasis.

Submit your abstract by the 30 November deadline and save the date to join us in Toledo, Spain, on 16-20th May 2017.

Co-organized by the WHO Collaborating Centre for Leishmaniasis of the Instituto de Salud Carlos III (Madrid, Spain) and the Drugs for Neglected Diseases initiative (DNDi, Geneva, Switzerland), the Congress scientific programme will cover all scientific and policy aspects of leishmaniasis today:

- from basic research to disease control and elimination – as targeted by the WHO Roadmap for Neglected Tropical Diseases and the 2012 'London Declaration';
- with a focus on patients' needs but also sessions on canine leishmaniasis and vector research;
- with dedicated symposia on drug discovery, trial standardisation, and advocacy to discuss the way forward with experts and key actors;

WorldLeish is also partnering with PLOS journals on a Special Collection on leishmaniasis that will compile publications on the key topics discussed at the Congress. Submission for articles is now open, with publication of the first articles in the series (which will be updated until the Congress) coming soon. More information: http://blogs.plos.org/collections/call-for-papers-worldleish6/

www.worldleish2017.org

2017 UPCOMING EVENTS

DATE	EVENT
February 21st – 23rd	WHO review meeting on Leishmaniasis control in East Africa, Nairobi Kenya
May 16-20, 2017	6th WorldLeish Congress on Leishmaniasis will be held in Toledo, Spain www.worldleish201.org
March 7 - 9, 2017	Africa Health Agenda International Conference (AHAIC) 2017, Nairobi Kenya

Word from the Director, DNDi Africa Regional Office

Greetings LEAP family from our new office at Tetezi Towers, in Nairobi, Kenya

The past one year has been very fruitful for LEAP. The 22nd LEAP meeting, held in Khartoum, Sudan in October 2015 was exceptional. Apart from our usual updates, we had the privilege of hosting the DNDi Executive Director, Dr. Bernard Pécoul, and the Sudanese Minister, for Higher Education and Scientific Research Dr. Somia Abu Kashawa. Their presence provided validity to the hard work that LEAP has done over the years. After this meeting, we had other important sessions including conferences in Nairobi and Kampala in the month of November 2015 to revise visceral leishmaniasis (VL) guidelines. These meetings were an example of great partnership and a testimony of our commitment to support Ministries of Health in VL policy change in the region .

In January 2016 we held a successful symposium themed ***Innovation for Access to Treatment for Neglected Diseases*** in Nairobi, Kenya, during the KEMRI Annual Scientific and Health Conference (KASH). What was more remarkable was that we held the symposium during the first ever American Society of Tropical Medicine and Hygiene (ASTMH) meeting held in Nairobi. The symposium served as a platform for bringing together regional experts in neglected diseases to develop strategies for patients and ensure that they get the treatments they need. We were happy to have a patient talk about his experience with the disease as well as the Executive Director of ASTMH who commended the work done by LEAP. The symposium called for more effective and seamless partnerships in tackling the issue of access to treatment for patients suffering from neglected diseases. DNDi also had the opportunity to participate in the Tokyo International Conference on African Development (TICAD) VI post - event focussing on infectious diseases where, again, LEAP was lauded for undertaking quality and accurate research.

Our studies have been moving on well in the past year. Although we had to stop our HIV/VL (LEAP 0511) recruitment process, due to lower than expected efficacy at the end of 1-month treatment, the strategy to provide an extended treatment (2nd cycle of therapy) for those who still had not cured has proven to be the right step towards a new approach for HIV-VL case management, by reaching very satisfactory efficacy. The work continues on the analysis of the long-term follow-up for the HIV-VL patients In parallel, our miltefosine pharmacokinetics study (LEAP 0714) which was assessing the exposure of the oral treatment in children using allometric dosing was successfully completed. Good protocol adherence and high quality research documentation according to Good Clinical Practice (GCP) standards were among the reasons for this success. Once again we saw clearly the value of capacity building in the effective running of the studies. Over the past one year, staff and partners have been trained on Good Financial Practices (GFP), GCP, Good Clinical and Laboratory Practices (GCLP), Communications among others. We have now earnestly begun our journey towards our ultimate target of an oral treatment for VL. In addition, a new cohort study for HIV-VL co-infection will be discussed with the Ethiopian authorities to consolidate the evidence for a new case management approach and to facilitate access for combination therapy in this patient population.

This year, we piloted the District Health Information System (DHIS2) tool in collaboration with the Ministry of Health and the World Health Organization in order to capture VL data and information in Kimalel, Baringo County. DHIS2 is an open source software tool designed for collecting, validating, analyzing, and presenting statistical data. The processes of data capture for DHIS2 takes place at the VL treatment site and can be done from source documents or patients hospital records making data collection easier and more valid. Furthermore, data collected through this tool will be key for planning future clinical research with new therapies for leishmaniasis.

After many successive consultative sessions, our LEAP publication was published by the Transactions of the Royal Society of Tropical Medicine. The publication titled ***The Leishmaniasis East Africa Platform (LEAP): strengthening clinical trial capacity in resource-limited countries to deliver new treatments for visceral leishmaniasis*** is on open access publication in the Royal Society of Tropical Medicine and Hygiene journal. Another publication arising from LEAP 0208 clinical trial titled ***Efficacy and Safety of AmBisome in Combination with Sodium Stibogluconate or Miltefosine and Miltefosine Monotherapy for African Visceral Leishmaniasis: Phase II Randomized Trial*** was published in PLOS NTD as an open access publication.

Finally, this is a great time for LEAP as we look back at our past successes and anticipate how we can improve and build the LEAP of the future. Let us continue to work hard for the neglected patients so that we can give them a voice!

Dr. Monique Wasunna

DNDi Research Updates: Visceral Leishmaniasis and Mycetoma

By Robert Kimutai

2016 has been busy for our flagship disease Visceral Leishmaniasis (VL) as well as the new kid on the block Mycetoma. In quarter one, we completed the last visit of the clinical trial on miltefosine for children in Kenya and Uganda, and a VL urine specimen collection study; and in quarter three the last visit of the HIV-VL trial in Ethiopia came to a close. We are now rolling up our sleeves in preparation for a new Phase III VL trial and a clinical trial in Post-Kalazar Dermal Leishmaniasis (PKDL) in 2017, and are also gearing up to enrol our first patient in the Mycetoma Study in quarter four of 2016.

