

EDITORIAL

To start the year on a happy note, we are pleased to offer you this third issue of the HAT Platform newsletter, which contains illustrations and photos showcasing the different achievements of the past year in the first part of the newsletter.

In January 2007, we published our first newsletter and hoped that the Platform would make substantial progress during the year. Have we done so?

An objective analysis is necessary. Therefore, the second part of this newsletter will cover the annual assessment that was produced during the Platform's Annual Meeting, which took place in Khartoum, Sudan, 27-29 November 2007.

In the opening speech, we stated, "Our long list of achievements should not hide the fact the Platform still has a long way to go. In pursuit of this, all the partners should be mobilized so that 2008 becomes a year of consolidation for the sake of progress – to achieve our mission and vision of clinical trial capacity building and make available new tools for diagnosis, treatment and control of sleeping sickness."

We thank all members of the HAT Platform for their various contributions in accomplishing these activities. We would also like to remind others that the Platform is open to all actors involved in the HAT field. These individuals and groups would not only contribute their experience, but would also benefit from the synergistic and dynamic activities of the Platform.

We would like to take this opportunity to convey our best wishes to all Platform members and partners.

– DR. AUGUSTIN KADIMA EBEJA
HAT Platform Coordinator

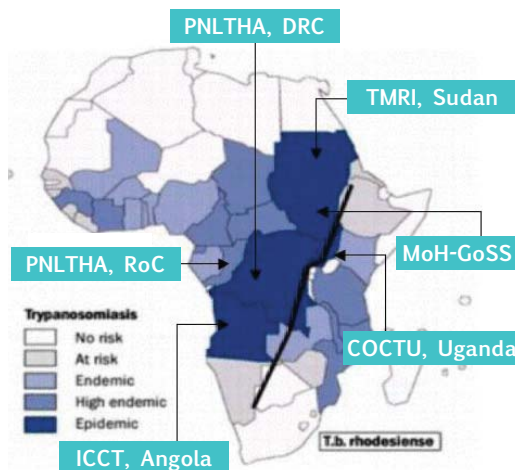
HAT Platform NEWSLETTER

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The above logo is a draft proposed to all members. Please provide your opinion and any comments so that it can be improved.

HAT Platform Partners



National HAT control programmes of most affected endemic countries

DNDi
Swiss Tropical Institute

Other partners:

- National and international HAT research groups - ITMA, INRB, CDC, TRC-KARI, etc.
- NGOs working in HAT control
- FIND
- WHO
- EANETT, PABIN, AMANET...

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1. 2007 HAT PLATFORM ACHIEVEMENTS

The HAT Platform offers an opportunity to increase research activities that should, contribute, in the long run, to better patient care, and should help to eradicate HAT as a public health threat.

All the activities mentioned below were achieved thanks to the efforts of our partners, to whom we are very grateful.

Far from being able to provide detailed reporting on all of the different activities of each member country during 2007, the HAT Platform will provide a brief summary table (Table 1). The photos are testimony to the important work and achievements of Member States so far.

Table 1: A Brief Summary on 2007 HAT Platform Member States

Activity	Place, date or achievement status
1. TRAINING OF ETHICS COMMITTEE MEMBERS	KINSHASA, DRC: MARCH 2007 KHARTOUM, SUDAN: JULY 2007 KAMPALA, UGANDA: NOVEMBER 2007
2. STEERING COMMITTEE MEETINGS	BASEL, SWITZERLAND: JUNE 2007 KHARTOUM, SUDAN: NOVEMBER 2007
3. FOLLOW-UP ON THE ETHICS COMMITTEE TRAINING	ONGOING
4. WORKSHOP ON CLINICAL TRIALS METHODOLOGY	KHARTOUM, SUDAN: NOVEMBER 2007
5. TRAINING OF PHYSICIANS-INVESTIGATORS	KINSHASA, DRC: APRIL 2007
6. HAT PLATFORM ANNUAL MEETING	KHARTOUM, SUDAN: NOVEMBER 2007
7. HAT PLATFORM NEWSLETTER AND BROCHURE	TWO ISSUES OF PLATFORM NEWSLETTER EDITED (JANUARY 2007 AND AUGUST 2007), BROCHURE WORK ONGOING
8. DEVELOPMENT OF THE PROCEDURE GUIDELINES	INFORMATION MADE AVAILABLE IN DIFFERENT COUNTRIES ; GUIDELINES YET TO BE FINALIZED (- PROCEDURES ON OBTAINING AUTHORISATION FOR CLINICAL TRIALS - PROCEDURES ON IMPORT AND EXPORT FOR CLINICAL TRIALS)



