



NEWSLETTER

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EDCTP



Word from the Director, DNDi Africa Regional Office

Dear LEAP Members and Partners,

It is with great pleasure that we are sharing the 7th issue of the Leishmaniasis East Africa Platform (LEAP) Newsletter, a publication highlighting recent major developments in our intensified pursuit towards addressing the diagnostics and treatment

needs of neglected leishmaniasis patients.

LEAP is a clinical research network bringing together scientists and research institutions spread across four countries namely: Sudan, Ethiopia, Uganda, and Kenya. The platform is dedicated to facilitating clinical testing and improved access to better treatments for leishmaniasis in the region.

This novel network has also been instrumental in closing existing clinical research capacity gaps attributed to the remoteness of the endemic areas and the geographic spread of the patients, most of whom live in the most impoverished areas. In 2020, a total of 138 people acquired diverse skills as needed to support the delivery of world-class clinical trials.

Through LEAP, DNDi's efforts to develop oral treatments for leishmaniasis through its discovery pipeline are bearing fruit. Together with partners, DNDi has built an unprecedented portfolio of new chemical classes that act against Leishmania parasites. This pipeline provides a strong basis for advancing towards user-friendly oral therapies for both visceral and cutaneous common in eastern Africa.

In this latest issue of our newsletter, we begin by reflecting on the extraordinary situations between 2019 and 2020 and the extraordinary wins realized. It is a period that witnessed a prolonged political crisis in Sudan and the subsequent emergence of the Covid19 pandemic that continues to ravage humanity across the globe.

Nevertheless, I am happy to report that our ongoing clinical trials continue to make good progress towards our target of delivering best treatment for the most neglected diseases. It is very encouraging to see that our

field activities have remained on track despite the external pressures. This is thanks to the collaborative strategies adopted by our partners and health workers.

Key amongst the ongoing studies included the phase III clinical trial investigating the combination treatment of miltefosine and paromomycin as a safer, efficacious and more patient-friendly treatment for visceral leishmaniasis which was able to complete participant enrollment in time. The Post Kalazar Dermal Leishmaniasis (PKDL) clinical trial in Sudan was successfully completed despite the challenges.

I am particularly inspired by health personnel determined to holistically attend to wounds of neglect suffered by patients devastated by cutaneous leishmaniasis (CL). Although CL is not life-threatening, it causes disfiguring skin lesions that can leave life-long scars and lead to severe social stigma, especially for women and children. Consequences include ostracism, less education opportunities, and economic loss.

Another fundamental pillar in the elimination of NTDs has been the integration of innovative practices in the ongoing initiatives. In this regard, it is interesting to read about the establishment of clinical trial supply chain management (SCM) systems that have helped streamline service delivery within trials.

As I wrap up the wins of the year 2020, I get the motivation to celebrate the power of collaboration. This is because it is through concerted efforts that witnessed the historical commemoration of the inaugural World NTD Day on 30th January. Another major stride achieved in the same year was the endorsement of the World Health Organization (WHO) NTD roadmap 2030 followed by launch in early 2021.

It is against this backdrop that I take this opportunity to appreciate our partners and health workers who have steadfastly supported our field sites especially during the pandemic period. Your dedication, commitment and courage deserve our deepest gratitude and admiration. Your service to patients is saving countless lives and making unimaginable impact.

I would also like to thank our donor community especially EISAI Co., Ltd for their generous donation of Personal Protective Equipment (PPEs) that ensured the lives of both our frontline health workers and patients are protected.

My message to everyone is to mask up, maintain social distance and regularly sanitize. Together we can prevent the spread of Covid19!

Dr Monique Wassenaar

Supporting clinical trial supplies in Sudan



Clinical trial staff at work in a laboratory in Dooka, Sudan. Consistent and timely supply of laboratory resources is crucial for the success of clinical trials.

By Ilham Osman

It all began in May 2016 when I was contacted by Prof. Ahmed Fahal from the Mycetoma Research Centre (MRC), Khartoum, who needed help purchasing some medical equipment. He informed me that an organization named Drugs for Neglected Diseases initiative (DNDi) was commencing clinical trials in Sudan for Mycetoma. At that time, I was not aware of the collaboration between MRC and DNDi.

I quickly acquainted myself with all the information I could find online about DNDi before a meeting with their staff. During the meeting, Mr. Simon Bolo, their Regional Operations Leader for Eastern Africa, explained to me their purpose for coming to Sudan and enlightened me on the projects that they planned to carry out. I was excited to hear about DNDi's work. I must admit, they had me from day one and I wanted to help them resolve some of the challenges they were experiencing in their work with neglected patients in the remote areas in Sudan. This is where Hippocrates Medical Enterprises (HME) came in.

