

HAT Platform

Strengthening regional capacity for clinical trials in sleeping sickness in Sub-Saharan Africa

Dr Freddie Kansiime
Deputy Director
Coordination Office for Control of
Trypanosomiasis in Uganda (COCTU)

HAT Platform Focal Person, Uganda

ASTMH, New Orleans, USA, 7-11 December 2008



Background – neglected diseases

- Only 1% of new drugs developed are for neglected diseases
- World pharmaceutical market currently worth > US\$ 518 billion per annum
- Approx. 1-2% is spent on R&D for neglected diseases
- 10/90 disequilibrium in health research spending
- 1975-1999: 1,393 new chemical entities marketed
- 68.7% registered products presented little or no therapeutic gain



Background - HAT

- HAT is a neglected disease
 - 60 million people at risk in sub-saharan Africa
 - Caused by trypanosomes transmitted by tsetse flies
 - affects the poorest of the poor, is rural
- Disease re-emerging with poor control during mid-century
- Of no strategic (military, security) interest
- Limited research & development (R&D), with almost no new drug innovation

Patients have:

- Minimal to no purchasing power at all
- No advocacy group to lobby for them



HAT treatment options



- Treatment options largely inadequate
 - Toxic, old
 - Difficult to administer
- Point-of-care diagnostics needed



Clinical research capacity

- **Research infrastructure in HAT-endemic regions has either:**
 - Not been sustained
 - Never existed



Challenges



- **Access to patients**
- **Political instability**
- **Health system barriers**



Where did the HAT Platform begin?

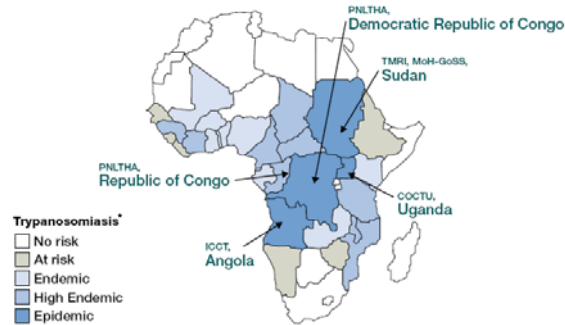
- Realizing the challenges mentioned above, DNDi & STI mobilise a network that brings together
 - Experts, clinicians, researchers from HAT-endemic countries
 - Along with international clinical trial and HAT specialists
- Inaugural meeting: August 2005; Kinshasa, DRC
- Aims to strengthen clinical trial and research capacity in HAT endemic countries



HAT Platform founded in Kinshasa, 2005



Who is the HAT Platform?



- National HAT control programs of most affected endemic countries
- DNDi, STI
- ITMA, INRB, CDC, KARI-TRC, Epicentre
- NGOs like MSF
- FIND
- WHO
- regional networks - eg. EANETT, PABIN, AMANET



*Figure based on epidemiological data adapted from Simarro et al. PLoS 2008.

Objectives

Main aim:

- To strengthen clinical trial capacity for sleeping sickness

Specific objectives:

- To improve human capabilities and physical infrastructure
- To overcome health system challenges for clinical research
- To share information on HAT research progress
- To improve HAT clinical trial methodologies



Building the network

South Sudan



Uganda



Angola



D.R. Congo



What has been done and achievements so far

- **Training:**
 - Good Clinical Practice (GCP) All countries
 - Ethics committees members training - All countries
 - Clinical trial monitors - (Kampala 25 participants)
 - MD training on standardisation of patient examination (DRC, Angola)
 - Clinical trial methodology workshops (efficacy assessment, protocol elements)



Participants and facilitators to ethics training – Kampala, Uganda



Achievements

- **Sharing information & advocacy:**
 - **Regular meetings:**
 - Launch conference in August 2005, Kinshasa
 - Annual platform meetings (Nairobi, 2006; Khartoum, 2007; Brazzaville, 2008)
 - Biannual steering committees



- **4 platform newsletters published**
- **Logo created for platform identity**
- **Presentations at various scientific congresses**

Sharing information during the Khartoum meeting



Sharing information & advocacy via HAT Platform newsletter

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 only a few years ago, 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 Kaduna Elaja

HAT Platform NEWSLETTER

ISSUE No. 2
August 2007

1. HIGHLIGHT ON SUDAN

Human African Trypanosomiasis (HAT) appeared for the first time in South Sudan in 1966. The country has since experienced several epidemics, largely limited to the southern district of the Equatorial region. Recurrent 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 NGLC 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 (i.e. Raja Leji, Nimule, Venkoo) of human African trypanosomiasis.