Visceral Leishmaniasis

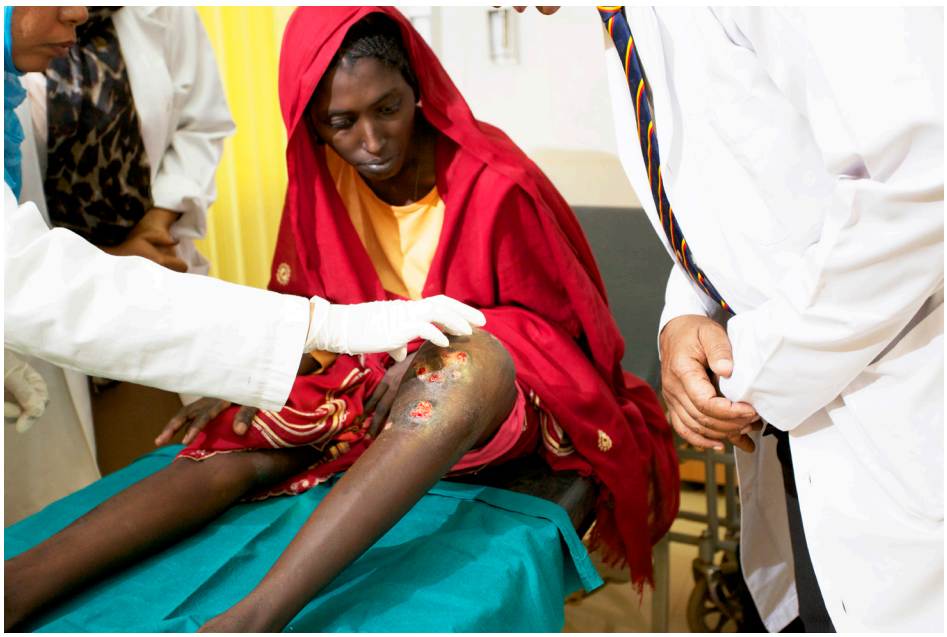
The two VL clinical trials (Miltefosine PK and HIV/VL co-infection) that are coming to an end this year have significant bearing in the future. The Miltefosine PK trial conducted in children in Kenya and Uganda has been pivotal to our understanding the complex dynamics of how children handle the oral Miltefosine treatment. This study was birthed after the realization in a previous trial that Miltefosine did not work in children as well as it did in adults. Since Miltefosine is currently the only oral drug for the treatment of VL, it is crucial for combination treatments. The HIV/VL clinical trial took place in Ethiopia and was seeking better treatments for patients co-infected with the two diseases. The existence of the two diseases in one individual not only makes the clinical presentation worse but the diseases much more difficult to treat.

We began the urine specimen collection study in 2015 and completed it in quarter one 2016. This is a diagnostics study that is different from other studies we have done before. The target of the study is to develop better and simpler tools for VL diagnosis that will use urine specimen instead of the very complicated and invasive splenic aspirate.

Going forward, we are planning a new clinical study using a combination of Paromomycin (PM) and Miltefosine. This study, which is in its conceptualization stage, seeks to provide a new and alternative treatment for the region as we look forward to testing new chemical entities in the coming years. In addition, we plan to start the first LEAP study on PKDL patients in Sudan, looking for alternative combination treatments for this patient population.

Mark Riongota, a Clinician at Kacheliba Sub-District Hospital inspects a child with Kala azar

Besides the clinical trials, DNDi and LEAP are key stakeholders in the WHO bi-regional



A patient with Mycetoma is inspected by the health team at the Mycetoma Research Centre in Khartoum, Sudan

meetings, where one of the gaps identified was the need to revise VL diagnosis and treatment guidelines in Kenya and Uganda and to unequivocally recommend the combination SSG&PM as a first line therapy and consequently its improved access. With the knowledge base we have built in the clinical trials for over a decade, we can provide robust evidence and guidance incorporated into VL diagnosis and treatment. In this regard we have organized meetings with the Ministries of Health (MoH) in Kenya and Uganda to review guidelines and are active taskforce members in the MoH working groups. DNDi also gives compassionate support to cutaneous leishmaniasis (CL) patients in Gilgil in central Kenya. DNDi also visited the hospital with the WHO and MoH officials, and eventually participating in a cutaneous leishmaniasis training.

Mycetoma

As you are already aware mycetoma was included in the list of WHO Neglected Tropical Diseases (NTDs) during 69th World Health Assembly. Mycetoma is one of the latest additions to DNDi's portfolio. We will be conducting the first ever mycetoma clinical trial in Africa. There is great anticipation and expectation that significant new information will be generated by the study with the goal of providing patients with a new, more effective treatment. The study which will be conducted at the Mycetoma Research Centre in Sudan, has already benefitted from DNDi's experience from VL trials and since it is more complex in nature, it will provide reciprocal lessons to VL studies even at its infancy.

Undertaking clinical trials is often a complex process that requires interaction of various players who must synergize their efforts. More importantly, patients must be given first priority. Their rights must be respected and trials should be done according to the stipulated international standards. Though the clinical trial process is standard, each study is unique and we learn valuable lessons. However, the enduring lessons are that teamwork, attention to detail and respecting patient rights are the critical success factors.

Milestone as Arba Minch Leishmaniasis Research and Treatment Centre is handed over to the Ethiopian Ministry of Health

By Joy Malongo

On May 19, 2016, Arba Minch Leishmaniasis Research and Treatment Centre (LRTC) was handed over to the Ministry of Health, Arba Minch Hospital. Simon Bolo, the DNDi ARO Regional Operations Manager officially conferred the centre to Mr Adamu Kiiro, the Chief Executive Officer (CEO) of ABH in the presence of Prof Asrat Hailu, the LEAP Chairperson, Dr Tamiru Shibiru the site Principal Investigator and the hospital's staff.

Built by DNDi in 2006 with funds from the Leopold Bachmann Foundation (a Swiss philanthropic organization), the LRTC has served as a treatment and research facility for patients suffering from VL in Southern Ethiopia for about ten years. Due to the rigorous treatment initiatives, the number of VL patients seeking treatment at the hospital has greatly declined.

In her handover letter, Dr Monique Wasunna, the Director of DNDi Africa noted that due to the diminishing patient numbers, it was inevitable that DNDi activities at the LRTC come to an end. However, patients will continue receiving free treatment thanks to KalaCORE; a partnership supporting the control and elimination of VL in six countries in Asia and Africa (including Ethiopia, Sudan and South Sudan). The KalaCORE project has identified 18 treatment centres within Ethiopia where this treatment will be delivered including ABH which will be a referral hospital for complicated VL cases in South Ethiopia.

"I believe that through this facility, the community in Arba Minch will continue to experience improved access to health care services and quality of life", said Dr Wasunna.

Dr Wasunna said that DNDi considered it a great privilege to have worked with the hospital especially in undertaking significant VL studies. The LRTC was Africa's first Clinical Research facility for VL and over the years, more than 1,000 patients have received treatment at the centre.

Simon Bolo, DNDi Africa's Operation Manager presents a letter to officially hand over LRTC. Looking on is Prof Asrat Hailu, the Country Principal Investigator and members of staff at Arba Minch Hospital

WHO fact finding mission on leishmaniasis

By Joy Malongo

On a mission to establish ways of contributing to improved leishmaniasis control in Kenya, the Ministry of Health (MoH) in partnership with the World Health Organization (WHO) and DNDi visited Baringo and Nakuru Counties in Kenya in April 2016.

The objective of the three day mission, led by Dr Davis Wachira, the national VL Focal Person in the MoH, was to identify challenges affecting implementation of programme activities and also determine possible solutions for these challenges. This visit provided a chance to solidify partnerships between county and national governments and the WHO in ensuring that issues affecting implementation of VL activities are addressed promptly. It was also an opportunity to discuss ways of improving leishmaniasis surveillance and data reporting using the District Health Information System (DHIS 2) tool.

In Baringo, the team was received by Dr Andrew Kwonyike, the County Executive Officer Health. In attendance were Dr Angela Tengekyon, Head, Medical Services Directorate and the County Health Management Team. He praised the work carried out by the national government and DNDi in VL in Baringo County and emphasized the need for continued partnerships. Dr Esther Kinyeru the Gilgil Sub-County Medical Officer of Health received the team in Nakuru County. She led the team on a tour of the villages bordering the rocky cliffs in the region where a total of 401 cutaneous leishmaniasis cases have been identified.