HME was founded in May 2000 to supply high quality products for the healthcare services in Sudan with specialization in laboratories. Working with international suppliers, we provide comprehensive packages of laboratory equipment including those used for research. Our competent staff are all specialized in their various fields and our engineers are certified from all the suppliers we deal with.

Having arranged a visit to the MRC team, my vision was broadened once I understood the kind of work they do.

This increased my enthusiasm to offer our comprehensive services and more. Initially, we only catered to their haematology needs but gradually their requirements increased outside our range and we had to go an extra mile and outsource supplies overseas.

Many of the items needed in the ongoing clinical trials could not be sourced locally and outsourcing supplies from outside the country while in Sudan is very strenuous. For each item outsourced we had to meticulously follow up making sure that the product has a local reliable agent with the capacity to service it, matched the specifications provided and delivery would be done as per the expected schedule. Naturally, we had to maximize our negotiation skills to get the best offer for DNDi.

In July 2019, I had the opportunity to visit the DNDi premises in Kenya to better understand some of the existing concerns and shared goals. Having prepared a presentation illuminating HME's capacity and services, I arrived in Nairobi and held successful deliberations.

Since we started working together, our services have broadened beyond the MRC. We also provide supplies to the leishmaniasis research projects in Umelkher and Dooka carried out by the Institute of Endemic Diseases, University of Khartoum and DNDi. Soon outsourcing became easier for us as our market database increased and we are now able to locate the quality products needed in less time.

Conducting Clinical Trials in the Midst of Adversity



Prof. Ahmed Musa from the Institute of Endemic Diseases and country Principal Investigator (PI) for the leishmaniasis projects in Sudan attends to a patient.

By Linet Otieno

Conducting clinical trials in crisis situations is a difficult endeavor. A well-conducted clinical trial requires very specific conditions and processes, and crisis situations can make the achievement of these processes more difficult.

In 2019 and in 2020, while in the midst of conducting two crucial Leishmaniasis clinical trials in Sudan, the Institute of Endemic Diseases (IEND), University of Khartoum, experienced intense crisis. Beginning in 2018, Sudan suffered an almost year-long political crisis that affected various sectors including transport, health and economics. Shortly after this crisis came to an end, there was a global outbreak of COVID-19. IEND had to therefore come up with coping strategies so that they can achieve important milestones in the clinical trials.

One of the studies was investigating the effectiveness of a combination treatment of miltefosine and paromomycin as a safer, efficacious and more patient-friendly treatment for visceral leishmaniasis. The second trial was geared towards discovering a treatment that is safer to use, easier to administer and thus shorten the length of hospitalization for patients with Post Kalazar Dermal Leishmaniasis (PKDL).

"We were in the middle of these two clinical trials

when we were hit with two crises back-to-back. It was a hectic period, but we had to act fast so that we can continue studies successfully," said prof Ahmed Musa, the country Principal Investigator (PI) for the leishmaniasis projects.

During the Civil unrest experienced until 2019, movement, especially to the countryside, was problematic. The study team had to look for ways of minimizing movement to Dooka from Khartoum over 400 km away. Some of the key staff involved in the clinical trial who would usually travel to and from Dooka stayed in the site consecutively for at least two months. Prof Musa carried out virtual meetings to monitor the study progress.

To ensure that the various functions of the studies ran without interruption, they ensured that they had extra supplies in the study site including enough fuel, reagents and medication. This enabled the recruitment processes and follow-ups to continue with minimal interference.

The first case of COVID-19 in Sudan was reported in March 2020 and like in many African countries, the government put in place stringent regulations including travel restrictions, partial lockdowns, quarantine and isolation. These regulations had the



Researchers from the University of Gondar in Ethiopia in full COVID-19 personal protective equipment.

potential of delaying the clinical trials and thus the study teams had to act fast. The PI continued to hold conversations virtually to track progress of the study in the site so that the study would continue smoothly.

IEND had to ensure that the patients and health workers working in the two VL clinical trial sites; the Professor Elhassan Centre for Tropical Medicine in Dooka and Um El Kher, Sudan were protected against COVID-19. To this end, the team implemented new strategies including clustering follow-up of patients and picking them up from specific stations to avoid unwarranted movement. DNDi allowed to deviate from the protocol follow-up window period provided that this is documented, in order to give the health workers more time to trace the patients. Laboratories were organized to attend to large numbers of samples at a time. Free masks, education and sanitizers were provided to all who came to the hospital.

“We plan to consolidate and develop guidelines for the future and add this to the training of the investigating team,” Prof Ahmed Musa, Country Principal Investigator, leishmaniasis projects.