PREPARATORY MEETING FOR THE TRAINING OF ETHICS COMMITTEE MEMBERS, KHARTOUM, SUDAN. FROM LEFT TO RIGHT: DR. ELS TORREELE, DR. FAIZA MOHAMED OSMAN, DR. INTISAR ELRAYAH, AND DR. AUGUSTIN K. EBEJA



GROUPS SESSIONS DURING THE TRAINING OF ETHICS COMMITTEE MEMBERS IN KAMPALA, UGANDA



PARTICIPANTS AND FACILITATORS OF THE TRAINING OF ETHICS COMMITTEE MEMBERS, KAMPALA, UGANDA

A second table (Table 2) outlines more complete information on the achievements that were accomplished in the Democratic Republic of Congo (DRC).

The DRC has the highest number of people suffering from sleeping sickness in the world. In 2006 alone, of the 11,382 total cases confirmed worldwide, 8,023 cases were from the DRC (70%). *Source: WHO Afro, Brazzaville.*

Table 2: Activities of Capacity Building Achieved in 2007 in DRC

TRAINING OF ETHICS COMMITTEE MEMBERS IN KINSHASA, DRC



Activities Accomplished	Results	Comments
1. TRAINING OF ETHICS COMMITTEE MEMBERS (MARCH 2007)	<ul style="list-style-type: none"> ▶ 13 PEOPLE PARTICIPATED IN THE WORKSHOP, INCLUDING: <ul style="list-style-type: none"> ● 9 MEMBERS OF THE MINISTRY OF HEALTH ETHICS COMMITTEE (HAT THEMATIC COMMITTEE) ● THE VICE-PRESIDENT OF THE NATIONAL ETHICS COMMITTEE ● 1 MEMBER OF THE INTERDISCIPLINARY CENTER OF THE PUBLIC HEALTH SCHOOL (UNIKIN) ● TWO RESEARCHERS FROM THE PNLTHA 	<ul style="list-style-type: none"> ▶ WORKSHOP LED BY MR. FRANCIS CRAWLEY (GCP-EUROPE ALLIANCE), WITH DR. AUGUSTIN KADIMA EBEJA (HAT PLATFORM), DR. DIDIER KALEMWA (ITS KINSHASA) AND DR. VICTOR KANDE (PNLTHA) AS FACILITATORS. ▶ MEMBERS RAISED THE ISSUE OF LACK OF EQUIPMENT
2. TRAINING OF PERSONNEL INVOLVED IN THE ON-GOING CLINICAL TRIALS (DB 289, NECT; APRIL 2007)	<ul style="list-style-type: none"> ▶ 22 PHYSICIANS TRAINED 19-21 APRIL 07, INCLUDING: <ul style="list-style-type: none"> ● 17 FROM DRC ● 2 FROM CONGO-BRAZZAVILLE ● 3 FROM ANGOLA ▶ 35 PEOPLE TRAINED 23-26 APRIL 07, INCLUDING: <ul style="list-style-type: none"> ● 18 PHYSICIANS (16 FROM DRC AND 2 FROM CONGO-BRAZZAVILLE) ● 17 NURSES FROM HEALTH CENTERS ▶ 4 PNLTHA PHYSICIANS INVOLVED IN THE NECT STUDY CONTRIBUTED TO THE DESIGN OF A NEW PROTOCOL FOR A FOLLOW-UP STUDY TO NECT. 	<ul style="list-style-type: none"> ▶ TOPIC: STANDARDIZATION OF THE CLINICAL TEST FOR PATIENTS SUFFERING FROM HAT: DR. JOHANNES BLUM (ITS BÂLE), DR. JORGE SEIXAS (IHMT LISBONNE), DR. PASCAL TSHIAMALA (CLINIQUE NGALIEMA), DR. LÉON KAZUMBA (CNPP) ▶ INVESTIGATORS MEETING ON DB289 STUDY, PHASE IIIb, INFORMATION ON THE PROTOCOL, BPC, ETC. (DR. CHRISTIAN BURRI, DR. GABRIELE POHLIG, DR. SONIA BERNHARD, DR. JOHANNES BLUM, MR. ERIC HUBER; ITS BASEL) ▶ FACILITATED BY THE PARTICIPATION OF DNDI (DR. ELS TORRELE), PASTEUR INSTITUTE (DR. MURIEL VRAY), SWISS TROPICAL INSTITUTE (DRS. GABRIELE POHLIG, CAECILIA SCHMID), AND EPICENTRE (DR. GERARDO PRIOTTO)
