

## EDITORIAL

In this second newsletter, the HAT Platform renews its communication efforts in order to rally all internal and external actors of the Platform to reinforce clinical trial capacities. Many thanks to those who submitted articles and have helped to publish this second information bulletin on time.

The Platform repeats the wish expressed early in the year, that “2007 be a year of concrete actions”.

As always, comments and criticisms to improve the presentation of this bulletin are most welcome.

On behalf of the  
HAT Coordination Team,

– Dr. Augustin Kadima Ebeja

# HAT Platform NEWSLETTER

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## 1. HIGHLIGHT ON SUDAN

**H**uman African Trypanosomiasis (HAT) appeared for the first time in South Sudan in 1906. The country has since experienced several epidemics, largely limited to the southern district of the Equatorial region. Recent HAT epidemics have been caused in part by the collapse of health services due to the civil war, which has raged in the region for the past fifty years. Continued insecurity hampers the efforts of the NGOs working to improve disease control. These difficult conditions, which have also prompted massive population movements, are responsible for the recent resurgence of several historical foci (Yei, Kajo keji, Nimule, Yambio) of human African trypanosomiasis.

Active and passive surveillance systems were used to monitor HAT in the country, but certain areas were not covered. Between 2002 and 2006, 8,568 people were diagnosed with and treated for sleeping sickness. A high number of relapses were recorded, particularly in cases treated with melarsoprol.

In the current post-war environment, there is an urgent need for essential measures, such as implementing active and passive screening, mapping the incidence of human African trypanosomiasis, as well as developing new treatment pro-



HAT PLATFORM TEAM IN KAMPALA, UGANDA

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## 1. HIGHLIGHT ON SUDAN (continued)

protocols and new drugs. Other activities, such as conducting clinical trials, improving diagnostic techniques, and mapping vectors, must also be implemented.

With the arrival of peace in Sudan, a coherent national control program was needed to cope with the resurgences of the disease in epidemic areas, mainly in west Equatoria. The coordination between the national HAT control program and NGOs specialists in the field will help improve general health services and disease control, thereby preventing future epidemics.

The Tropical Medicine Research Institute (TMRI) is now working with the Health Ministry of the Government of Southern Sudan (MOH-GoSS)/Research Department, with the assistance of the HAT platform and the European Union, to develop and reinforce clinical trial capacities. This will aid the Sudanese program in conducting joint studies on the concrete problems associated with sleeping sickness, such as therapeutic failure with melarsoprol and evaluating the safety and efficacy of new drug candidates.

The unflinching commitment of the Platform, TMRI, and MOH-GoSS will help boost national research capacities on HAT. Such efforts will undoubtedly contribute to the improvement of health services to the population affected by the disease.

– Dr. Intisar Elrayah

*Tropical Medicine Research Institute (TMRI) – Khartoum, Sudan*



RECENT HAT RESURGENCE

## 2. PEOPLE COME AND GO, BUT INSTITUTIONS REMAIN

### a. Reinforcing the capacities of ethics committees

“People come and go, but institutions remain.” Once again, this old saying is confirmed in the Republic of Congo (RoC) – also known as Congo-Brazzaville to differentiate it from its nearly homonymous neighbour, the Democratic Republic of Congo (DRC or Congo-Kinshasa).

The Platform takes this opportunity to inform readers that, after heading the national control programme against trypanosomiasis in RoC, Dr. Rudy Manthelot has moved on to another organization. Dr. Stephane Ngampo takes over for Dr. Manthelot in RoC. The HAT Platform would like to thank Dr. Manthelot for his actions that secured his country’s commitment to the cause of the Platform. The Platform hopes that he will remain a member, as the group will no doubt have need of his valuable scientific expertise on HAT in the future.

The Platform also welcomes Dr. Ngampo. As he has previously been at the head of this same programme, the Platform is confident that he will have no difficulties taking up the tasks of the position.

Concrete actions are taking place in the RoC. This is evident from the participation of three RoC physicians (including Dr. Stephane Ngampo) at the two training sessions organized in Kinshasa (Standardization of the clinical examination of trypanosomiasis patients, and Workshop for the investigators of the Phase IIIb of the DB289 study). However, there is still much work to do. The Platform relies on the enthusiasm of Dr. Ngampo to rally all the actors of HAT in RoC and carry through the plan of actions of the platform.

### b. HAT Platform welcomes Dr. Vatunga in Angola

In Angola, the Platform welcomes Dr. Gedeon Vatunga, who will be taking over several of the duties of Dr. Ndinga Dieyi Ditunganga.

