



HAT

REGIONAL PLATFORM FOR CLINICAL RESEARCH

Platform

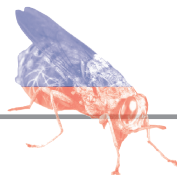
NEWSLETTER N°15,

September 2014



Fexinidazole Investigators meeting

From 03 to 05 April 2014, Kinshasa, DRC



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Editorial



*Dr Augustin Kadima Ebeja ;
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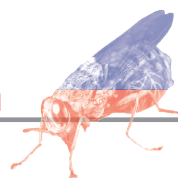
Dear Readers,
With this fifteenth issue, we bring you once again up to date on our achievements and on the latest news on this neglected topic of sleeping sickness.

From the epidemiological situation of sleeping sickness in 2013, to the latest events, scientific meetings and recent publications on HAT, you will find all your usual features in the Newsletter, with the exception of the latest news on ongoing research. Within

two weeks from the publication of this Newsletter, the joint EANETT/HAT Platform meeting will address several aspects of this question under the theme of 'The contribution of R&D to the elimination of sleeping sickness'.

We promise to produce a special issue before the end of the year to recap on this event.

Enjoy this issue and please do not forget to circulate it widely.



HAT Epidemiological Situation in the Platform Countries at the end of 2013

prepared by Dr Olaf Valverde Mordt
based on information provided by the National HAT
Control Programmes and Institutes

We present here the epidemiological trends in the HAT Platform countries between 2011 and 2013, based on data reported by the national control programmes, as was done for the two previous years (see Newsletters 11 and 13).

Results may vary slightly, but final figures will be officially validated by WHO.

The number of cases per country and annual variations are given in the table below. Decreases are represented by a negative figure and increases by a positive figure.

Table 1. Number of cases in the HAT Platform countries

HAT Platform member countries	Number of cases			Variation in %	
	2011	2012	2013	2011-12	2012-13
DRC	5595	5983	5647	6,7	-5,6
CAR	122	371	49	204	-87
South Sudan	297	327	116	10	-64,5
Chad	247	197	193	-20,2	-2
Uganda	123	99	52	-19,5	-47
Angola	154	69	69	-55,2	0
Republic of Congo	61	40	20	-34,3	-50
Total HAT Platform	6599	7086	6146	7,2	-13

In 2013, only three countries reported over 100 cases. This trend for 2013 is encouraging, as no country has reported an increase in the number of cases. Differences remain linked to variations in activity, which we will comment individually per country below. However, before any conclusion can be drawn, a clear reduction in the number of cases must be maintained over time. In all countries, the number of cases was lower in 2013 than in 2012, in spite of the intensification of active screening activities in some of them (DRC, Chad, Angola, and South Sudan). In the first three, the small drop in absolute figures belies a greater reduction in the detection rate.¹ More investments are needed to boost case detection and consolidate diagnosis and treatment skills in the fixed facilities in endemic areas.

Democratic Republic of the Congo

The DRC alone reports 92% of all cases in the HAT Platform countries.

A small reduction in the number of cases was observed in the DRC, but figures vary depending on the sources. Cases occurring in the provinces under the direct responsibility of PNLTHA dropped from 4,927 in 2012 to 3,867 in 2013 (-22%), in spite of the increase in the number of people screened, which rose from 1,670,638 in 2012 to 2,115,749 in 2013 (+27%). In the northern area of the Province Orientale where MSF is active, an additional team was created in 2013, bringing to three the number of intervention sites in Bas-Uélé (versus two beforehand). The

number of persons screened rose from 58,579 in 2012 to 97,878 in 2013 (+67%), and the number of cases also rose from 1,056 to 1,780 (+68%). Towards the end of 2013, the number of cases dropped sharply in these districts following several tours by the mobile teams, and MSF decided to leave towards the end of 2014. The overall detection rate was 0.27% (0.19% for PNLTHA and 1.85% for MSF).

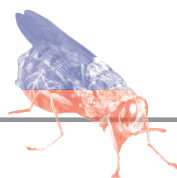
Central African Republic

The civil conflict in the Central African Republic has had a direct impact on PNLTHA operations. Facilities were ransacked, money was stolen, and vehicles were destroyed.

The only report that reached us was from Batangafo. As this focus supported by MSF is located in the centre of the conflict zone, active screening is currently impossible in the villages, and concentrates for the moment on displaced populations and on the town of Batangafo.

The strong reduction in the number of cases detected since the end of 2012 and during 2013 is due to the conflict, which causes massive displacements of the rural population in endemic areas, often to surrounding shrub savannah areas infested with tsetse flies. We may see higher numbers of cases in the future, but the increase will become apparent only once screening services have resumed. In the Batangafo focus alone, 49 cases have been detected out of 5524 persons screened, i.e. a detection rate of 0.9%. The situation in 2014 remains unstable, and the Batangafo focus is still right in the middle of the conflict zone.

¹ Detection rate: number of cases detected divided by the total population screened actively and passively.



South Sudan

The number of new cases dropped sharply compared to 2012, in spite of increased active screening activities over the first 4 months of 2013, with the direct support of MSF's international mobile team. In January, 2,766 persons were actively screened with the help of Malteser in Yei, in February 4,239 with the help of the diocese of Mundri, and in March 5,493 and April 6,077 with the help of the government in Tambura, which brings the total number of persons screened actively to 18,575. Furthermore, 3,471 persons were screened passively.

The detection rate was thus 0.5% (116/22,046). Most of the cases were diagnosed at stage 2 (75/116, i.e. 64%). The most active foci remain in Mundri (Lui), Yei, and Tambura. On 15 December 2013, a civil conflict erupted in the country, but for the moment it has no direct impact on the disease's endemic foci.

