HAT

Human African Trypanosomiasis Platform

Building sustainable clinical research capacity
to deliver new tools for patients in need

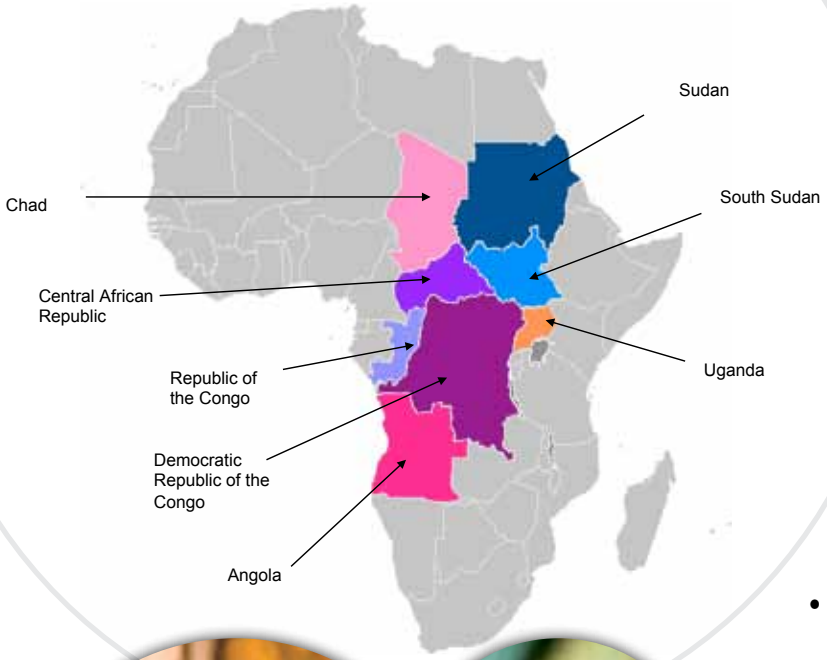
DNDi
Drugs for Neglected Diseases *initiative*

Human African Trypanosomiasis

Human African trypanosomiasis (HAT), or sleeping sickness, is caused by a protozoan parasite (*Trypanosoma brucei gambiense* in West and Central Africa and *Trypanosoma brucei rhodesiense* in East Africa) transmitted by the bite of a tsetse fly. Stage 1 of the disease often causes non-specific symptoms for years until infection crosses into the central nervous system and brain – stage 2. Without treatment, sleeping sickness is fatal. Currently available treatments are limited to drugs developed decades ago that are either highly toxic, difficult to administer in resource-limited settings, or are only effective in one stage of the disease. In addition, prior to being treated, the stage of the disease must be determined using a diagnostic spinal tap to extract cerebrospinal fluid from the patient.

Human African Trypanosomiasis – HAT Platform

Member Countries



About the platform

Launched in Kinshasa (Democratic Republic of the Congo - DRC) in 2005, and supported by the Drugs for Neglected Diseases *initiative* (DND*i*), the HAT Platform is a clinical research and access-supporting network that brings together key regional actors involved in the control of HAT in endemic countries, notably Ministries of Health, National Control Programmes, regulatory agencies, academia, clinicians, the World Health Organization (WHO) and NGOs.

Why focus on human African trypanosomiasis?

- Sleeping sickness is fatal if left untreated.
- Currently available treatments are either toxic, effective in only one stage of the disease, or not suited for peripheral healthcare centres.
- While current numbers of reported cases are decreasing, similar periods of decline have occurred in the past but have been followed by re-emergence of the disease due to lack or abandonment of surveillance and control efforts.
- An easy-to-use, oral treatment, active against both stages of the disease, combined with a simplified diagnostic test (rather than the currently used spinal tap), is necessary to contribute to sustainable elimination of the disease. This would allow mobile teams to detect and treat patients in remote areas, where the disease occurs.

Objectives

The overall aim of this platform is to build and strengthen clinical trial capacities (human resources, infrastructure, equipment) and methodologies in HAT-endemic countries so that new and promising treatments for this fatal disease can be rapidly and effectively evaluated, registered, and made available to patients.

To do so, the HAT Platform addresses specific objectives:

- Define patient needs, notably by establishing and adapting the ideal target product profile for treatments
- Create and further develop local capacity to conduct HAT clinical trials
- Improve clinical trial methodologies
- Share knowledge and information, including research progress, among HAT-endemic countries
- Advocate for policy change to include new treatments in national policies
- Facilitate patient access to treatments.

Main challenges

The HAT Platform continuously works to address and overcome the following:

- System challenges related to administrative and regulatory requirements
- Difficulties with access to sites in remote settings
- Resources required for set-up and conducting of new clinical trials (e.g. Phase II/III for Fexinidazole, a drug candidate for stage 2 HAT).

Capacity Strengthening

A vital aspect of the HAT Platform is its contribution to building capacity in endemic countries. Since its inception, the HAT Platform has offered training to hundreds of researchers, monitors, and practitioners in Good Clinical Practices (GCP), research ethics, pharmacovigilance, and HAT patient examination techniques.

Communication and Advocacy

- Regular updates on HAT research and HAT Platform activities are disseminated via the bi-annual *HAT Platform Newsletter*.
- Advocacy in member countries for quick adoption of NECT as first-line treatment for stage 2 HAT.
- Establishment and dissemination of an Ethics Evaluation in Research Guidance for HAT.

ACHIEVEMENTS

NECT
Nifurtimox-Eflornithine Combination Therapy

Treatments

The HAT Platform has facilitated the implementation and access of nifurtimox-eflornithine combination therapy (NECT) for stage 2 HAT in platform member countries, by working closely with national authorities and control programmes. NECT represents the first improved therapeutic option for sleeping sickness in 25 years. Currently implemented in 12 endemic countries, nearly two-thirds (62%) of stage 2 HAT patients were treated with NECT in 2010. NECT was included in the World Health Organization's Essential Medicines List (EML) in 2009.

Clinical trials

- Participation in the ongoing clinical trial NECT-Field, covering six trial sites in DRC, assessing the clinical response of NECT administration in field conditions, including pregnant and breastfeeding women as well as children. To date 629 patients treated.
- Participation in the forthcoming pivotal Phase II/III clinical trial, covering six trial sites in three endemic countries, for Fexinidazole, a promising oral drug candidate for stage 2 HAT.

HAT Platform members

HAT Platform meeting, Bangui, Central African Republic, May 2011

Partner Institutions and Networks

- National Control Programmes of most endemic countries (Angola, Uganda, Centra African Republic, Democratic Republic of the Congo, Republic of the Congo, Sudan, South Sudan and Chad)
- Institut National de Recherche Biomédicale (INRB), DRC
- Centre Interdisciplinaire de bioéthique pour l'Afrique francophone (CIBAF), DRC
- Tropical Medicine Research Institute (TMRI), Sudan
- Kenya Agricultural Research Institute – Trypanosomiasis Research Centre (KARI-TRC), Kenya
- Institut Pasteur (Bangui), Central African Republic
- Regional networks such as Eastern Africa Network for Trypanosomosis (EANETT)
- Swiss Tropical and Public Health Institute (Swiss TPH), Switzerland
- Institute of Tropical Medicine (ITM), Antwerp, Belgium
- Médecins Sans Frontières (MSF) International
- Epicentre, France
- Foundation for Innovative New Diagnostics (FIND), Switzerland
- World Health Organization (WHO), Department of Control of Neglected Tropical Diseases, observer

Donors

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HAT PLATFORM

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