3. TRAINING OF THE CLINICAL TRIALS SUPERVISORY TEAM AT THE SWISS TROPICAL INSTITUTE (STI). (JUNE 2007)	<ul style="list-style-type: none"> ▶ 5 PERSONS WERE TRAINED, INCLUDING 3 FROM PNLTHA (1 PHYSICIAN, 1 NURSE, 1 LABORATORY TECHNICIAN) AND 2 PEOPLE FROM STI-KINSHASA 	<ul style="list-style-type: none"> ▶ ORGANIZED IN BASEL BY STI
4. CAPACITY BUILDING IN QUALITATIVE RESEARCH METHODS (OCTOBER 2007)	<ul style="list-style-type: none"> ▶ 3 PHYSICIANS FROM PNLTHA TOOK PART IN THIS TRAINING, "INTRODUCTION TO THE METHODS OF QUALITATIVE RESEARCH" 	<ul style="list-style-type: none"> ▶ ORGANIZED BY IMTA (PROF. PIERRE LEFEVRE) WITH INRB (DR.PASCAL LUTUMBA)
5. TRAINING OF TECHNICIANS FOR SPECIMEN BANK (OCTOBER 2007)	<ul style="list-style-type: none"> ▶ 34 PEOPLE TRAINED, INCLUDING 4 PHYSICIANS, 16 NURSES, 11 LAB TECHNICIANS, AND 3 SECRETARIES OF THE MOBILE UNIT. 	<ul style="list-style-type: none"> ▶ FACILITATED BY WHO, GENEVA (DR. MARC GASTELLU, DR. JOSÉ RAMON FRANCO) AND PNLTHA (DR. CLAUDE SESE) ▶ SITE KINSHASA, MALUKU ▶ SITE MBUJI MAYI
6. REQUEST AUTHORIZATION TO IMPORT RESEARCH DRUGS (DB289) (OCTOBER 2007)	<ul style="list-style-type: none"> ▶ IMPORT AUTHORIZATION OBTAINED FROM DRC MINISTRY OF HEALTH FOR DB289 (NOVEMBER 2007) 	<ul style="list-style-type: none"> ▶ WE HAVE A FULL FILE ON HOW TO OBTAIN IMPORT AUTHORIZATION OF A NEW RESEARCH DRUG IN DRC.
7. STRENGTHENING THE PLATFORM AROUND ITS COUNTRY FOCAL POINT THROUGH ASSOCIATION OF OTHER INSTITUTIONS	<ul style="list-style-type: none"> ▶ RELATIONSHIP ESTABLISHED WITH THE PARASITOLOGICAL DEPARTMENT OF UNIKIN AND ADHESION OF 4 ASSISTANTS-PHYSICIANS. 	<ul style="list-style-type: none"> ▶ THE PLATFORM REMAINS OPEN TO ANY PERSON OR INSTITUTION INVOLVED IN HAT FIELD RESEARCH.

2. 2007 OPERATIONAL ANALYSIS

Upon the occasion of the Platform's Annual Meeting, it is worthwhile to remind ourselves of our main objectives, to identify our strengths and weaknesses in 2007, and to consolidate our achievements for better performance in the future.



PARTICIPANTS TO THE HAT PLATFORM ANNUAL MEETING, NOVEMBER 2007, KHARTOUM, SUDAN

Strengths

POLITICAL COMMITMENT

- Health and scientific authorities from all member countries were involved, and all signed the Consortium Agreement.

HUMAN RESOURCES

- Physicians, laboratory technicians, nurses, and other relevant human resources are available; some of them have been trained within the Platform framework.

INTERNATIONAL PARTNERS

- At the international level, many partners advocated for neglected diseases research, including sleeping sickness; such efforts have contributed in mobilizing funds.
- The Platform also welcomes the scientific progress achieved by universities and research institutions that are made available for the researchers in clinical trials and for general physicians.