The group from DNDi, WHO and the Kenyan Ministry of Health visit CL patients in Gilgil

I Have Gained So Much and Now Ready to Pass on the Knowledge to Others

By Ermias Diro

It started with what looked like simple questions asked during my routine work at University of Gondar (UoG) hospital.

"What shall we do with this patient who is co-infected with HIV and VL? The test of cure is always showing LD bodies, what can be done next?"

We were treating the VL and putting the patients on anti-retroviral treatment (ART) but the VL was recurring. Sometimes patients presented with oral lesions and we thought it was Kaposi sarcoma or oral lymphoma but the test results showed that it was leishmaniasis. There were many several interesting and challenging cases of leishmaniasis at the Leishmaniasis Research and Treatment Center established by DNDi in Gondar, Ethiopia. I presented some of these cases during a short training course at the Institute of Tropical Medicine in Antwerp and there my journey started.

I have learned a lot since then. I did not know that there were so many things to consider while conducting clinical trials – the resources needed, the monitoring visits, quality issues, the data cleaning and analysis, the ethical aspects and so on. I also learned the importance of frank and timely communications as well as patience and partnership. I really feel that I have grown to be an expert in the field. Thanks be to all those who supported me from the beginning to the end – ITM, DNDi, MSF, and UoG.

Dr. Ermias Diro (centre) during his graduation

During the last day of my defence, one of the guests said to me, "it is not defending PhD that shows your success, it is the number of PhDs that you will produce in the future". Thus, I am ready to pass on my knowledge and skills to those who like to pursue in this path.

Dr. Ermias Diro is the Principal Investigator at the University of Gondar VL clinical trial site

My 12 Year Journey to Becoming a Neglected Disease Research Expert

By Yegnasew Takele

Poverty and infectious diseases have created a synergistic effect in developing countries leaving millions dead. Many people in these countries hope that science can provide a solution to their health needs. For many years, infectious diseases such as VL did not get enough attention. DNDi opened the door to push the scientific community to address these diseases, conducted clinical trials and brought better treatment options. For VL, they not only conducted research but also offered free treatments to thousands of poor patients. Moreover, DNDi has invested in training local professionals and built the capacity of research centres in conducting research. One of the centres that benefited from this investment is the Leishmaniasis Research and Treatment Centre (LRTC) at the University of Gondar (UoG), Ethiopia. This is the centre where I had my first experience in research and began my career.

I started working as a Technician in the Centre in 2004. By that time, I had a diploma in Medical Laboratory. Following the continuous support and the trainings (Good Clinical Practice, Good Clinical Laboratory Practices) organized by DNDi, my colleagues and I realized the importance, principles and ethics of conducting clinical trials. In 2007 I did my BSc in Medical Laboratory Sciences. My research project described

Continued on page 8

Continued from page 7

the ***prevalence and trend of visceral leishmaniasis in Addis Zemen District in North West Ethiopia***. Thereafter, I got full scholarship from DNDi in 2009 and completed my Masters in Infectious and Tropical Diseases in 2011 from the University of Gondar. My project was titled '***Arginase Activity in the Blood of Patients with Visceral Leishmaniasis and HIV Infection'***. In 2013 I published three research findings as a first author and co-author. Moreover, working in the LRTC and attending important meetings organized by DNDi and its partners helped me to meet people and network with the scientific community. Through my networks, I started applying for research grants as a Principal Investigator and co-applicant.

In 2014 I have secured two research grants; one for a Masters Training Fellowship in Public Health and Tropical Medicine at the Wellcome Trust and the other from the International Exchanges Scheme, Royal Society together with Dr. Ermias Diro and Dr. Pascale Kropf as the Principal Investigator. In 2015 I graduated from Imperial College London with a Masters in Immunology. From 2014 to date, I have published seven research findings with local and international collaborators. I am now training MSc Immunology students at the UoG and creating opportunities for them to get support for their projects from local and international funders. Since 2013, a total of 10 students from the School of Biomedical and Laboratory Sciences at the UoG have completed their MSc project at LRTC.

All the students were successful because of the centre that DNDi put in place as well as the continuous technical and expert support from DNDi and its partners. I am now enthusiastic to continue my career in research and working with collaborators to apply for funding for my PhD project ***'Understanding the immune response and immune pathology in patients with VL and VL/HIV co-infected patients'.***

Finally, through the opportunities created by DNDi, I hope that we will manage to open eyes and ears that will see and listen to the neglected patients!

Yegnasew works at the DNDi-LEAP clinical trial site at the University of Gondar

My Experience combining Doctoral Studies and A full-time Job

By Thaddeus Egondi

It is exciting to get an opportunity to pursue PhD studies whether full-time or part-time (sandwich). A sandwich program is where a student spends some time in a university abroad and the rest of time within their local institution. Although it seems more appealing to focus on studies before beginning employment, most postgraduates will find themselves doing both at some point.

Each individual situation is different, and it might be hard to generalize the average length of a PhD programme. Generally speaking, a PhD thesis would require about 3-4 years working full time. This is likely to vary from one person to the other. For one to take the same period while studying only part-time requires a lot of dedication, sacrifice and good time management. From my experience as a sandwich PhD student and also from others who have gone through this form of study, the price of doing a part-time higher degree bears a heavy personal cost.

However, it is a rare opportunity offered by few non-academic institutions in the region so the opportunity should be seized whenever they arise. DNDi is one of the institutions in the region that offers opportunities to support its full-time staff to pursue postgraduate studies. Dr. Raymond Omollo; the Head of the Data centre successfully completed his PhD in 2015 as a part-time student supported by DNDi. I also completed my PhD in the same year under sandwich arrangement between Umea University in Sweden and African population and health Research Center (APHRC) in Kenya.

Though it was quite demanding to combine PhD and full-time work, there are few points that can contribute to timely completion of studies while working full-time. They include; 1) being in an environment with experienced researchers that are supportive, 2) identifying one's strengths and weaknesses and having a team who can complement the weaknesses, 3) selecting a PhD topic related to your daily work, 4) setting targets with clear timelines and constantly evaluating your progress. The four points may seem obvious but can lead to great success if implemented effectively.

Dr. Thaddeus Egondi is a Statistician at the DNDi Africa Regional Office

"The GCLP trainings have been of great help. I now have a better understanding and know-how on internal and external quality assurance, sample management including sample shipment. This has helped me improve on lab activities, bearing in mind international standards. I have also improved on data and information management including facility, safety and security, and inventory management".
– Edwin Nyagwa Abner, Laboratory technologist, Kacheliba sub-county hospital speaking about the value of GCLP trainings he has attended.

WHO/TDR Fellowship and the birth of a VL Data Sharing Platform

By Michael Otieno

As soon as I settled down in Oxford, an action plan for developing a pilot platform for Visceral Leishmaniasis (VL) data sharing was developed. This was not only an exciting project, but also one with a steep learning curve, having to work closely with a team in a multi-disciplinary setup including experts in bio-informatics, data management and statistics as well as established scientists, all working with a common goal – a successful data sharing platform for VL. This was a practical opportunity to understand the building blocks of managing data from heterogeneous studies in a controlled framework of an individual patient data sharing platform.

