

DNDi in East Africa



2018 Highlights:

Building Partnerships
for Neglected Patients

DNDi^{AFRICA}
Drugs for Neglected Diseases *initiative*

DNDi holds 11th Partners Meeting in Kampala, Uganda to celebrate African leadership in R&D innovation

More than 400 partners from over 150 institutions drawn from more than 40 countries, gathered in Kampala, Uganda to celebrate African leadership in innovation for R&D and access to medicines for neglected diseases during Drugs for Neglected Diseases initiative's (DNDi's) 11th Partner's meeting held on October 4th, 2018.



Over 400 participants drawn from various partner institutions and government agencies attended the meeting.

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The meeting highlighted the importance of partnerships and the continued need to break new ground in African-led R&D, harmonized regulation, and health access strategies for neglected

patients that ultimately provide a template for universal health coverage.

During his opening speech, the Prime Minister of Uganda, Right Honourable Dr Ruhakana Rugunda, called the meeting a 'true testament of collaboration and partnership for neglected patients' and reiterated his own government's commitment to supporting the search for improved treatments for neglected diseases and patients. Other notable partners who attended included DNDi's global

R&D partners, journalists, key African government officials, and eminent figures in human health research, including Dr Kelly Chibale, Director of the H3D Centre, the drug discovery institute at the University of Cape Town, who was among Fortune magazine's 50 World's Greatest Leaders in 2018.

The Partners' Meeting was the culmination of week-long disease-specific meetings on leishmaniasis, sleeping sickness, paediatric HIV, and filarial diseases held at the same venue.

Inaugural DNDi's science journalism workshop calls for better news coverage of neglected diseases in Africa

In October 2018, 18 journalists from 11 African countries converged in Kampala, Uganda for DNDi's first-ever training on health and science journalism. The three-day training was conducted on the sidelines of DNDi's 11th Partners' Meeting.

The objective of the workshop was to help reporters and editors better understand neglected diseases prevalent in the region and grasp the science behind efforts to develop new drugs for these diseases, to enhance the quality of media coverage on NTDs.

Otula Owuor, a veteran Kenyan science journalist and trainer with the World Federation of Science Journalists, facilitated the training.

The journalists learned about neglected diseases from DNDi experts, including onchocerciasis (river blindness), human African trypanosomiasis (sleeping sickness), and leishmaniasis, and neglected patient populations such as children living with HIV. Dr Nathalie Strub-Wourgaft, Director of Neglected Tropical Diseases at DNDi, helped to 'demystify' the clinical trials process with an in-depth talk on drug development.

Equipped with new skills and understanding, the journalists developed several news articles about the topics of discussion.

SELECTION OF ARTICLES PUBLISHED BY PARTICIPANTS OF THE WORKSHOP:

The Citizen [11 October 2018]
"Children's HIV drug formula developed"

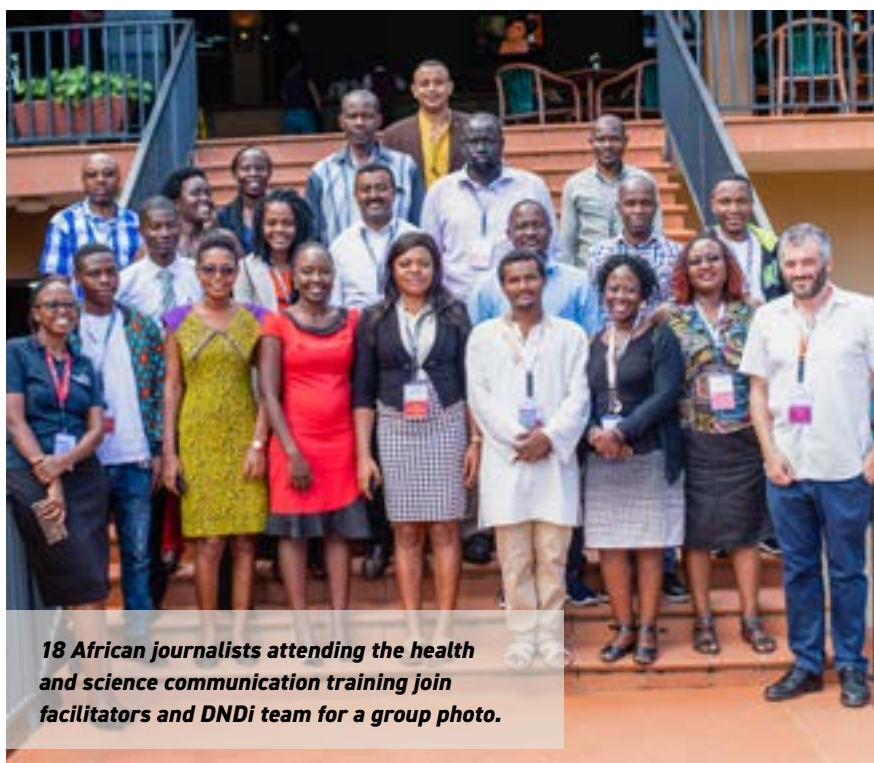
Ghana Web [11 October 2018]
"More resources needed to fight against neglected tropical diseases – Health experts."