At the treatment centre, solar panels were installed to help with consistency in electricity supply and temporary shelters were put up to reduce overcrowding.

According to prof Musa, the two experiences taught the study sites a lot of lessons that have impacted the way they will manage clinical trials going forward.

“We plan to consolidate and develop guidelines for the future and add this to the training of the investigating team” he said.

Despite the challenges experienced, the Clinical Trial team was able to complete recruitment of participants into the two studies in May 2020 and have continued to carry out follow-up activities despite the COVID-19 pandemic.

Enhancing supply chain management systems in clinical trials



Arega Yesanew, the Head of Laboratory at the Leishmaniasis Treatment Centre, University of Gondar, Ethiopia, stores samples in a freezer. A system has been developed to ensure that supplies arrive at the right time to the clinical trial sites.

By Josephine Kesusu

Clinical studies are increasingly becoming complex and dynamic. This situation has necessitated the establishment of clinical trial supply chain management (SCM) systems that are fast, flexible and responsive. The objective is to ensure that clinical supplies arrive at the right time, in the right place, and within the set budgets.

The LEAP platform is building a solid SCM system within the study sites to avoid logistical hitches that may derail ongoing clinical trials. A holistic framework has been put in place to integrate resources, processes and technologies.

One of the key considerations is ensuring that the right product is available and accessible. At the early stages of a clinical trial planning, a list of products that the trial is expected to consume is generated. Once the list is developed, a market survey is conducted to get more information about the products and thereafter competent suppliers are identified to deliver the products.

A second and very crucial step is to confirm that the supplies are of quality. This can be achieved by requesting the suppliers to provide a certificate of analysis and conducting the necessary due

diligence. Products that require cold chain storage are transported with temperature monitoring devices which upon arrival are checked to ascertain that storage conditions have been maintained.

Effective planning ensures that products with short shelf life are ordered in the right quantity and thus wastage is avoided, and storage is adequate. Forecasting must therefore be done based on clinical trial enrollment rates and monthly consumption. Supplies must be purchased at the right time and procurement requests monitored to avoid depletion especially since clinical trials consume different products at different stages.

To ensure that goods from overseas arrive in good time, import permits are processed prior to shipping. Once a shipment is dispatched, tracking is done online until the product is received by consignee. Only then is the shipping process considered successful.

The DNDi procurement team undertakes continuous market surveys of pricing so that supplies are procured competitively to guarantee value for money and maintain purchases within the approved budget.

Preparing for proof-of-concept New Chemical Entity (NCE) Study in the Eastern Africa region



Arega Yesheanew (Right) and Roma Melkamu share a light moment at the Leishmaniasis Treatment Centre, University of Gondar, Ethiopia. DNDi is working with partners to prepare for a proof-of concept NCE study.

By Linet Otieno

DNDi's efforts to develop innovative treatments for leishmaniasis through its discovery pipeline are bearing fruit. Together with its partners, DNDi has built an unprecedented portfolio of new chemical classes that act against *Leishmania* parasites. This pipeline provides a strong basis for advancing towards one or more new oral therapies for both visceral and cutaneous leishmaniasis. Dr. Monique Wasunna explains the next steps as Eastern Africa region prepares to carry out proof of concept for the new leishmaniasis treatments.

1. What are the current challenges facing leishmaniasis treatments?

Leishmaniasis is a grossly neglected disease. The treatment currently used to treat the disease in the region are a combination of two drugs that includes antimonials, which are about 80 years old. There has been very little research to find new treatments and drugs remain sub-optimal. Leishmaniasis treatments are difficult to administer, require long hospitalization, all of them have limitations related to toxicity and are expensive.

2. What kind of treatments are required by kala azar patients?

To effectively treat kala azar patients we need an all-oral short term combination treatment that is active against the parasite in the different geographical regions and suitable for all populations, including children, pregnant or lactating women and immunocompromised patients.

3. Are there any clinical trials for new treatments currently taking place?

DNDi has been conducting clinical trials to find better treatments for leishmaniasis. For Eastern Africa, we now have a combination treatment of sodium stibogluconate (SSG) and paromomycin (SSG&PM) as the first line treatment, which is an improvement from the 30-day SSG monotherapy. Results of the study assessing the combination PM with MF are expected in 2021, which would be an improvement as it replaces the toxic SSG component with oral miltefosine. However, this is not sufficient, we need new user-friendly therapies. DNDi and partners have progressed



A healthworker attends to a patient at the University of Gondar, Ethiopia.

five oral new chemical entities to phase I development. A phase II proof of concept (POC) clinical trial is planned to be submitted in Eastern Africa in 2022.