Over the last seven years, the WorldWide Antimalarial Resistance Network (WWARN), which is now embedded under the IDDO umbrella, has successfully set up an effective data sharing platform for malaria using bespoke tools and systems designed to facilitate the storage, standardisation and analysis of clinical trial data. Since these tools can be re-used, the VL data sharing platform will be developed using existing WWARN technology making it a more economic venture.

Systematic review of previous VL studies

At the beginning of the fellowship, a proper understanding of VL studies and the feasibility of establishing a VL platform was critical. I was engaged in a systematic review of VL studies undertaken between 1983 and 2015. The systematic review not only highlighted key platform design considerations but also gave me an in-depth understanding of VL as a neglected tropical disease. Drawing on the insights from the systematic review and my prior experience in VL data management, I developed, together with the University of Oxford, a data management plan and data dictionary which we then used to set up a pilot VL data sharing platform using the existing technology and infrastructure at IDDO.

Pilot data sharing platform for VL

About one year into the fellowship, the pilot platform was fully set up and ready to receive VL data. The pilot platform is a set of tools that are seamlessly integrated to make pooled data analysis possible for researchers' use. It consists of a web portal which enables contributors to share data from their VL studies after agreeing to the platform terms of submission. The submitted data is then received by the platform data managers who undertake a data curation process, identifying any discrepancies in the submitted data and then providing feedback to data contributors for resolution. After all queries have been resolved, the data is considered clean and the platform Data Manager proceeds to standardize the submitted data in a VL data mapper – a web application which transforms raw patient level data files into standardized data held in the VL data sharing platform. This pooled data can then be used for analyses of specific questions relating to VL treatment options.

Skills, Knowledge Gain and Networking

My fellowship at IDDO has contributed greatly towards my personal career development. Other than the opportunity to work on the pilot VL platform together with top-notch programmers in the informatics team, it also created a chance to acquire new skills from the wider University of Oxford IT community. I attended short courses in data management as well as in advanced programming skills such as Java and Agent Based Modelling (ABM). As a WHO/TDR fellow, I am also grateful for networking opportunities with other fellows through the alumni meeting held in Geneva in June 2016. An ongoing and active forum has been created to enable young scientists work together after their fellowship placements.

Transferring knowledge and expertise

Setting up a pilot data sharing platform for VL is a first step in the right direction for the VL scientific research community as it aims at pooling all available data on VL treatment. Pooled data analysis has the potential to narrow knowledge gaps in VL treatment and thus accelerate the development and production of future treatments. I am excited to share the data management skills and expertise gained at Oxford with data management teams throughout the region. These skills will also improve the quality of data that emerge from the various studies that DNDi conducts.

Much appreciation goes to WHO/TDR for accepting my application to participate in a career development fellowship program, to IDDO for accepting to host and to generously share their expertise with me, and also to DNDi and Strathmore University for granting me leave to participate in this program.

DNDi Data Manager, Michael Otieno, spent a year in Oxford developing a pilot VL data sharing platform that would maximize the use of data generated from VL clinical trials conducted globally. Upon successful application to the WHO/TDR Career development fellowship program, Michael started his fellowship placement at the Infectious Diseases Data Observatory (IDDO) in September 2015. IDDO is based at the Centre for Tropical Medicine and Global Health at the University of Oxford in the UK.

Raymond Omollo Describes his Journey to attaining Doctoral Degree

By Joy Malongo

Congratulations on earning your PhD. A doctoral degree is no mean feat. How was the journey?
Thank you. The journey was a mixture of many factors. When I look back however, it was a worthwhile experience. There were several false starts, but the courage to pick myself up and get going and support from the people around me and God made it possible.

What were you studying?
I was undertaking a PhD in Applied Statistics at Maseno University, Kenya. I enrolled for the program in July 2011 and graduated in December 2015. My thesis was on the "Design and Analysis of Endpoints in Clinical Trials for Visceral Leishmaniasis (VL)".

Why did you choose Maseno University?
It was mainly because I wanted supervisors (both local and international) who had the knowledge of applying statistics to health problems and an interest in the subject area I wanted to study. I also wanted a flexible program given my other responsibilities at work and with my family.

Why your specific research topic?
I wanted to make a contribution to what my fellow scientists are already doing to find improved treatments for VL. One existing challenge is the duration it takes to treat the disease as well as when to declare a patient cured. In addition, there is lack of interest in evaluating alternative clinical trial designs useful for cutting down time taken in conducting clinical trials.

"I thank DNDi for the capacity building done at our site, Kacheliba sub-county hospital; through training, purchase of equipment and participation in clinical trials. This is going to bridge the gaps in the treatment and access to proper health care services to the community. I am proud to be part of a team that gained new knowledge through training and participation in a clinical trial for the first time".
Martin Kundu Sunguti, Lab Head Kacheliba, West Pokot, Kenya on participating in trials for the first time

What were your findings?
I established that it is possible to shorten the time taken to evaluate cure/failure for treatment of VL. Viable alternatives exist in estimating cure at extended follow up in sequential designs particularly triangular test, although there isn't adequate evidence to associate the use of Sodium Stibogluconate with cardiotoxicity in Eastern Africa patients.

How did you balance between work, school and social life?
It required a lot of discipline especially in terms of time management and goal setting. I got a lot of support from my director who constantly followed up on my progress. My family provided a good environment at home and was very understanding when I had to stay away from home for long periods particularly in the last year of the program. I had very supportive colleagues in the office who were interested in what I was doing and even spent their time reviewing my work.

What was the most difficult or challenging issue you experienced?
Keeping the schedule and striking the balance between work and family demands.

What next for you after completing your PhD?
Locally, not a lot is available in terms of mentorship and I hope to do my bit in providing this to upcoming scholars where possible. I need to add value to my work by being more involved in the design and management of trials in the region.

Any word of advice to those who may be thinking about walking this path?
There is never a 'most ideal' time to start a PhD; it's never too late to start. A PhD is largely about the experience you have and how you can apply that experience in solving problems that you have come. The first thing is to look for a mentor/supervisor who will have time to advice and guide you but always remember that this needs to be more about what your interest is in answering specific questions rather than someone else's.

What lessons did you learn from this process?
Patience is important. At one point I almost gave up but believed that it can be done. You also have to be open to criticism and positively acknowledge feedback even if it means starting afresh. There is a lot of value in support from seniors and other people around you like the family. Also, trust in God and the ability to get things done.

Dr Raymond Omollo is the Head of Data Centre and Statistician at the DNDi Africa Regional office.

Reflecting on Best Practices in Data Management: The case of Miltefosine Allometric Trial

By Truphosa Omollo

Continuous improvement in data management is a perquisite for high quality data and efficient delivery of clinical trial results. The Data Center (DC) is responsible for data management for trials conducted by DNDi Africa Regional Office (ARO) and has an objective of continuously improving data and using innovative approaches to facilitate high quality data management. Data management (DM) is a critical phase in clinical trials. The DM process starts right from the planning phase, through implementation to the end of the trial. Critical activities of DM process include Case Report Form (CRF) design, Database design & validation, Query Management and Quality Control. The DC has developed best practices to ensure a smooth process in managing clinical trial data.