### c. Reinforcement of the Platform Team in South Sudan, with the appointment of Dr. Apollo as head of the program

In South Sudan, the Platform is happy to welcome Dr. Apollo Oliver Duku, the first head of the HAT control program of MOH-GoSS. This new recruit will strengthen the team working with Dr. John Rumunu and Dr. Olivia Lomoro. The Coordination Team is committed to doing all it can to help the South Sudan team implement the activities of the HAT platform in their region.

–Dr. Augustin Kadima Ebeja

*Coordinator of the HAT Platform*

## 3. TURNING WORDS INTO ACTION

### a. Reinforcing the capacities of ethics committees

#### i. In DRC

The Coordination Team of the HAT Platform, DNDi, GCP Alliance-Europe, STI and PNLTHA organized a training session on the reinforcement of the capacities of ethics committees on March 20-21, 2007, in the Nganda Catholic Centre of Kinshasa.

Fourteen participants (see photo below) took part in this training session.

The main objective of this training session was to rekindle the enthusiasm of the ethics committee by reinforcing the capacities of its members through exchanges, discussions, and documentation sharing.



TRAINING ETHICS COMMITTEE MEMBERS IN KINSHASA, DRC., WITH TRAINER DR. F. CRAWLEY (GCP ALLIANCE EUROPE)

The chosen topics prompted very constructive discussions. The speakers presented different processes, which led to the creation of ethics committees in several countries throughout the world. They also showed how, in spite of their differences, such committees share the same objectives and problems.

The debates focused on the role of ethics committees, their relations with investigators and sponsors, and the concept of informed consent. The working groups addressed the committees' concrete objectives, as well as their strong and weak points, in order to determine how they could be improved. A model of the forms used by other ethics committees was also analyzed.

This training session was a success and will contribute greatly in helping the ethics committee with fulfilling its objectives in the future.

#### ii. Projects in other countries

The Platform must take advantage of the experience accumulated in DRC, analyzing its strong points and weak points in order to inform training sessions that will be provided for other countries members of the HAT platform.

The Coordination Team is committed to collaborating closely with each country in order to update their ethics committees. The team will be working specifically to identify the specific needs of each country and design suitable training sessions.

A calendar will be proposed during the Meeting of the Platform Steering Committee to be held in Basel, Switzerland, on June 26-27, 2007.

– Dr. Augustin Kadima Ebeja

### b. Training of physicians participating in HAT clinical trials

The representatives of the Swiss Tropical Institute within the HAT Platform (Dr. Caecilia Schmid and Dr. Didier Kalemwa), the coordinator of the Platform in Kinshasa (Dr. Augustin Ebeja), and PNLTHA Kinshasa organized a training session for physicians participating in the clinical trials on sleeping sickness. The goal of the training was to standardize clinical examination of patients.

The training session took place on April 16-19, 2007, at the Ngaliema Clinic and the CNPP (*Centre Neuro-Psycho-Pathologique*) in Kinshasa, RoC. The following experts coordinated and taught theoretical and practical sessions: Dr. Johannes Blum (Internal and Travel Medicine, STI Basel), Dr. Jorge Seixas (Internal and Travel Medicine, IHMT Lisbon), Dr. Pascal Tshamala (Internal Medicine, Director of the Ngaliema Clinic), Dr. Limbole (Cardiology, Ngaliema Clinic), and Dr. Leon Kazumba (Neurology, CNPP).

A total of 25 physicians from DRC, RoC, and Angola took part in this 4-day session. The topics covered the clinical examination of patients, with a special focus on the cardiovascular, respiratory, osteoarticular, endocrine, urogenital, gastrointestinal, and nervous systems.

### 3. TURNING WORDS INTO ACTION (continued)

Participants were also given a presentation on the recent studies on HAT: Cardiology and endocrine involvement in HAT (Dr. J. Blum) and Encephalopathic syndromes in HAT and their management (Dr. J. Seixas).

The training was highly appreciated both by the trainers and by the physicians, who participated actively and provided interesting exchanges among the experts. One of the Platform's priorities is the standardization of clinical examination, and some participants suggested the creation of a patient examination sheet to standardize data. A model was drafted and distributed by Dr. Seixas and Dr. Blum, to be tested and adapted to requirements in the field.

Once the real needs of physicians participating in the clinical trials and working in the field will have been established, ongoing training sessions for physicians should be organized in the francophone member countries of the Platform. Similar training approaches should be provided in English for Platform members in East Africa, based on their specific needs.