PATIENTS' PRESENCE

- All agreed on the need to develop new diagnostic and treatment tools, an to provide post-therapeutic surveillance for thousands of patients suffering from sleeping sickness in the member countries of the HAT Platform, which is paradoxically a strength for the Platform.

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
- Provide Strengthen clinical trial capacity (human resources, infrastructure, and equipment)
- Share information and strengthen communications between endemic countries

Weaknesses

FOCUS ON THE IMMEDIATE IMPACT OF DISEASE, LACK OF FOCUS ON CLINICAL RESEARCH

- The Platform notes that main Platform actors focus (as they should) in the immediate fight against HAT, but clinical trials receive minor attention, namely when national budgets are allocated.

LACK OF LOCAL INITIATIVES

- The Platform regrets the poor reaction of focal points to messages received, the lack of local initiatives, and the lack of participation of certain countries in key meetings such as the steering committee.

For the consolidation

The HAT Platform proposes reinforcement around focal points in each country along with appropriate reactive mechanisms set at this level.

Along with finalizing their guidelines on authorization procedures of clinical trials, each member country should determine how they will address regulatory hurdles in place for import and export of trial inputs.

Reinforcement mechanisms should also include dissemination and sensitization, so that the Platform will be recognized by and attract young researchers.

The Platform encourages all partners to have meaningful dialogue with their respective governments in order to obtain

the necessary financial resources for their work, or to actively seek other donors for this purpose. All members should respect Platform commitments and should conscientiously respect the deadlines in the achievements of the scheduled activities.

Finally, the Platform proposes to formalize a Platform governance structure, with a simple, transparent, and efficient structure, so as to organize the Platform leadership and to facilitate discussions and strategic decisions.

Backed by the strength of its members' political commitment, available human resources, and international partners, the Platform can move forward and will be able to contribute substantially to the provision of better diagnostics and treatment for patients suffering from HAT.

– DR. AUGUSTIN K. EBEJA, HAT PLATFORM COORDINATOR
– DR. VICTOR KANDE BETU KUMESU, DIRECTOR, PNLTHA DRC

3. “SLEEPING SICKNESS CLINICAL TRIALS METHODOLOGY” WORKSHOP

In September 2004, in order to define a common methodology to establish and to compare efficacy of HAT treatments through clinical trials, the World Health Organisation (WHO) and the Special Programme for Research and Training in Tropical Diseases (TDR) organised an informal consultation among HAT experts, clinicians and the HAT research community. The recommendations of this meeting have now been published, and are available on the TDR website (http://www.who.int/tdr/publications/publications/clinical_hat.htm).

The recommendations propose a common methodology for the diagnosis and staging of patients, with minimal inclusion/exclusion criteria to be used in trials with stage 1 and stage 2 patients, respectively. Furthermore, given the high proportion of patients that will be lost by the end of the traditional 24-month follow-up period, methodological considerations were recommended to describe, calculate, and compare cure rates. Therefore, 18 months can be recommended as the relevant end point to compare cure rates in clinical studies, instead of the previous standard of 24 months.

On 27 November 2007, a one-day workshop was held with the participants of the HAT Platform Annual Meeting (28-29 November), to introduce and to discuss the aforementioned recommendations, as well as to identify other methodological difficulties or challenges that could be addressed in the future. Workshop presenters and facilitators were Dr. Els Torreele (DNDi), Dr. Cecilia Schmid (STI), Dr. Gabriele Pohlig (STI), and Dr. Veerle Lejon (ITMA).

– DR. ELS TORREELE, DNDi (DRUGS FOR NEGLECTED DISEASES INITIATIVE)

4. ORGANIZATION FOR CONTROL OF WIDESPREAD ENDEMIC DISEASE IN CENTRAL AFRICA OCEAC JOINS THE HAT PLATFORM

In response to the goal of State Members of the Economic and Monetary Community of Central Africa (CEMAC) and the Economic Community of Central African States (CEAC) to eradicate HAT in 2015 in the sub-Central African region, the Organization for Control of Widespread Endemic Disease in Central Africa (OCEAC), based in Yaoundé, Cameroon, established the Sub-regional Program on the Fight Against HAT” (PSR-HAT) in June 2007. The program’s geographic scope of action covers 8 countries: Angola, Cameroon, Congo, Gabon, Equatorial Guinea, Central African Republic, Democratic Republic of Congo, and Chad.