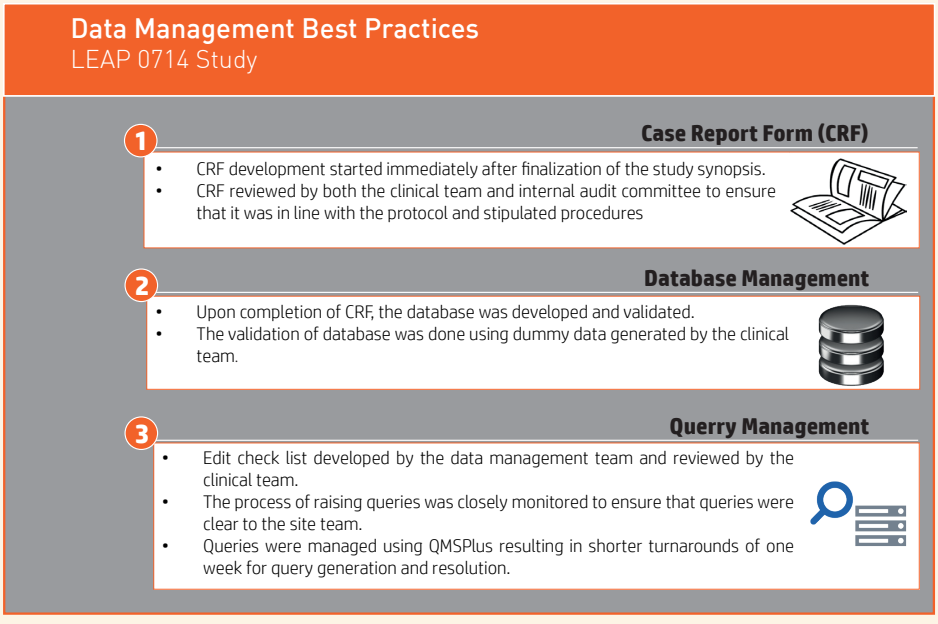
To describe the data management process at the DC, we reflect on a recently completed trial; Miltefosine PK. The trial was assessing the pharmacokinetic, safety and efficacy of Miltefosine using allometric dosing in the treatment of children with primary Visceral Leishmaniasis (VL) in eastern Africa. The trial recruited 30 participants in two sites; Kacheliba in Kenya, and Amudat in Uganda.

The CRF development started immediately after finalization of the study synopsis. After the CRF was designed, it was reviewed by both the clinical team and internal audit committee to ensure that it was in line with the protocol and the stipulated procedures.

Upon completion of CRF design, the database was developed and validated. The validation of database was done using dummy data that was generated by the clinical team with different scenarios. The edit check list for query generation was developed by the data management team and reviewed by the clinical team. The process of raising queries especially on safety data was closely monitored by the clinical team to ensure that queries were clear to the site team. An in-house innovation to manage queries using the QMSPlus was utilized resulting in shorter turnarounds of one week for query generation and resolution. This short turnaround time ensured timely updates to the dataset and led to soft lock of the database within 3 months after last patient, last visit. This was a huge improvement in the data cleaning process. In previous studies, the database lock has been at least six (6) months after last patient last visit. A detailed Data Management report was generated at the end of the study capturing the various activities and challenges encountered during the trial. This report captured all the unsolved queries, the ongoing Adverse Events' (AEs), and the deviations that were reported during the study period. This ensured the statistician was well informed on the missing or inconsistent data; thus avoiding a back and forth process.

Despite the remarkable improvement in the processes, there were a number of lessons learnt that can greatly improve the processes. To begin with, there need for continuous review of the data entry quality checks including the development of AEs and edit checklist during trial implementation. In addition, data cleaning

should be a continuous process and used as a learning process. Finally, more people who are not directly involved in the study should also be involved to review the study programs. These lessons indicate the need for continuous improvement. We should consider using new and innovative approaches such as the eCRF and also conduct risk based monitoring to improve data capture. Teamwork and close functioning between DC, clinical trial teams and study teams is essential for high quality data as well as a highly efficient and timely process.



Our Vision for Neglected Tropical Diseases in Kenya

By Linet Otieno

Dr. Sultani Matendechero is the Head of the Neglected Tropical Diseases (NTDs) Unit in Kenya. The Unit oversees the control and management of neglected disease projects in the country. He speaks about the Kenyan Ministry of Health's vision for NTDs and more specifically for leishmaniasis

1. **What are Neglected Tropical Diseases? –** These is a group of communicable diseases found in tropical and subtropical regions and according to WHO, affect more than one billion people, costing developing economies billions of dollars every year. Currently there are 18 neglected diseases listed by WHO.

2. **What NTDs does the Ministry of Health focus on in Kenya? –** Out of the 18 neglected diseases listed by the WHO, we are focussing on 15 that are either confirmed or suspected to be endemic in Kenya. Only Chagas disease, Buruli ulcer and Yaws are not prioritized. Leishmaniais is an important disease of emphasis within the NTD Unit.

3. **When was the NTD Unit set up and what was is its mandate?**
   The unit was set up in 2013 to coordinate the control of NTDs in the country.

4. **What milestones have been experienced in the NTD Unit since its inauguration**
   One of the greatest milestones we have had is this year's launch of our five year strategic plan. This strategic plan will act as a guide to the implementation of our NTD activities. In addition, over the past three years, we have strengthened activities around some specific NTDs such as trachoma and lymphatic filariais and have begun seeing important milestones. Leishmaniasis will be an area of considerable focus in our next phase.

5. **What is the MoH's vision for Leishmaniasis in Kenya?**
   We are targeting elimination of leishmaniasis. This may take a long time but we will begin by first setting targets and then program our activities towards this.

6. **What are the main challenges experienced in treating and controlling leishmaniasis**
   The main challenge we experience is the lack of integration. We have a lot of stakeholders working in silos but we are not integrating effectively. The NTD unit intends to offer coordination and build the confidence among partners to view integration as a positive step towards controlling leishmaniasis and other NTDs.

   Another challenge that we have had is the lack of accurate records and documentation. Because of this, we are not able to map out where the diseases are and to determine if the efforts we are putting in place are working effectively. This is what we will be focussing on in the upcoming years.

7. **What has the government been doing towards access of treatments for leishmaniasis**
   Access has been a major challenge in the country but we have begun activities towards improving and strengthening this component. We are planning to respond to this issue in two main ways; systemically and socially.
   - We plan to improve budgeting and forecasting to determine the needs and gaps in the endemic areas.
   - We realized that we already have treatments in our stores that were purchased or donated but have not been distributed. We plan to distribute this to the endemic regions.
   - We are speaking to the IDA Foundation so that we can begin purchasing treatments affordably.
   - We want to strengthen advocacy efforts at the community level so that those who live in endemic areas can seek for treatment on a timely basis.

8. **What are some examples of innovative steps or measures taken by the NTD Unit in the fight against leishmaniasis**
   We are in the process of developing our leishmaniaisis strategy and although much has been done in the past, we want to focus on future plans. We plan to set up a taskforce that will focus solely on leishmaniasis. This taskforce will include various stakeholders. This will ensure that we have an inclusive approach and the burden for the disease is distributed among stakeholders. We want to strengthen existing partnerships and build new ones to make this possible.

   Through the years, we have identified capacity building as a crucial component for the fight against leishmaniasis. We want to jumpstart this component and execute it in a more coordinated manner.

   Finally, as a unit, we recognize the value of monitoring and evaluation as well as research. Our five year strategy places a lot of emphasis on this. We want to mobilize resources for leishmaniais research so that we have better control and treatment and more cost-effective mechanisms to reach out to more people.