Ghana Web [11 October 2018]
"Pediatric HIV victims get attention."

Daily Monitor [10 October 2018]
"HIV-positive children to take soluble ARVs."

The Star Tribune [8 October 2018]
"Health organization celebrates 15 years fighting neglected diseases globally."

New Business Ethiopia [3 October 2018] **"New clinical trials for neglected diseases in eastern Africa in progress"**



18 African journalists attending the health and science communication training join facilitators and DNDi team for a group photo.

'There is urgent need to build a critical mass of African journalists who will be able to promote media coverage of NTDs. The training served as a foundation into unpacking DNDi's life-saving research and development efforts. The next and urgent step is the need to demystify this scientific information to promote public knowledge on NTDs.' **Mr Otula Owuor, veteran Kenyan science journalist, and trainer with the World Federation of Science Journalists.**

DNDi Africa Office, Nairobi awarded new ISO 9001: 2015 Certification



Dr Monique Wasunna, DNDi Africa Director and Bureau Veritas official with the ISO certificate awarded.

From the first quarter of 2018, the DNDi office in Nairobi embarked on a process to upgrade its International Organization of Standardisation (ISO) Certification from ISO 9001:2008 to ISO 9001:2015.

The upgrading process involved enhancing processes and systems to align with the new standard. The most noticeable changes in the new ISO standard are its new structure and risk-based approach, which makes its management system easier. Following the completion of the recertification process, an audit exercise was successfully conducted by Bureau Veritas-Kenya in July 2018. In January 2019, the ISO 9001:2015

certificate was officially awarded to the DNDi Africa Regional Director, Dr Monique Wasunna, in the presence of the staff.

Speaking during the ceremony to celebrate the recertification, Dr Monique Wasunna, expressed her joy and thanked the team for their commitment in establishing the robust quality management system that led to the award.

'It has been a long, challenging, and exciting journey that could not have been successful without collective efforts from each one of us. It is a great honour to be recertified.

Receiving the certificate does not mark the end of the journey but a continuous process towards enabling the DNDi office in Nairobi to meet the demands of patients and interested parties,' she stated after receiving the certificate from a representative from Bureau Veritas Kenya.

'We are extremely happy to record, this is an outstanding accomplishment. We remain committed to fully implement this standard in our efforts to deliver quality products and services to our customers,' stated Simon Bolo, the Management Representative who spearheaded the upgrading process.

A clinical trial to find a new treatment for visceral leishmaniasis begins in eastern Africa

A new study to find a safer, more effective and patient-friendly treatment for people infected by visceral leishmaniasis (VL) began in eastern Africa, within the new AfriKADIA Consortium with funding from the European & Developing Countries Clinical Trials Partnership (EDCTP). The large-scale Phase III clinical trial seeks to assess the efficacy and safety of a combination of miltefosine and paromomycin (PM) in treating VL in eastern Africa. The current first-line treatment for VL in eastern Africa is sodium stibogluconate and PM given through injection or intravenously for 17 days.

If found to be efficacious, the introduction of miltefosine (the first oral treatment registered for VL in 2002 in India) in combination with paromomycin will reduce the difficulty in treatment administration and lengthy hospital stays for patients from 17 to 14 days with one injection instead of two.