4. What is a POC clinical trial

A POC study is a highly specialized clinical trial that is done in the early stage of clinical drug development, when a compound has shown potential for human therapeutic use, after preclinical animal models and early safety clinical testing. This step often links Phase I (first in human in healthy volunteers) and dose-ranging Phase-II studies in patients. The data usually provides evidence on efficacy, safety and pharmacokinetics, to assess if a drug is likely to be successful in later stages of drug development until drug registration.

5. Clinical trials that have been conducted in the Eastern Africa region are usually Phase II and III, are we prepared to carry out a POC study?

We have some expertise in the region to carry out the POC study, but this capacity needs to be strengthened so that we can get high quality evidence. Luckily, capacity strengthening is one of the key pillars of DNDi and we will support potential sites to be able to conduct these clinical trials.

6. What do the sites in the region need so that they can carry out POC studies

For sites in the region to be able to conduct these studies, they require specialized conditions. An accredited centralized laboratory, a trained

investigator as well as an intensive care unit ward are some of the requirements for a POC clinical trial.

7. What is the importance of conducting POC studies in the region?

It is important to carry out the clinical trials in the regions where the disease is found because this will ensure that the new treatments are effective for the genetic make-up of the patients, and the new treatment will respond to the needs of the patients affected by VL.

8. What improvements do we hope to have in leishmaniasis treatments if the NCE clinical trials are successful?

We are excited, eagerly waiting and cautiously optimistic about the NCEs that are coming up. This is because we know that if it works the patients will have a treatment that is safe and easy to administer, therefore access to diagnosis and treatment will be implemented closer to the communities, reducing time between onset of symptoms and having an impact in reducing morbidity, mortality and breaking the transmission cycle. This will impact not only their health but also their socio-economic life. Personally, I feel this long journey of the search for oral treatments for visceral leishmaniasis by DNDi, LEAP and partners has been exciting, challenging with many lessons learned. Once we have these NCEs registered for VL and access to treatment guaranteed, it will be time to celebrate and retire knowing that the most neglected patients will have improved options for their VL. Our goal will have been achieved.

The Psychological Burden of Leishmaniasis on Patients



Mary Alamak, a Kala-azar survivor from West Pokot County, Kenya.

By Danyell Odhiambo

Mary Alamak is a mother of four, living in Longelai village, tucked in the remote rugged hills of West Pokot County in Kenya. She almost breaks into tears while recounting her horrid experience living with leishmaniasis. It is a tale that is best described as going through hell and back. Her emotional distress began when she fell ill, when pregnant, in March 2010.

"I had continuous bouts of fever, constant coughs and belly pains. At first, I suspected that the condition would have been as a result of my pregnancy. My weight drastically reduced from 80 to 45 kilograms. I had to be carried around because I was too weak to walk. I later sunk into depression because I couldn't stand the fear of losing the baby I was carrying," she reveals this as she clenches her hands.

Within a few weeks, her health condition had worsened prompting her to seek treatment at the Kacheliba District hospital where she was tested for malaria, brucellosis and even HIV. Surprisingly, all the tests turned out negative.

Later in her conversations with the doctor, she happened to have mentioned her husband who had previously suffered from similar symptoms before being treated for kala-azar, locally known.

"My husband had informed me about the long needle that was used to 'stab' his abdomen when testing and the excruciating pain associated with the numerous injections administered in the treatment of kala-azar. I couldn't imagine myself undergoing that horrific experience. Luckily for me, the doctor prescribed alternative testing and treatment because I was expectant." She narrated.

Towards the end of March, the same year, a rapid diagnostic test was conducted to confirm that she was ailing from Kala azar. In April, Mary was further put on an initial intravenous dosage of AmBisome® under close medical supervision.

"By the end of May, I had gained 20 more kilograms. Further tests were conducted five months later to confirm that I was free kala azar" she says this as her cheeks fold into a broad smile.

After that terrible experience, she says, there was nothing as exciting holding the little bundle of joy in her arms. A decade later, mother and child are both living a healthy life and appreciate the efforts made by health workers to save their lives.

Attending to Wounds of Neglect: Kenyan Doctor working with communities to lessen the burden of Cutaneous Leishmaniasis



Dr Esther Kinyeru attending to a cutaneous leishmaniasis patient at a health facility in Nakuru County, Kenya.

By Danyell Odhiambo

It is almost seven years since Dr. Esther Kinyeru started supporting marginalized communities living within Gilgil sub-County of Nakuru County in Kenya to fight against the severely neglected Cutaneous leishmaniasis (CL) disease.

Her story can be summarized by just three words: wounds, scars, and stigma. It is from these three words that she developed her intense passion for fighting for the neglected patients ravaged by CL.