Among other activities, the PSR-HAT plans to prepare field research in the sub-region, establish new diagnostics trials, develop new therapeutic protocols, hold and support clinical trials, etc. Likewise, it was natural that, during the 29th CSIRLT in Luanda, PSR-HAT has approached the HAT Platform to study ways in improving program synergies.

– DR. FRANCIS LOUIS, COORDINATOR PSR-HAT

The HAT Platform would like to give a warm welcome to the team from OCEAC Yaoundé: Dr. Nicolas DOLOGUELE, Dr. Francis LOUIS, and Ms. Lisette KOHANGE.

6. RECENT HAT PUBLICATIONS

We remind members of some key dates for upcoming Platform activities:

March 2008: Training of Program Monitors in Kampala (Uganda)

March 2008: Training of Ethics Committee Members in Juba (South Sudan)

April 2008: Training of the Ethics Committee Members in Brazzaville (Congo)

May 2008: Training of Ethics Committee Members in Luanda (Angola)

June 2008: Meeting of the Steering Committee in Juba (South Sudan)

End of October - Early November 2008: Annual Platform Meeting in Brazzaville (Congo)

- 1** Blum J. A., Burri C., Hatz C., Kazumba L., Mangoni P., Zellweger M.J.; Sleeping Hearts: The Role of the Heart in Sleeping Sickness (Human African Trypanosomiasis); *Tropical Medical International Health* 2007; 12 (12); 1422-1432.
- 2** Blum J. A., Schmid C., Hatz C., Kazumba L., Mangoni P., Rutishauser J., La Torre A., Burri C.; Sleeping Glands: The Role of Endocrine Disorders in HAT; *Acta Trop* 2007; 104 (1); 16-24.
- 3** Priotto, G., Kasparian, S., Ngouama, D., Ghorashian, S., Arnold, U., Ghabri, S., Karunakara, U.; Nifurtimox-eflornithine combination therapy for second-stage *Trypanosoma brucei gambiense* sleeping sickness: a randomized clinical trial in Congo. *Clinical Infectious Disease* 2007. 45(11), 1435-1442.
- 4** Chappuis F.; Melarsoprol Free Drug Combinations for Second Stage HAT: The Way to Go; *Clinical Infectious Disease* 2007; 45 (11); 1443-1445.
- 5** Lutumba P., Makieya E., Shaw A., Meheus F., and Baelaert M.; HAT in a Rural Community, DRC; *Emerging Infectious Diseases* 2007; 13 (2); 248-254.
- 6** Checchi, F., Piola, P., Ayikoru, H., Thomas, F., Legros, D., and al.; Nifurtimox plus Eflornithine for Late-Stage Sleeping Sickness in Uganda: A Case Series. *PLoS Neglected Tropical Disease* 2007; 1 (2); e64.
- 7** Lejon 2007, Treatment failure related to intrathecal IgM, CSF IgM and IL-10 in first stage HAT; *CVI*, 2007 June;14(6);732-737.
- 8** 2007 WHO TDR Recommendations of the informal consultation on issues for clinical product development for HAT (http://www.who.int/tdr/publications/publications/clinical_hat.htm).
- 9** Woodrow C. J., Abel P. M., Krishna S.; Randomized, Controlled Trial of Treatments for Second-Stage Sleeping Sickness. *Infectious Disease* 2007; 196 (4); 650-651.

5 FOLLOWING STEPS

A print version of this Newsletter is available at the HAT Platform Coordination office.

COORDINATOR OFFICE ADDRESS

HAT PLATFORM COORDINATION OFFICE
11 AVENUE MPEPI
BUREAU DE LA REPRÉSENTATION
DE L'INSTITUT TROPICAL SUISSE
QUARTIER SOCIMAT
LA GOMBE, KINSHASA,
DEMOCRATIC REPUBLIC OF THE CONGO
EMAIL: AEBEJA@DNDI.ORG
TEL: +243 81 081 22 38

EDITOR:

DR. AUGUSTIN KADIMA EBEJA

CONTRIBUTORS:

DR. INTISAR ELRAYAH, DR. CAECILIA SCHMID, DR. GABRIELE POHLIG, DR. ELS TORREELE, DR. VICTOR KANDE BETU KUMESU, AND DR. GÉDÉON VATUNGA

COPY EDITORS:

SADIA KAENZIG, NOËLLE CHEHAB

DESIGN + LAYOUT:

JULIE GARVEY