The study will run concurrently with an assessment of innovative non-invasive diagnostic tools for managing VL cases within routine patient care. The trial, which began in January 2018, will take place in seven sites in Ethiopia, Kenya, Uganda, and Sudan for three years and enrol a total of 576 patients.



Hope for PKDL patients in Africa, after study to find safer and easier treatment, begins in Sudan

A clinical trial to find a better treatment for severe or chronic cases of post-kala-azar dermal leishmaniasis (PKDL) in Africa was initiated in Dooka, Sudan in 2018.

PKDL is a form of leishmaniasis, a neglected disease, which can develop after a person has completed visceral leishmaniasis (VL) treatment. In Sudan, 50-60% of VL patients will develop PKDL within six months after the end of the treatment. This is the highest PKDL rate worldwide. In Africa, the current treatment for PKDL is sodium stibogluconate, a drug that is associated with a high risk of toxicity when used for 40-60 days.

The Phase II clinical trial being conducted by the DNDi and the Institute for Endemic Diseases (IEND) at the University of Khartoum seeks to shorten the

length of hospitalization for PKDL from the current 40 – 60 days, to between 7 – 14 days, and deliver a treatment that is safer to use and easier to administer.

This clinical trial will assess the safety and efficacy of two new treatment combinations. The first is a combination of paromomycin, an injectable treatment, with the oral drug miltefosine. The second is a combination of intravenous liposomal amphotericin B, currently used as a second-line treatment for VL in Africa, with miltefosine.

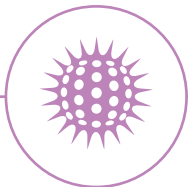
If either of these treatment options is proven to be safe and efficacious, PKDL patients can be treated for a few days at the hospital, then complete the oral treatment at home.

LIVING Study appreciates Nairobi field health staff for their support in the completed patient follow-up exercise

Over 70 field health staff from LIVING study sites in Nairobi attended a ceremony convened by DNDi on 13 December 2018 to appreciate their efforts in the successful finalization of patient follow-up. The meeting presented an opportunity for the field teams to speak about their experiences during the clinical trial.

All the site staff were awarded certificates of appreciation for their immense contribution.

'I am happy that our participation in the LIVING study gave us a unique opportunity to learn how to conduct clinical trials. This was the first clinical trial that we conducted. It was truly an eye-opening experience for our team,' **Dr Joseph Mbutia, Site Principal Investigator for Gertrude's Children's Hospital.**



Dr Joseph Mbutia (centre) and the team from Gertrude's Children's Hospital take a group photo as they display appreciation certificates .

LIVING study interim results provide evidence of significant viral suppression in young children

The trial is evaluating the effectiveness of 2-in-1 oral lopinavir/ritonavir pellets in addition to AZT/3TC (or ABC/3TC) paediatric fixed-dose combinations under routine treatment conditions in infants and young children living with HIV who cannot swallow tablets.

DNDi has been running the LIVING implementation study in Kenya, Uganda, and Tanzania since 2015. As of December 2018, the study had enrolled

1,003 children in 12 sites in Kenya, Uganda, and Tanzania, and follow-up was completed for the Kenyan and Ugandan sites. Interim results from this study have shown very high levels of treatment adherence and clinical improvement as well as lower HIV viral loads, showing that improved formulations can lead to better treatment outcomes. These results provide evidence that 2-in-1 therapy is effective and well-tolerated by children.

“The 2-in-1 pellets is a great innovation. The beauty of this treatment formulation is that it is easier to administer because you can mix it with meals. This plays a significant role in promoting acceptability and adherence among children, especially adolescents. Our major challenge now is to make the drug available to this vulnerable group of patients.” **Sister Mary Owens, Executive Director, Children of God Relief Institute and Lea Toto Clinics**

Anne Wanza, mother of Mary, living with HIV and treated at the Lea Toto Kariobangi site in Nairobi, Kenya administering pellet medication.