9. **Any thoughts about R&D and**

documenting of leishmaniasis cases country wide

In our recently launched strategic plan we placed a lot of emphasis on evidence-based decision making. We want more research to take place so that we can make more informed decisions. In view of this, we have come up with a bottom-up approach towards documentation. In this approach, we are engaging coordinators at county (47) and sub-county (290) level to collect information on a monthly basis and enter it into an NTD database which we are about to launch. This database will cover all the NTDs including leishmaniasis. We want a one stop shop for all NTD information. The database is very flexible and easy to use; both the Ministry and partners can contribute to it. Once we launch this, we will be able to have a better picture of endemicity and also how treatments are reaching people infected with leishmaniasis. Better records will help us evaluate what we are doing and how well or poorly our efforts are working.

10. **How do you work with other partners in the country towards reducing the burden on NTD**

We greatly value all our partners in the country and realize that without partnerships we cannot reduce the burden of NTDs. We have already included partners in our Technical Working Groups to improve integration and we look forward to including more. We are also beginning to have individual meetings with partners to strengthen relationships. In the future we want to have joint activities with all our partners.

11. **What are your thoughts on partnerships with other MoHs in the region e.g. Sudan, Uganda**

We are already speaking to other countries to forge some partnerships to fight NTDs. We have started cross-border activities with Tanzania to fight trachoma and also with South Sudan to fight Guinea worm. We haven't started any cross-border partnerships for leishmaniasis yet but are open to it.

The KalaCORE Consortium: Towards Elimination of Visceral Leishmaniasis

By Margriet den Boer

KalaCORE is a partnership supporting the control and elimination of visceral leishmaniasis (VL) in six countries; three in Asia (India, Nepal and Bangladesh) and three in Africa (Ethiopia, Sudan and South Sudan). The programme is funded by the UK Department for International Development (DFID). KalaCORE brings together the Drugs for Neglected Diseases initiative (DNDi), the London School of Hygiene & Tropical Medicine (LSHTM), Médecins Sans Frontières (MSF) and Mott MacDonald. The country teams are supported by a Programme Management Group based in the UK.

The scope of KalaCORE encompasses access to treatment, surveillance, behaviour change communication, operational research, vector control and monitoring and evaluation. To date, projects have been selected and designed, implementing partners identified and agreements with respective governments initiated. The implementation phase of the programme will end on 31 October 2018.

The main objective of KalaCORE in Africa is to impact the disease burden by reducing costs to households and providers, and to minimize VL case fatality. All activities are defined in close collaboration with governments. In Ethiopia and Sudan, WHO is a key implementation partner; other implementing partners are non-governmental organizations such as Amigos da Silva in Ethiopia, and IMA World Health in South Sudan. The focus is supporting existing National Control Programmes through the provision of technical support and on-the-ground reinforcement of control measures, while ensuring that key research questions that will directly assist control strategies are answered.

In practice, this translates to the following activities:

- Ensuring there are no gaps in the supply of VL drugs and diagnostics.
- Refurbishment of VL treatment facilities (30 facilities in Sudan and 17 facilities in Ethiopia). In South Sudan outbreak preparedness and response is supported by establishing VL services where these have been destroyed or abandoned. Currently, 26 treatment sites have been re-capacitated for this purpose.
- Continuous health worker training and provision of on-site clinical mentoring through mobile teams. These include training sessions in Sudan by KalaCORE, training and set up of mentoring teams in Ethiopia by WHO and training of over 200 health workers in Juba.
- Strengthening of VL surveillance in all countries.
- Evaluating innovative vector control methods and mapping of endemic areas.
- Improving access to treatment and providing health education to migrant workers and other groups at risk of infection. In Ethiopia and Sudan, a study into barriers to treatment access is in progress.

Magriet Den Boer from KalaCORE speaks during a kala azar treatment access symposium at the KEMRI Annual Scientific & Health Conference

The Search for Treatments for VL-HIV Co-infected Patients Continues

Tadelu Ajemu, a nurse at the Abdurafi Health Centre speaks to Tsadik, a HIV/VL patient

By Linet Otieno

Thirty-Five year old Tsadik is a visceral leishmaniasis (VL) patient who is also infected with HIV. He is gaunt, weak, tired with sunken eyes and each breath he takes is laboured. He has been receiving treatment at the Abdurafi Health Centre in North-Western Ethiopia where DNDi together with MSF-Holland and LEAP are carrying out a study to find improved treatments for patients with VL and HIV co-infection. In an interim evaluation it was observed that the drugs used in the study, both in the monotherapy arm (Ambisome alone) and in the combination arm (Ambisome and Miltefosine) did not meet the desired efficacy rates at the end of 1-month treatment. However, the strategy of providing a 2nd cycle of treatment for patients who were not yet cured have shown that the combination treatment is reaching very satisfactory efficacy rate for such hard-to-treat patients. The study team has recently finalized patient follow up and is currently cleaning the data and performing the analysis of the 12-months follow-up period before embarking on study close out process.

VL and HIV co-infection has increasingly become a major problem. It is difficult to manage clinically due to poor response to treatment, poor tolerability of treatment with many side effects, frequent relapses and it may eventually have a fatal outcome. Over the years there have been major strides in treatment for both VL and HIV independently. However, treatments for patients infected with both diseases have remained elusive despite efforts in research.

Since August 2014, DNDi has been evaluating the efficacy of both the combination and monotherapy regimens in two sites in Ethiopia; Abdurafi and Gondar. These regions are characterised with high VL-HIV co-infection mainly because they are, first, endemic for VL and men such as Tsadik travel from their homes many kilometres away to work in farms leaving their wives behind and are thus prone to HIV infection. The current

study on HIV-VL patients in Ethiopia is showing that a new approach based on case management with combination therapy for 1 or 2 cycles (depending on the individual response to treatment) may bring much better outcomes for these patients. Upon finalization of the data analysis for the follow-up period, we will also understand how to better manage the patients after parasite clearance is achieved to avoid recurrence of relapses.

Four years ago, Tsadik left his home in Tieraf about 70 km from Abdurafi in search for work. He left his wife and three children behind promising a better life once he began his job as a Farm Labourer. Shortly after he settled in the small agricultural village, he fell sick and was diagnosed with VL. He went through a 30 day treatment with SSG and soon got back to work. One year later, he was tested and found to be infected with HIV. He suspects that HIV had something to do with the recurrence of his VL infection.

"This disease has destroyed my life," he says, "my wife left me, I can't see my children as much as I used to and I was fired from my job because I was too weak to work. All that I had was used to pay medical bills."

Tsadik started treatment at a hospital close to his house but after relapsing five times, he moved to Abdurafi Health Centre to access better treatment. Abdurafi Health Centre, in collaboration with MSF-Holland, offers free and better treatment as well as care (nutrition) but even with this, he has not been cured of VL. Since he started his treatment at Abdurafi, he has relapsed twice.

"Usually VL patients in this country are treated either with Sodium Stibogluconate (SSG) alone or SSG and Paromomycin (SSG&PM) according to the national guidelines even if they are co-infected. However, this has not been effective for patients and there is need to find a better treatment. There are also concerns of toxicity in using SSG in the HIV co-infected population," says Samuel Kassahun, A Health Officer at Abdurafi Hospital.

It is for this reason that Abdurafi Health Centre and MSF Holland had been trying out other combinations of treatments such as Ambisome and Miltefosine. "DNDi in collaboration with Gondar Leishmaniasis Research and Treatment Center came in to determine if these new treatment combination options are an improvement from SSG and PM," says Peninah Soipei, Clinical Research Associate with DNDi Africa.