“My passion was ignited, in 2014, by my first interaction with the patients who visited the Gilgil Sub-county hospital to seek treatment. It pained me to see children, women, and the elderly who were suffering yet neglected. It is from this situation that I discovered my purpose in life -to restore smiles on the faces of community members affected by CL.” She cheerfully stated.

Dr. Kinyeru, who currently serves as the focal person in charge of CL in expansive Nakuru County, says CL is a severely neglected parasitic disease transmitted through the bite of sandflies that carry the *Leishmania* parasite. “The difference between CL and Visceral leishmaniasis (VL) is

that the latter affects the inner body organs, including the liver, bone marrow, and spleen, while CL affects mostly face area, limbs, and other exposed body parts” she adds.

CL neglected tropical disease (NTD) because it poses a severe public health burden to marginalized communities. Although not life-threatening, CL can cause severe stigma and psychological trauma. People with lesions and scars are often victimized and excluded from public life. Interestingly, it does not attract much attention in the national, continental, and global health agenda.

This situation has resulted in the overall neglect of patients because they are unable to access quality healthcare. The treatment options available are either too expensive, unavailable, or have severe side effects. In addition, most government healthcare centers lack specialized physicians to treat such cases. This means that patients have to travel long distances to access treatment in larger towns – something many cannot afford to do.

The Current standard of care for CL is Sodium Stibogluconate (SSG) which is injected in the area around the itchy lesion. This injection is a dreadful experience for patients “It is traumatizing to see patients wail in pain as during the treatment.” She remarks.

“I am glad that we are collectively rewriting the CL story. Early last year, five patients who were completely not responding to the standard of care treatment consisting of Sodium Stibogluconate (SSG) ever after receiving treatment for two years responded to oral miltefosine treatment,” she says excitedly.

Her appeal is for donor agencies, research and development, and governments to invest more funds, skills, and creating awareness on NTDs just like they have done with the Covid-19 pandemic.

“There is nothing that will make me happier than waking up to a day when CL patients will swallow oral pills instead of enduring the painful injections. When that is done, half of the war against CL will have been won.” She declares.

Passion Driven: Supporting neglected VL patients in Ethiopia reclaim their lost hope

By Danyell Odhiambo



Dr. Helina Fikre attends to a patient at Leishmaniasis Research and Treatment Centre, University of Gondar, Ethiopia.

"I am taking my son home so that his brothers and sisters can watch over him before he dies. I am forced to take this painful decision because I cannot afford the cost of transporting his body home if he happens to lose his life in the hospital." These are the words of a desperate father who recently visited Ethiopia's Gondar University Hospital seeking treatment for his eighteen-year-old son, a visceral leishmaniasis (VL) patient.

"The young man arrived when he was very weak. After performing several tests, we realized he also had other health complications. It took a lot of convincing for his father to accept for his son to be finally admitted. About three weeks later, the patient was discharged after his health dramatically improved." Dr. Helina Fikre, a Co-Principal Investigator for leishmaniasis clinical trials in Gondar, was highlighting some of her bittersweet moments working with VL patients.

Such anecdotes are typical in many of her conversations that touch on the triumphs and tribulations in her career, and her relentless passion that is rooted in supporting neglected VL patients to access quality healthcare.

Dr. Helina's relationship with VL patients can be traced back to eight years ago.

"I always dreamt of becoming a doctor because I enjoy caring for people. I can say it was by sheer luck that I landed a job as an investigator at the Leishmaniasis Research and Treatment Centre (LRTC) of the University of Gondar." She happily remarks.

Consequently, she is grateful to the Leishmaniasis East Africa Platform (LEAP) for establishing the LRTC - Africa's first clinical research facility dedicated to VL. The facility, she says, has helped address the needs of VL patients who had long been neglected because of lack of access to appropriate diagnosis and treatment.

"I am particularly happy that through the establishment of this facility, I have been offered an opportunity to serve as a clinician and actively participate in clinical studies. That way, I am living my dream which is to contribute to efforts to alleviate human suffering through fighting diseases." She explains in appreciation.

VL is one of the growing public health challenges in Ethiopia with over 3.2 million people at risk and estimated up to 4000 new cases per year. Dr. Helina is fascinated

by the fact that the centre is providing affected communities with free and quality treatment.

"I always enjoy the experience of seeing weak patients who arrived at the centre on wheelchairs walk back home with radiant smiles. For me this is not a job but the realization of dream to serve in a position that benefits the underprivileged communities." She quips.