– Dr. Caecilia Schmid  
*Swiss Tropical Institute*



HATCAP MD TRAINING IN KINSHASA, APRIL 2007. FROM RIGHT TO LEFT: TRAINERS DR. BLUM (STI), DR. LIMBOLE (KINSHASA) AND DR. SEIXAS (IHMT LISBON) WITH DR. EBEJA (PLATFORM COORDINATOR) AND ANGOLAN PARTICIPANTS DR. DALA AND DR. MOIO

#### c. Other achievements

- MEETING OF THE STEERING COMMITTEE OF THE HAT PLATFORM (BASEL, SWITZERLAND, JUNE 26-27, 2007)
- 4TH CONGRESS OF INFECTIOUS AND PARASITIC PATHOLOGIES (KINSHASA, DRC, JULY 4, 2007)
- TRAINING OF THE MEMBERS OF THE ETHICS COMMITTEE (KHARTOUM, SUDAN, JULY 24-26, 2007)

##### NEXT STEPS

- FINALIZE THE HAT PLATFORM BOOKLET (END OF AUGUST 2007)
- PARTICIPATE IN THE 29TH INTERNATIONAL SCIENTIFIC CONGRESS FOR THE RESEARCH AND THE CONTROL OF THE TRYPANOSOMIASIS (LUANDA, ANGOLA, SEPTEMBER 2007)

– DR. AUGUSTIN KADIMA EBEJA

## 4. CURRENT NEWS ABOUT ON-GOING CLINICAL TRIALS

### a. Workshop for the investigators of the DB289 study Phase IIIb

The investigators of the DB289 study, whose Phase IIIb is currently being designed, met in Kinshasa, DRC, on April 23-25, 2007. This fruitful and constructive meeting was attended by 36 representatives of health zones, hospitals, and various health centers, as well as the provincial coordinators of HAT programs in DRC and RoC. The study is expected to begin in the second quarter of 2007. It will start in the HAT centers in the Bandundu region of the DRC and will gradually include all the sites in DRC, RoC, as well as other countries where possible.

–Dr. Gabriele Pohlig  
*Swiss Tropical Institute*

### b. Preparation of a new study, NECT-2

A workshop took place in Kinshasa, DRC, on April 19-21, 2007, to discuss a possible new study on the nifurtimox-eflornithine combination, aiming to document the safety and efficacy of this combination in real-life conditions at HAT treatment centers in DRC.

## 4. CURRENT NEWS ABOUT ON-GOING CLINICAL TRIALS (continued)

DNDi organized the workshop in collaboration with experts from STI, Epicentre, Institut Pasteur, as well as with the investigators of the first NECT study in DRC.

The objective of this workshop was twofold:

1) To train local investigators in the basic elements of a study protocol, according to the GCP guidelines

2) To develop a consensus on the design of this new study, particularly its objectives, justification, target population, and endpoints in terms of safety and efficacy measurements

After a one-day training on the essential elements of a study protocol, the main session started with a presentation of the preliminary results of the NECT study conducted



WORKSHOP FOR THE INVESTIGATORS OF THE DB289 STUDY PHASE IIIb (AT THE CAP, KINSHASA D.R.CONGO DRC)

by Epicentre, with a special emphasis on the preliminary safety and efficacy results of the nifurtimox-eflornithine combination. Discussions then followed on the rationale, objectives, and design of this new trial, as well as on the number of subjects, inclusion and exclusion criteria, and safety and efficacy evaluation. These elements will now form the basis of a full protocol development. The study will be carried out in several treatment centers of PNLTHA in DRC (to be specified).

– Dr. Els Torreele  
DNDi

## 5. MISCELLANEOUS

### a. Call for HAT Platform logo proposals

During the Brazaville meeting in November 2006, the Platform discussed the need for a HAT Platform logo. All members are welcome to submit prototype logos. Proposed logos can exhibit the specific spheres of activity of the Platform and demonstrate the contribution of the each country's unique artists. Logos should be sent to the Coordination Team (Dr. Augustin K. Ebeja) by the end of September 2007.

– Dr. Augustin Kadima Ebeja

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## 6. RECENT SCIENTIFIC ARTICLES

The electronic versions of the following articles may be obtained by contacting Dr. Augustin Kadima Ebeja.

- 1 Delespaux. Drugs and Drug Resistance in African Trypanosomiasis. *Drug Resistance Update* 2007; 10: 30 -50.
- 2 Kabasa. PPP works to stamp out sleeping sickness in Uganda. *Trends in Parasitology* 2007; 23 (5): 191-192.
- 3 Kass. The Structure and Function of Research Ethics Committees in Africa, a case study. *PLOS Medicine* 2007; 4 (1): 26-31.
- 4 Lutumba. HAT in a rural community, DRC. *Emerging Infectious Diseases* 2007; 13 (2): 248-254.
- 5 Robays. Drug toxicity and cost as barriers to community participation in HAT in DRC. *Trop Med Int Health* 2007; 12 (2): 290-298.
- 6 Rosenberg. The Site Monitor Reborn as Consultant, Trainer and Manager. *J Clin Res Best Practices* 2007; 3 (3): 1-4.
- 7 WHO. Online clinical trial tool. *Weekly Epidemiological Records* 2007; 19: 167-168.

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