Although the complete study results including the follow-up period are yet to be analysed, the results of the initial treatment phase are very satisfactory pointing to the combination of Ambisome with miltefosine as a better treatment option for patients such as Tsadik. Ultimately DNDi's target is an oral, safe, effective, low cost, and of short course for all patients with VL including co-infected patients.

"My dream is to be cured so that I don't have to come to hospital all the time. Then I can work and make sure my children remain in school. A new treatment will give me a better chance to do this," concludes Tsadik with a smile on his face.

"Through research, a better treatment for co-infected patients can be found," Says Ethiopian Nurse

Tadelu Ajemu is a nurse at the Abdurafi Health Centre in North-Western Ethiopia where DNDi is carrying out studies to find treatment for patients with VL and HIV co-infection.

She was employed by MSF-Holland as nurse at the Health Centre in December 2012 and has worked there since then. She enjoys working with patients especially those who are co-infected but she is saddened that there is still no effective treatment for them.

"Most of these patients are young; between the ages of 20 to 30 years and have come to Abdurafi in search for work in the farms. They work hard but this disease is ruining them. They are always in the health centre due to relapses and opportunistic infections. I have seen some who come to hospital every other week." She comments.

In 2014, Tadelu got the opportunity to support the DNDi HIV-VL study that was taking place at Abdurafi. Her roles included new patient enrolment, creating patient appointments and overall management of the patients.,-Tadelu knows that it is only through research that a better treatment for co-infected patients can be found.

"From such studies, my hope is that patients would finally get better treatments and have a normal life with no relapses," says Tadelu "if they are cured of VL they can go back to work and be happy. This will also be my joy."

Tadelu Ajemu, a nurse at the Abdurafi Health Centre

LEAP Praised in Post-TICAD VI Event

The LEAP platform was recently lauded by a renowned scientist and researcher; Prof Ogobara K. Duombo from the Malian Ministry of Health. During the international Joint Symposium for the Promotion of Infectious Disease Research Cooperation between Africa and Japan held on 15th and 16th September in Nairobi Kenya, the professor said "I can attest that what has been said is true! The LEAP platform carries out its research in the highest standards." He was speaking after DNDi Africa Dr. Monique Wasunna made a key note presentation titled '**Fighting Neglected Diseases: Research & Collaborations for Africa** where she focussed on LEAP as an example of a thriving collaboration.

The symposium was part of the Tokyo International Conference on African Development (TICAD) VI held on 27th and 28th August 2016. A total of 180 participants from Kenya, Japan and 22 other African countries attended the event.

Tatsuro Kozuki from the DNDi Japan office gives a presentation on DNDi's model of work

Dr. Robert Kimutai from DNDi Africa Regional Office with Prof Ahmed Fahal from the Mycetoma Research Centre in Sudan at the event

Dr. Monique Wasunna gives the keynote presentation at the event

Good Clinical and Laboratory Practices Training

From February 29 – March 2, DNDi brought together representatives from the LEAP clinical site laboratories for a Good Clinical and Laboratory Practices (GCLP) training. The training, held at the Amber hotel in Nairobi, was a follow up to the GCLP training conducted in December 2014 at the LRTC in Gondar. The training, organized as part of the process towards standardization of methods across LEAP clinical site laboratories, an initiative supported by the AfriCoLeish project, brought together 21 laboratory technologists from Ethiopia, Kenya, Sudan and Uganda. The training was lauded by participants as being relevant to the activities performed in the laboratories.

On March 3 and 4, a Good Clinical Practices (GCP) training focusing on clinical monitoring was also conducted and attended by the DNDi ARO team.

Participants in a group photo after the training

Stakeholders Calls for Partnerships to Improve Access to Treatments for VL

As one of its strategies towards advancing access to treatment for neglected tropical diseases (NTDs), DNDi organized a symposium titled **"Innovation for Access to treatment for neglected diseases"** on February 9th 2016 at the Boma Inn Hotel in Nairobi. The symposium served as a platform to bring together regional experts in neglected diseases and partners from the national government, county government, non-governmental organizations, research institutions and international organizations.

There were over 100 participants in attendance from the Ministry of Health, Neglected Tropical Diseases Unit (MoH NTDU), Pharmacy and Poisons Board (PPB), MoH Marsabit County, World Health Organization (WHO) Kenya country office, Kenya Medical Research Institute (KEMRI), Science Africa, London School of Hygiene and Tropical Medicine (LSHTM), KalaCORE, KEMRI-FACES, MSF-France, CDC-FELTP, Kacheliba Hospital, MSF Belgium, KELIN, Gertrudes Hospital, University of Nairobi and DNDi. The objectives of the symposium were to discuss innovative ways to improve access to treatments for neglected patients and develop strategies to have the most effective treatments for neglected diseases such as visceral leishmaniasis (VL) reach the patients who need them most.

Participants at the Neglected Disease access symposium KEMRI Annual Scientific & Health Conference

Karen Goraleski, Executive Director at ASTMH with Dr. Monique Wasunna, Director DNDi Africa

DNDi ARO participates in the Annual Open Research Day and International Clinical Trials Day (ICTD) Celebrations

On June 13, 2016, the College of Health Sciences, Addis Ababa University, held a meeting with the theme ***"R&D for Innovative Therapeutics in Africa".*** This meeting brought together numerous participants from Ethiopia and the broader Eastern Africa region. The meeting addressed a variety of issues related to pharmaceuticals R&D within Africa, including R&D financing frontiers in Africa, capacity building for excellence and the need for innovation of a new model of international collaboration. Dr Robert Kimutai, Clinical Trial Manager, DNDi, made a presentation titled "Innovative repurposing of drugs for neglected diseases: the case of VL and Mycetoma". Prof Asrat Hailu, the Chairperson of the LEAP Platform served as a moderator in the session.

2016 DNDi STAFF ARRIVALS

Gina Muthoni Ouattara joined the DNDi Africa Regional office as a Clinical Project Coordinator in January 2016. She is a medical graduate from the University of Nairobi. She has extensive experience in clinical trials having worked as a Trial Physician, Study Coordinator, Principal Investigator and Site Medical Manager.

She has previously worked with the Ministry of Health as a Medical officer, and in clinical trials at the International Centre for Reproductive Health, and the University of Nairobi. Prior to joining DNDi, Gina most recently worked at the University Of Nairobi - KAVI Institute Of Clinical Research as a Site Medical Manager implementing Phase 1 and Phase 3 clinical trials as well as epidemiological studies.

Poline Gacheri joined the team, in April 2016, as receptionist. She has over 7 years' experience in Front Office and a background in Business Management from the Kenya Institute of Management. Before joining DNDi, Poline worked with Royal Minni Inn as the supervisor in charge of Front Office.

Whim Manogo joined the DNDi Africa office this year as Finance Manager. His key roles are budgeting/budget management, treasury management, partner financial reporting and general financial reporting. He has over 10 years' experience in financial management mainly for donor funded missions. Prior to joining DNDi, Whim worked with ActionAid International.

He holds an MBA in Accounting from the University of Nairobi, Kenya; Bachelor of Business Management Degree in Finance from Moi University, Kenya; Diploma in Business Administration and is pursuing the ACCA qualification.