Supporting Leishmaniasis Research in East Africa through improved diagnostics



A Doctor prepares to carry out a splenic aspirate to get a sample for Visceral leishmaniasis (VL) diagnosis. Partners are working with DNDi to find new and easy-to-use diagnostics for VL.

By Dr. Henk Schallig

For over two decades, the department of Experimental Parasitology at the Amsterdam University Medical Centers (AMC) has supported the improvement of diagnosis and management of several parasitic diseases in Africa.

With one of the areas of focus being Visceral Leishmaniasis (VL), the center has closely collaborated with renowned East African research institutes to improve the diagnosis of cutaneous and visceral leishmaniasis and is currently supporting DNDi and LEAP partners through the AfriKADIA project to explore new diagnostic options for VL that are more patient-friendly and field-amenable.

There are two common diagnostics for leishmaniasis. The first, known as Direct Agglutination Test is considered as the gold standard for the sero-diagnosis of VL and performs very well (high sensitivity and specificity) in all Kala-Azar endemic regions. In 2019, over 50,000 test kits were supplied worldwide. Recently, the World Health Organization has included the DAT on their list of essential diagnostics. The second test is microscopy which is still used as gold standard in clinical research (due to limitations of serological tests for test of cure).

The second type of tests are molecular diagnostics which are at times more suitable to diagnose an active ongoing

infection than serology, due to antigen persistence after successful treatment. When properly performed, this test may have a higher sensitivity and specificity. AMC has an extensive track record in developing, evaluating and implementing molecular diagnostic tests for all kinds of parasitic diseases including leishmaniasis. This work includes standard polymerase chain reaction (PCR) assays and quantitative assays (qPCR).

Luka Verrest and Thomas Dorlo from the Netherlands Cancer Institute in partnership with DNDi recently demonstrated in a retrospective pooled analysis of samples from LEAP studies that blood Leishmania parasite load, determined by qPCR, is a promising early biomarker to predict relapses in VL patients and might particularly be useful in the context of dose finding studies of new chemical entities.

To circumvent some of the technical difficulties which are encountered with normal amplification platforms like PCR, AMC, in close collaboration with the Foundation for Innovative Diagnostics (FIND), developed a loop-mediated amplification (LAMP) test for all types of leishmaniasis. LAMP is performed at a single temperature thus not requiring sophisticated equipment, and the read-out of the test is very simple. The diagnostic performance of the LAMP assay has been evaluated for both cutaneous as well as visceral manifestations of leishmaniasis, and this work has indicated that it may also serve as a possible test of cure. This feature of the LAMP is being explored further within the AfriKADIA project in LEAP sites in Ethiopia, Kenya, Sudan and Uganda. The availability of such a test will significantly improve treatment decisions and patient management.

As part of the capacity building efforts within the AfriKADIA project, AMC has supplied DAT to all study sites and supported training to local laboratory staff in its execution and interpretation. It is important that study staff are properly trained in performing DAT as this enables site-to-site comparison of the test results. In addition, in collaboration with FIND, the London School of Tropical Medicine (LSTM) and Hygiene and Instituto de Salud Carlos III, AMC trained laboratory staff in the execution of various other serological and molecular assays, including LAMP.

KEMRI marks 40 years of transforming health research in Africa

By Danyell Odhiambo

In February 2020, The Kenya Medical Research Institute (KEMRI), celebrated 40 years since its establishment. The event provided an opportunity to celebrate the institutions' continued contribution to health research.

'We have been at the forefront of scientific innovation in Africa. Our success is majorly attributed to strong partnerships and collaborations both locally and internationally,' said Prof. Yeri Kombe, the then Director General, KEMRI

The celebration also marked the official opening of the 10th KEMRI Annual Scientific and Health Conference held under the theme "Towards Sustainable Universal Health Care in Kenya: Utilization of Research Evidence through Multi-Sectoral Collaboration",



Former KEMRI Director General Prof. Yeri Kombe, speaks at the event.

In the past four decades, the institute has grown from a handful of scientists to a world re-known institute in human health research, with 15 research and laboratory centers spread across Kenya. "When I see KEMRI commemorate 40th anniversary as one of the best research institutes in Africa, I feel like crying. We started from two rooms in the ministry of health headquarters." Prof Kihumbu Thairu, the founder chairman of KEMRI.

The institute, which is one of DNDi's founding partners, currently ranks as one of the leading Centres of Excellence in health research in Africa.

Annual Meeting of the LEAP Advisory Committee

By Joy Malongo

On 3rd December 2019, LEAP held its second meeting of the LEAP Advisory Committee (LEAP AC), hosted by its Chair, Dr Sultani Matendehero. The meeting provided an opportunity for current committee members to discuss the role that the platform can play to achieve the universal health coverage (UHC) agenda at the national, regional, and global levels.

