THREE CLINICAL RESEARCH PLATFORMS IN AFRICA AND LATIN AMERICA
TO BUILD SUSTAINABLE RESEARCH CAPACITIES

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INTRODUCTION
The Drugs for Neglected Diseases initiative (DNDi), as an integral part of its business model and with a view to developing field adapted treatments for neglected diseases, has supported the set-up of three disease-specific platforms in Africa and Latin America for the three kinetoplastid diseases (Human African trypanosomiasis or sleeping sickness, visceral leishmaniasis and Chagas disease). These platforms serve to define patients needs, strengthen local capacities, conduct clinical trials, and facilitate recruitment and uptake of new treatments.

LEAP Leishmaniasis East Africa Platform

Why focus on Visceral Leishmaniasis (VL) in East Africa?
- Almost all symptomatic patients die within months if untreated
- Field-relevant treatments are scarce and the cost optimal
- VL is in Africa primarily affects children (0-9 years)
- East Africa is one of the most important foci for it, in the world. Population displacements have exacerbated its spread.

About the Platform
Launched in 2003 with the support of DNDi, LEAP brings together scientists and institutions in East Africa to develop clinical trial capacity in order to bring new treatment options to registered VL patients in the region. LEAP is coordinated by the Malaria and Infectious Diseases Research Institute (MIDRI).

Objectives
- The overall aim of the platform is to strengthen clinical research capacity, which is lacking in part due to the remoteness and geographic spread of the patients, most of whom live in the most impoverished regions of the world.
- The platform also serves as a platform for engaging stakeholders and social cooperation between the countries in the East Africa region and standardization of procedures in order to expand the region, as far as possible within the confines of local regulation.
- LEAP implements, validates, and facilitates registration of improved treatment options that address needs for VL in East Africa (Ethiopia, Kenya, Sudan, and Uganda).

Achievements
- The LEAP Platform has provided support to seven treatment centers, clinical trial sites in the 5 endemic areas - Kenya (2), Uganda (2), Sudan (2), and Ethiopia - by building and/or remaking clinical trial sites as well as providing staff training, drugs, medical equipment, and material.
- Significant capacity building was also focused on local partners particularly in strengthening institutions in the region.
- The LEAP Platform now has facilities for the patient's enrolment and the implementation of SGSM in East Africa in VL, and the LEAP Platform will also provide training and facilitate implementation of pharmacovigilance and observational studies to meet each country's requirements.

Since its inception, LEAP has become an important regional network of virology research and control, trusted by the international scientific community.

Leishmaniasis East Africa Platform

HAT Platform (Human African Trypanosomiasis)

Why focus on Human African Trypanosomiasis, or sleeping sickness in Africa?
- Human African Trypanosomiasis (HAT), also known as sleeping sickness, is one of the neglected diseases in Sub-Saharan Africa with severe social and economic consequences.
- Translated by the term, trypanosoma, is transliterated into Tumaini.
- At all stages of clinical trial, at all levels of the trial, and involves a rich mix of partnerships.

About the Platform
Launched in Kinshasa (DRC) in 2005 and coordinated by DNDi, the HAT Platform is a clinical research network that brings together researchers involved in the control of HAT in endemic countries, notably Ministries Of Health and National Control Programmes, regulatory agencies, academics, clinicians, and civil society groups from Angola, Chad, Central African Republic, Democratic Republic of Congo, Republic of Congo, Sudan, and Uganda.

Objectives
- The HAT Platform’s mission is to build and strengthen treatment methodologies and clinical trials capacity in HAT endemic countries, so that new treatments for this fatal disease can be rapidly and effectively evaluated, registered, and made available to patients. After the success of the Nkabua–Efoulou Continuous Treatment Trial (NECT), included in the WHO list of essential medicines for the treatment of stage 1 HAT, the primary goals of the HAT Platform are to develop appropriate clinical trial methodologies for HAT, overcome system challenges related to administrative and regulatory requirements, strengthen clinical trial capacity (human resources, infrastructure, equipment), and share information and strengthen ties among endemic countries.