DNDi's mycetoma team attends the International Society for Human and Animal Mycology Congress

DNDi's mycetoma team attended the 20th Congress of the International Society for Human and Animal Mycology (ISHAM) that took place in Amsterdam, Netherlands from 30 June to 4 July 2018. Prof. Ed Zijlstra and Dr Sahar Bakhiet from the Mycetoma Research Center (MRC) in Khartoum, Sudan made presentations in a session entitled: Closing the mycetoma knowledge gap.

Topics discussed during the session included: holistic

approaches to mycetoma management, the mycetoma treatment landscape, isothermal amplification techniques, and a tool for molecular diagnosis of eumycetoma. The session was concluded by a panel discussion moderated by Prof. Ahmed Fahal of the MRC and Dr Wendy van de Sande from Erasmus University in Rotterdam, the Netherlands.

The Congress enabled partners to meet and discuss challenges and opportunities in mycetoma research.



Mycetoma Study team takes a group photo during the conference.



'Shot in the arm' for mycetoma study as protocol amendment increases patient recruitment rates

Following slower than anticipated recruitment, a protocol review and amendment was conducted in 2018 to extend the inclusion criteria in relation to lesion size and site, and age range of participants. By the end of 2018, 75 patients had been enrolled in the

study, which is evaluating the drug fosravuconazole for the treatment of fungal mycetoma. An interim analysis in 2019 will determine which of two treatment arms will be retained for the remainder of the trial (200mg vs 300mg of fosravuconazole weekly).

Mycetoma Research Center hosts partner delegation

The Mycetoma Research Center (MRC) in Khartoum, Sudan hosted a partner delegation for a four-day-visit that commenced on 8 July 2018. The team consisted of representatives from the Global Health Innovative Technology (GHIT) Fund, a donor organization supporting the mycetoma study, accompanied by officials from Eisai, a pharmaceutical company providing the foscarnazole treatment in an ongoing DNDi clinical trial, and a team from DNDi.

The delegation visited the Wad Onsa Health Centre in Sennar state (which has high numbers of recorded mycetoma patients in Sudan) and the MRC. An upgrade of existing laboratory facilities in Wad Onsa is planned to allow for pre-screening of patients in the satellite centre before being referred to the MRC in Khartoum. Also present during the tour was the Japanese Ambassador to Sudan and the Director of the Japan International Cooperation Agency.

Patients sit at the waiting lounge at the Mycetoma Research Centre.



DNDi participates in healthcare worker training on prevention and diagnosis of VL in Lodwar, Kenya

Over 30 government health workers from three leishmaniasis-endemic counties in Kenya attended a five-day training held from 16-21 June 2018 in Lodwar, Turkana County.

The training equipped participants with practical skills on prevention, diagnosis, treatment, and

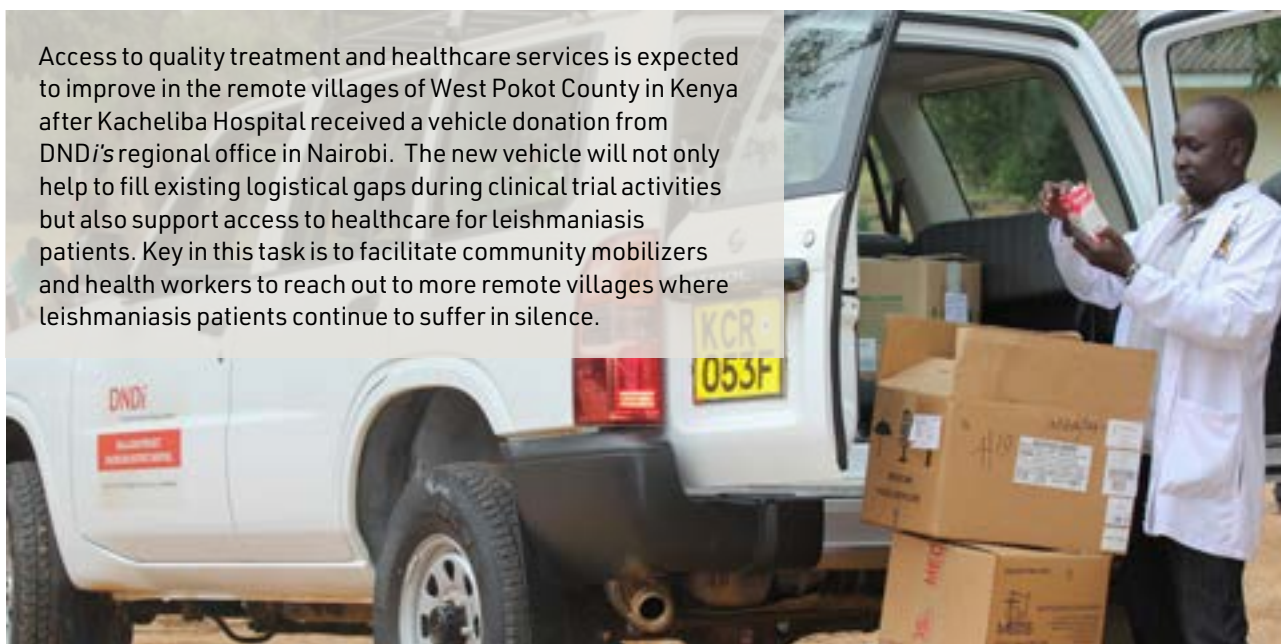
management of concomitant diseases related to VL. Other topics discussed included the emerging challenges of rising cases of post-kala-azar dermal leishmaniasis (PKDL) and HIV-VL co-infection. Representatives from DNDi, the World Health Organization in Africa (WHO), and Kenya's Ministry of Health facilitated the training.