Dr Monique Wasunna and Dr Jorge Alvar, DNDi's Senior Leishmaniasis Advisor presented a brief overview of

the LEAP leadership structure and medium-term plans while Dr Fabiana Alves the DNDi's Head of Visceral Leishmaniasis, DNDi spoke about the NCE studies which are expected to begin in 2021/2022 in eastern Africa.

After the presentations, Dr Matendehero highlighted priorities for Ministries of Health leishmaniasis control programmes.

AfriKADIA Consortium participates in the 13th Annual Neglected Tropical Diseases (NTD) Conference

By Joy Malongo

The AfriKADIA consortium was represented at the 13th Annual NTD Conference held on 4th – 6th December 2019. The conference which was jointly organized with the 1st International Conference on NTDs (IncoNTD) in Africa called for partner countries to embrace Cross-border partnerships towards achieving control and elimination of NTDs.

As part of the side events, the AfriKADIA Consortium hosted a symposium titled “Translating research results into policy



Participants at the event.

for control and elimination of leishmaniasis in eastern Africa”. This symposium provided a forum to critically reflect on the gaps and opportunities in current efforts to control towards preparing the ground for a Leishmaniasis control and elimination strategies for eastern Africa. The session attracted over 70 participants drawn from partner institutions and Ministries of Health in the region.

Congratulations to Dr Brima Musa for attaining his PhD in Immunology

By Joy Malongo

Dr. Brima Musa Younis Mohammed is a Lecturer at the Institute of Endemic Diseases, University of Khartoum, reader in pediatrics and has gained cumulative experience in tropical medicine. He is a graduate of medicine from the faculty of Medicine, University of Khartoum. His research area is on infectious diseases. His postgraduate training was at Mahidol University (DTM&H and MSc Tropical pediatrics. He obtained a PhD in immunology from the Graduate College, University of Khartoum. His PhD work has explored the role of micronutrients in the immune response to leishmania parasites infection and susceptibility to progress to a full-blown picture of visceral leishmaniasis. Dr. Brima has been extensively trained in ethics and Good Clinical Practice. He



Dr Brima Musa.

participated in several clinical trials (preventive therapeutic vaccines and new treatments for visceral leishmaniasis and PKDL). He has mentored young doctors and participated in capacity building projects as PI and lead co-investigator. He is a member of Leishmaniasis Research Group at the Institute of Endemic Diseases and Leishmaniasis East Africa Platform (LEAP). He has been working as the Director of EL-Hassan center for Tropical Medicine in Eastern Sudan and contributed significantly to several publications in peer reviewed journals which have changed the treatment guidelines of Visceral Leishmaniasis in Sudan and Eastern Africa.

Visit by Laurent Fraisse and Eric Stobbaerts to Leishmaniasis Clinical Trial Site in Kenya and Uganda

By Linet Otieno

From the 26th to 28th February 2020, Dr. Laurent Fraisse, DNDi's Research & Development Director and Eric Stobbaerts, the International Development Director visited two LEAP sites.

Starting with the Amudat site in Northern Uganda and thereafter Kacheliba in North western Kenya, Dr. Fraisse and Eric visited patients, the laboratory, pharmacy and met with clinical trial teams. They were both excited at the level of commitment by the teams in carrying out clinical trials in these resource limited regions.



Dr. Laurent Fraisse, and Eric Stobbaerts speak to a Laboratory staff member at Kacheliba Hospital laboratory, West Pokot, Kenya.

They concluded their visit at the Moi Teaching and Referral Hospital which was one of the locations that was being evaluated to carry out clinical trials for upcoming Leishmaniasis new chemical entities. They were accompanied by Dr Monique Wasunna, Director Eastern Africa Regional Office and colleagues from the Nairobi office of DNDi.

Scaling Up laboratory practices across LEAP Clinical Sites through adopting global standards

By Joy Malongo

As part of the continuous efforts of ensuring the LEAP Clinical sites comply to the globally accepted Good Clinical and Laboratory Practice (GCLP) standards, the AfriKADIA Consortium organized a refresher training in Nairobi from the 5th-7th March 2019. The training brought together a total of 26 lab personnel drawn from eight LEAP trial sites in Kenya, Uganda, Ethiopia, and Sudan. Also in attendance were laboratory staff from Mycetoma Research Center in Sudan and DNDi staff in Nairobi.

"Compliance to GCLP is a step towards strengthening the capacity of the participating laboratories to enhance reliability, quality, consistency, and integrity of data generated. Laboratory results are critical to ensuring the



Participants at a Good Clinical and Laboratory Practice (GCLP) training.

safety of patients and the generation of quality data that determines the outcome of any clinical trial." Dr Varalakshmi Elango from P95 a research organization.