Active and passive surveillance systems were used to monitor HAT in the country, but certain areas were not covered. Between 2000 and 2004, 8,560 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, respecting the incidence of human African trypanosomiasis, as well as developing new treatment protocols.

CONTENTS

- 1 HIGHLIGHT ON SUDAN
- 2 PEOPLE COME AND GO BUT INSTITUTIONS REMAIN
- 3 TURNING WORDS INTO ACTIONS
- 4 CURRENT NEWS ON ON-GOING CLINICAL TRIALS
- 5 MISCELLANEOUS
- 6 RECENT PUBLICATIONS

HAT Platform

Newsletter | October 2008
Issue No. 4

EDITORIAL

Thanks to the support of our partners, the regional platform for clinical trial capacity strengthening in the field of human African trypanosomiasis (HAT), most commonly known as sleeping sickness, is forging ahead.

In this fourth issue of the HAT Platform newsletter, we are pleased to share with you our experiences and to present to you the latest scientific progress made by some of our partners, particularly in the development of new diagnostics and therapeutic tools against sleeping sickness.

Since we are still in the research phase, we are aware that we still have a long way to go. But we will continue to address the most urgent needs of our region and contribute to provide adequate treatments to the most vulnerable who suffer from this disease.

In conclusion, we are looking forward to welcoming you at our next annual meeting in November during which we will update each other on the activities of the platform. At this occasion, we will be able to share our experiences and concerns with our partners, who have always given us their valuable support in the relevant training for conducting clinical trials. Through dynamic sharing of experiences, knowledge, and problem-solving techniques, we will be able to move ahead collectively!

CONTENT

	P.2	TRAINING WORKSHOP FOR MEMBERS OF THE ETHIOPIAN COMMITTEE IN ANGOLA: A TRYPANOSOMIASIS COLLABORATION
	P.2	THE TRAINING OF CLINICAL MEDICIN IN KARTOUM: AN ESSENTIAL MEDICIN
	P.3	THE STEERING COMMITTEE MEETING IN KARTOUM
	P.3	THE MISCELLANEOUS OF THE AFRICAN UNION AGAINST HAT
	P.4	DEBILISING RELAPSE RATES IN CHAD
	P.4	A NEW ALLIANCE FOR CLINICAL RESEARCH AND EPIDEMIOLOGY IN DRC
	P.5	A MICROSCOPE FOR THE 21 ST CENTURY
	P.5	AN UPDATE ON THE PROGRESS MADE IN TRYPANOSOMIASIS RESEARCH AGAINST HAT
	P.6	HAT RELATED EVENTS
	P.6	RECENT HAT PUBLICATIONS

Institutional capacity strengthening

- Study staff now better equipped to manage ss cases through training in GCP, Ethics
- More dedicated to their work
- Have capacity to conduct clinical trials
- Having multiplier effect- general improvement in patient care noted in health units among all health workers
- Anxiously looking forward to taking on more challenging tasks



Examples Rehabilitation Katanda (NECT)



Before (2005)



After (2006)



Rehabilitation of Omugo Health unit- Uganda



Lessons learned

- Platform has provide a forum to bridge
 - HAT research and disease control activities
 - Regional barriers (differences in laws, guidelines, methods, languages, concepts etc.)
- A needs-driven approach, adapted per region:
 - Training of trial staff (needs, level, methods)
 - Ethics concepts (GCP, informed consent etc)
 - Standard operating procedures (SOPs)
- Opportunities
 - Facilitated multi-country, multi-centre studies
 - Regional pool of clinical trial expertise has been created



Conclusions

- **HAT Platform has brought about a new approach:**
- To create synergies between current efforts to train and maintain
 - Clinical trial investigators and other staff, monitors
 - Ensured functional ethics committees are in place
- Support clinical trials in HAT
 - Current and *future*
- Ensure the development and utilisation of new tools
- Exchange experiences and new results between regional partners – breaking the barriers hitherto hindering very close collaborations



Acknowledgements

Members of the HAT-Platform: National control programmes of Democratic Republic of Congo, Angola, Sudan, Uganda, Republic of Congo

Facilitation, funding, and support:

- Drugs for Neglected Diseases *initiative*: Els Torreale
- Swiss Tropical Institute: Cecile Schmid

Financial support

- DNDi has allocated core and project-specific funding from the following:
 - European Union FP6
 - Ministry of Foreign Affairs (MAE), France
 - Department for International Development (DFID), UK
 - Médecins Sans Frontières (MSF)



- WHO/TDR



**Your attention has been
valued**

- **MERÇI**
- **OBRIGADO**
- **THANK YOU**
- **ASANTI SANA**