Mark Riongoita, a health worker from the Kacheliba district hospital takes the participants through a session on diagnosis and treatment of VL.

Major boost for Kacheliba District Hospital as DNDi donates new vehicle to enhance access to healthcare

Access to quality treatment and healthcare services is expected to improve in the remote villages of West Pokot County in Kenya after Kacheliba Hospital received a vehicle donation from DNDi's regional office in Nairobi. The new vehicle will not only help to fill existing logistical gaps during clinical trial activities but also support access to healthcare for leishmaniasis patients. Key in this task is to facilitate community mobilizers and health workers to reach out to more remote villages where leishmaniasis patients continue to suffer in silence.



LEAP marks 15 years of delivering treatment to leishmaniasis patients

A total of 73 participants from six leishmaniasis-endemic countries in Africa and other countries around the world gathered in Kampala, Uganda on 3-4 October 2018 for the 25th LEAP Platform Meeting. The theme of the meeting was Improving access to treatments for leishmaniasis patients through partnerships, providing an opportunity to review the collaborative approaches that LEAP and its partners have adopted within the region, and to consider future strategies for the management of leishmaniasis.



LEAP members and partners in a meeting in Uganda that marked 15 years since its inception

This year marked 15 years since the inception of the LEAP Platform. Meeting participants came from Ethiopia, Uganda, Somalia, South Sudan, Sudan and Kenya which, together, carry the highest burden for the disease in the world. The meeting also attracted representatives from key research organizations, academic institutions, and health ministries.



A nurse at Amudat Hospital with a kala azar patient

'Finding new oral treatment combinations will be a major milestone in our Research and Development efforts around visceral leishmaniasis. As we transition to LEAP 2.0, we want to begin by bridging the existing gaps in regulatory harmonization framework within Africa.' **Prof. Asrat Hailu, Chairman of the Leishmaniasis East Africa Platform (LEAP)**






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A not-for-profit research and development organization, DNDi works to deliver new treatments for neglected diseases, notably leishmaniasis, human African trypanosomiasis, Chagas disease, specific filarial infections, and mycetoma, and for neglected patients, particularly those living with paediatric HIV and hepatitis C.

Since its inception in 2003, DNDi has delivered eight treatments: two fixed-dose antimalarials (ASAQ and ASMQ), nifurtimox-eflornithine combination therapy (NECT) for late-stage sleeping sickness, sodium stibogluconate and paromomycin (SSG&PM) combination therapy for visceral leishmaniasis in Africa, a set of combination therapies for visceral leishmaniasis in Asia, paediatric dosage forms of benznidazole for Chagas disease, a 'super-booster' therapy for children co-infected with HIV and TB, and the first all-oral drug for sleeping sickness (fexinidazole).

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