The three-day course was a follow up to the GCLP trainings held in Gondar in 2014 and Nairobi in 2016. The training was based on the emerging needs highlighted by clinical trial site staff. The training covered seven modules through a problem-based approach, interactive lectures, practical case studies, tests, and open discussions including on ways to improve supplies management, providing a wealth of continual improvement opportunities for sites to adapt.



"After the first cases of COVID-19 were confirmed in countries where the study was running, we were worried about how we could ensure the safety of both the health staff working on the trial and the study participants and at the same time complete the trial.

The measures put in place by the national governments in each country to prevent spread of COVID-19 e.g restrictions on movement in addition to the widespread fear associated with COVID-19 meant that a lower number of patients than usual were coming to hospital seeking care. Despite these and other challenges related to the COVID-19 pandemic, the Principal Investigators and study teams at the sites worked extremely hard under very difficult circumstances and ensured enrolment into this vital study was completed". – Ayub Mpoya, Former Senior Clinical Project Manager, Leishmaniasis

"In this challenging covid19 period, we are left with no option but to take precautionary measures to protect the safety of both patients and health workers through adhering to government procedures. When I put myself in the shoes of a desperate patients seeking for treatment, I am compelled to attend to their healthcare needs knowing that mine not only a job but a calling to serve humanity." Edwin Abner, Kacheliba Sub County Hospital, Kenya



Media Mentions 2019-2021



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6. Identification of Resistance Determinants for a Promising Antileishmanial Oxaborole Series. Van den Kerkhof M, Leprohon P, Mabilie D, Hendrickx S, Tulloch LB, Wall RJ, Wyllie S, Chatelain E, Mowbray CE, Braillard S, Ouellette M, Maes L, Caljon G. Microorganisms. 2021; 9(7):1408. <https://doi.org/10.3390/microorganisms9071408>
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LEAP ROUNDUP

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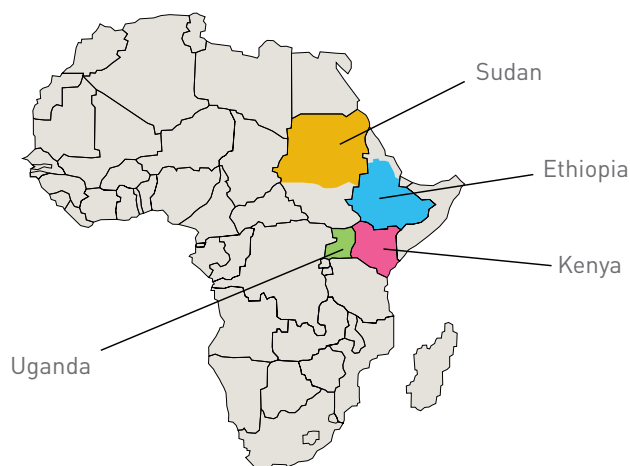
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1. Amudat Hospital clinical site team in Uganda receive personal protective equipment (PPE) donated by pharmaceutical company EISAI, Japan, one of DNDi's industry partners.
2. Health workers in the donated PPE.
3. Dr. Monique Wasunna, with the French Ambassador Aline Kuster-Ménager and Dr. Pierre-Yves Bello, Regional Health Counsellor at the French Embassy. Dr. Wasunna was awarded the rank of Officer of the prestigious French National Order of Merit in recognition of her work helping people with neglected tropical diseases.
4. Journalists from two Kenyan media houses; KTN Kenya and NTV speak to Dr. Solomon Psakwa from Kacheliba Hospital in West Pokot, Kenya about leishmaniasis activities.
5. Dr Laurent Fraisse, Eric Stobbaerts, Dr. Monique Wasunna and Simon Bolo from DNDi meet with the Governor of West Pokot, Professor Hon John Lonyang'apuo at an event. They spoke briefly about the leishmaniasis activities in the region.
6. Partners during a consultative meeting for DNDi's Strategic Plan 2021-2028. The Plan was officially launched in March 2021.
7. A health worker loads drugs into a vehicle that was donated to Kacheliba Hospital to support clinical trial activities for leishmaniasis.
8. Nita Bhalla, a journalist from Thomas Reuters Foundation News speaks to Isaac Nyeris, community representative and a leishmaniasis patient at the Kacheliba hospital, West Pokot, Kenya.



Leishmaniasis East Africa Platform (LEAP) is a clinical research network that brings together experts from leishmaniasis endemic eastern African countries to facilitate clinical testing and improved access to better treatments for leishmaniasis in the region

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