Achievements
- The HAT Platform facilitates the implementation and access of alltrypa-nae to the Nkabua–Efoulou Continuous Treatment Trial (NECT), for stage 2 HAT in 15 endemic countries, with working closely with national authorities and control programmes. Thanks to its work, more than half (52%) of stage 2 HAT patients were included in NECT in 13 African endemic countries in 2016. NECT is included in the Essential Medicines List (EML) since 2018.
- The Platform participates in the ongoing clinical trial NECT-Field, assessing the clinical response of NECT co-administration under field conditions. It will also participate in the coming clinical trial NECT-Endeavor, the promising cost drug candidate for second stage HAT.
- Every year, the HAT Platform organizes 2-3 trainings on Good Clinical Practice (GCP) for researchers, on HAT, and as on HAT patient workshop for clinical monitor and general principles.
- Since its inception, the HAT Platform has trained investigators and clinical monitors to run clinical trial sites.

Chagas Clinical Research Platform

Why focus on Chagas disease in Latin America?
- 21 countries in Latin America are endemic
- 100 million people are at risk of contracting Chagas disease
- Approximately 8 million people live with Chagas disease
- Chagas disease kills more people in the region each year than any other parasite-borne disease, including malaria
- Chagas is the leading cause of heart failure or cardiomyopathy worldwide
- Each day, 3 babies (benificial) and 121 babies (benificial) were born 60 years ago, have limited efficacy in the treatment phase, poor teratogenic profile in adults, long treatment period and a painful inflammation

About the Platform
The Chagas Clinical Research Platform was launched in 2006 and brings together partners, experts, and stakeholders in a network, which provides coordination of new treatments for Chagas disease. The Chagas Disease Research Platform is coordinated by DNDi and the Latin America office based in Río de Janeiro, Brazil.

Objectives
- The overall aim of the Chagas Platform is to strengthen its capacity to Latin America to conduct clinical trials, review, and facilitate registration and recommendation of new therapies for Chagas disease. The platform also provides a forum for technical discussions and facilitates the implementation of new treatments such as apanical benzimidazoles.

Achievements
- The expert meeting which led to the creation of Chagas platform defined a new drug target product profile (DTP) for Chagas disease that became established every year.
- Pedisaff基准岛的分化，新适应症药物的开发
- Chagas disease DNDi and the Pharmaceutical Laboratory of Parasitology (SAPDO) joined in 2008 to develop the first pan-disease formulation of benzimidazoles called spleen for release in 2011, the new pan-disease formulation will soon be feasible, which will facilitate the treatment of children and babies. The product is designed for patients up to 2 years of age and up to 20kg, and will be sold at cost to countries that show the need.

In 2008, the platform was instrumental in launching a global advocacy campaign to raise awareness on R&D and treatment needs for Chagas disease on the occasion of the 100th anniversary of the discovery of the disease.

A New Scenario
The year of 2011 reflects new scenarios for the development of new drugs for Chagas dis-

case due to the initiation of new clinical studies in Latin American and Spain, pointing out potential paths for a new perspective of hope in the future for thousands of people living with Chagas:

- 1322 – DNDi & CPT
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- Paracoccidio (DASSAOGAL & OCT Chagas) – CI Spain & Mexico
- CPT – Canadian Institutes of Health Research, Darieo Parasite Research Institute; Population Health Research Institute; Hospital of Clinics of Biological Path (PSP) and
- TAMEA – National Parasitology Institute Dr. Maria Faustina-Arribery, Argentina

DND also organized training in Good Clinical Practice (GCP) as well as standardization methodology courses to evaluate the effectiveness of drugs used for treating Chagas infection.

CONCLUSIONS
1. The three regional platforms have the specificity of bringing together regional actors, notably Ministries of Health and National Control Programmes, regulatory agencies, academia, clinicians, NGOs, and pharmaceutical companies with a common goal.
2. They define patient needs in the local and national contexts where the diseases are endemic.
3. They utilize, capitalize upon, and reinforce research and clinical capacities in endemic regions, particularly by creating clinical trial methodologies in compliance with Good Clinical Practices (GCP) standards as well as by providing on-site training in clinical research in sometimes very remote settings. They also address infrastructural requirements where necessary.
4. They are crucial to increasing the chances of registration, uptake, and sustainable patient access to new treatments.

The work of the platforms was vital to making available 2 new treatments against neglected diseases: NECT against sleeping sickness, and SGSM against visceral leishmaniasis.