Dr Olawale Salami is the Pediatric HIV Clinical Program Manager at DNDi. His work focuses on generating evidence needed to support the clinical development of new pediatric HIV treatment formulations. He is also involved in supporting countries in Africa who are scaling up new Lopinavir/ritonavir-based formulations. Prior to joining DNDi, Dr Salami completed a Marie-Curie FP-7 post-doctoral Fellowship at the University of Lausanne, Switzerland and Preclin Biosystems AG, Switzerland.

He combines his experience in clinical infectious disease research and program management spanning over a decade in various settings in Africa and Europe. In 2010, he worked with AIDS Healthcare Foundation as the founding Country Manager. Dr Salami Holds an MD, and has published in various peer reviewed journals.

DNDi Officially Opens its New Offices

DNDi staff in a group photo during the event

DNDi Executive Director cuts the ribbon to officially open the new Africa office

DNDi Africa Regional Office (ARO) officially has a new home! At a grand opening ceremony in Nairobi on Tuesday, September 6, 2016, in the presence of over 25 special guests, friends and partners, the DNDi Executive Director, Dr Bernard Pécoul assisted by the Director of the Kenya Medical Research Institute (one of DNDi's Founding Partners), Dr. Gerald Mkoji cut the ribbon to present the new office.

An exciting event for everyone associated with DNDi, the ceremony took place at the new building – Tetezi Towers, in the heart of Kilimani, Nairobi. Partners, stakeholders, staff members and friends attended the occasion which was seen as a bold statement about DNDi AROs future plans; a step into this new phase of consolidating growing opportunities in Research & Development (R&D) in Africa.

TRIBUTE TO DR. RASHID JUMA

Dr. Rashid Juma passed away on January 17th 2016 after a short illness. Until his death he was a member of LEAP and the Kenyan Principal Investigator for DNDi's VL study sites. He is survived by his wife and three children. He will always be remembered for the significant contribution he made to LEAP. Following his death, staff members, colleagues, friends and all those who knew him paid tribute to him. Below are selected comments made by his colleagues from DNDi. May his soul rest in eternal peace.

"I first met Dr. Rashid when I joined KEMRI in 2008. By then he was a Senior Research Officer. Dr Rashid was a hardworking man who was always ready to face challenges. He did not differentiate between junior and senior staff. Everyone was treated equal. Dr Rashid had advice for everyone he came across. When you met him, he would look at you smile, ready with jokes to start the talk. He was friendly to everyone. He loved to socialize. I will remember *daktari* as a man who had a passion for DNDi. May God rest his soul in eternal life *– John Ambasa, Office Assistant, DNDi*

"It was shocking and distressful news for all of us, and it will take a long time for us to come to terms with the loss" – *Dr Bernard Pécoul, CEO, DNDi.*

"Dr Rashid was one of the best listeners I have ever known. I adored his odd sense of humour, his ability to analyse a situation quickly and offer words of wisdom. I appreciated his passion for life, seen in his dance moves; but most of all I envied his dedication to clinical research and his closeness to science – *Rhoda Owiti, Data Management Officer, DNDi.*

"What a loss! All we can do now is to pray for him and the family" – *Dr Jorge Alvar, Head of Visceral Leishmaniasis, DNDi.*

"Dr. Rashid was a very warm person who embraced hard work and thoroughness." – *Lilian Were, Clinical Research Associate, DNDi.*

"I find it very shocking to hear the death of Dr Rashid. May Allah accept him and support his family. It is a great loss to the whole region. He is such a dedicated person to the poor in Africa" – *Dr. Ahmed Musa, Institute of Endemic Diseases, University of Khartoum*

"It is unbelievable and difficult to accept the news of the sudden death of Prof Juma Rashid. May God comfort his family at this time of grief. May his soul rest in peace" – *Prof Joseph Olobo, Makerere University*

"Our sincere condolences to the family". "May God bless his soul" – *Prof Eltahir Khalil Institute of Endemic Diseases, University of Khartoum*

This is indeed tragic for the family, and a big loss for the LEAP and KEMRI. I pray that God blesses his soul. - *Prof Asrat Hailu, Addis Ababa University and current LEAP Chairperson*

"Dr Rashid will be remembered as a

friend, a mentor and an influential voice in the field of neglected tropical diseases. His commitment to science and to the LEAP Platform was relentless. He never wavered when his conscience dictated that he take a course of action, no matter how unpopular. He will be greatly missed" Dr Rashid and I first met at the University of Nairobi Medical School many years ago! He was one year behind me. When I was an intern at the Kenyatta National Hospital, Rashid was in his final year in Medicine and we worked in the same ward. As young scientists, we worked closely at the Kenya Medical Research Institute (KEMRI), and rose through the ranks to be Chief Research officers. When DNDi was created in 2003, we again found ourselves working together and were among the founding partners of the Leishmaniasis East Africa Platform (LEAP).My friend Rashid and I have a long working experience together, memories I will cherish forever. Kenya has lost an exceptionally intelligent researcher and a Clinical Trialist, I have lost my best friend. Fair thee well Rashid and rest in Eternal Peace! – *Dr Monique Wasunna, Director, DNDi Africa Regional office Nairobi*

RECENT VL SCIENTIFIC PUBLICATIONS

PUBLICATIONS

1. **Efficacy and safety of AmBisome in combination with sodium stibogluconate or miltefosine and miltefosine monotherapy for African visceral leishmaniasis: Phase II randomized trial.** by Wasunna M, Njenga S, Balasegaram M, Alexander N, Omollo R, Edwards T, Dorlo TPC, Musa B, Sharaf Ali MH, Elamin MY, Kirigi G, Juma R, Anke E. Kip, Schoone GJ, Hailu A, Olobo J, Ellis S, Kimutai R, Wells S, Khalil EAG, Strub Wourgaft N, Alves F, Musa A. PLOS Neglected Tropical Diseases 2016, doi:10.1371/journal.pntd.000488
2. **The Leishmaniasis East Africa Platform (LEAP): strengthening clinical trial capacity in resource-limited countries to deliver new treatments for visceral leishmaniasis.** by Wasunna M, Musa, A, Hailu A, Khalil EAG, Olobo J, Juma R, Wells S, Alvar J, Balasegaram M.Transactions of the Royal Society of Tropical Medicine and Hygiene 2016, 1–3 doi:10.1093/trstmh/trw031.

LEAP
LEISHMANIASIS
EAST AFRICA PLATFORM

LEAP PARTNERS

Sudan:
IEND - University of Khartoum

Ethiopia:
Gondar University
Addis Ababa University

Kenya:
KEMRI

Uganda:
Makerere University

LEAP collaborates with DNDi, Ministries of Health in the various countries, MSF, iOWH - India, IDA, WHO -TDR and other partners in visceral leishmaniansis R&D work in East Africa.

DNDi AFRICA
Drugs for Neglected Diseases *initiative*

The LEAP Newsletter is a Publication of the LEAP Platform.
The Leishmaniasis East Africa Platform (LEAP) is a regional clinical research network that brings together experts from leishmaniasis-endemic eastern Africa countries, including Ethiopia, Kenya, Sudan, and Uganda. The platform set up by DNDi, incorporates partners from across the spectrum of clinical research and disease control organizations/institutions working in leishmaniasis in these countries.

LEAP mandate - To facilitate clinical testing and improved access to better treatments for leishmaniasis in the region

For More information contact the 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