Chad

Most of the screening activities and detected cases are concentrated around the Mandoul focus. A total of 191 cases were diagnosed in this focus, 127 through active screening and 64 through passive screening. With one exception, all cases were diagnosed by the Centre de Santé Catholique in Bodo.

In the other foci, passive screening detected one case in Moissala, but no cases were detected during the active screening campaign conducted in 4,287 persons. In the former Danamadji focus (last case recorded in 1978), one case was detected at the Hospital of Doba. In 2013, the number of persons screened actively was up by 71% over 2012 (36,942 vs 21,616), which suggests that the drop in the number of cases may be greater than shown in the main table. The overall detection rate is 0.52%.

Uganda

All cases were detected passively. The reduction in the number of *T.b. gambiense* cases was confirmed in 2013 (9 cases vs 23 in 2012). The number of patients infected with *T.b. rhodesiense* also dropped in 2013 (43 vs 76 in 2012).

Lwala remains the site with the highest prevalence with 40 cases detected. All patients infected with *T.b. gambiense* were at the stage 2 of the disease, versus 30/42 for the patients infected with *T.b. rhodesiense*.

Angola

Reported active screening activities increased nine-fold over 2012 (122,021 vs 13,940), and yet only eight cases were detected with this method. However, the number of cases was unchanged compared to the previous year, which should indicate that prevalence is dropping. The number of cases reported in the Northwest provinces remains unchanged: Luanda (20), Kwanza Norte (16), Bengo (15), Zaire (10), and Uige (8).

A total of 160,515 persons were screened, which brings the detection rate to 0.04% (69/160,515). On the other hand, the proportion of HAT stage 2 cases was high at 94% (65/69).

Republic of the Congo

In 2013, 20 cases were diagnosed, i.e. half the number reported in 2012. The national programme was unable to carry out all the scheduled screening activities for lack of funding. Only five cases were detected through active screening (25% of the total) out of a total of 6,730 persons screened, bringing the detection rate to 0.07%, similar to the 2012 rate. All cases originated from the Ngabé focus. Brazzaville (7), Nkayi/Loudima (6) and Mossaka (2) reported 15 cases through passive screening, with 13 patients at stage 2 of the disease (65%).

Guinea

Although this country is not yet a member of the HAT Platform, we included it in this article due to its dynamism in HAT control activities and growing number of cases detected.

Three foci are still active in the region of Lower Guinea along the Atlantic coast. This area contains many islands with a mangrove ecosystem, to which tsetse flies are well adapted. In 2012, most treatments were concentrated in the centre of Dubreka, but since then, two other centres (Boffa and Forécariah) have been trained and equipped to treat the disease directly (see table below).

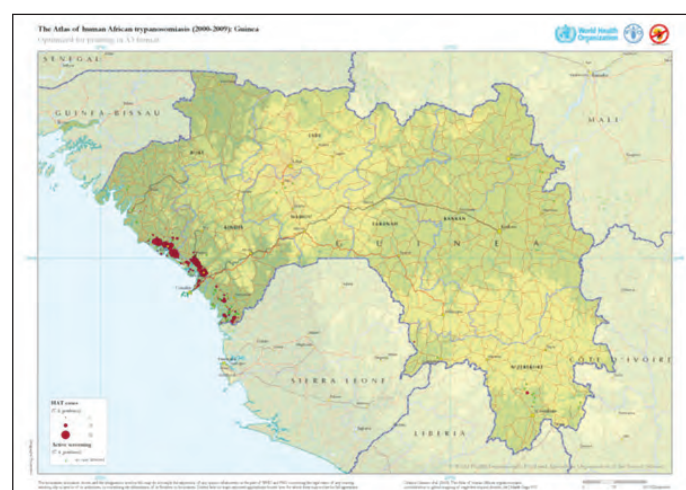
Major efforts were exerted to eliminate the flies from the Loos Islands lying off Conakry, and extended since then to the coastal islands and to the mangrove region.

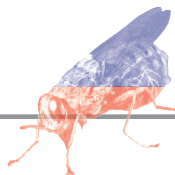
Table 2. Number of cases treated since 2012

Treatment centres	2012	2013
Dubreka	43	56
Boffa	27	21
Forécariah	-	10
Total	70	87

*over 80% of cases were stage 2 patients

The WHO map below shows the distribution of cases between 2000 and 2009, particularly along the coast. A small focus is found in the forest region, near Ivory Coast, but no cases have been reported there recently.





Latest scientific events and miscellaneous information

Meeting of fexinidazole site investigators

The second investigator meeting, held on 3-5 April 2014, helped not only analyse the pivotal Phase II/III DNDiFEX004 study performed in adults with advanced stage 2 gambiense HAT, but also define the basis of two new complementary studies, DNDiFEX005 (adults at stage 1 or early stage 2) and DNDiFEX006 (children at any stage).

The meeting started with a minute of silence in memory of our two colleagues who passed away, the honourable Miaka Mia Bilenge and Muwanga Tebe Alléluia, investigating physician. This was followed by a description from each of the partners involved in DNDiFEX004 of their activities and role in the project: DNDi (Drugs for Neglected Diseases initiative), Swiss TPH (Swiss Tropical and Public Health Institute), the National HAT Control Programme (PNLTHA), CBCO (Communauté Baptiste du Congo), and of course the HAT Platform to which we all belong.

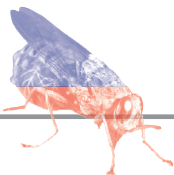
Approximately 30 participants presented the sites of the DNDiFEX004 study in Bandundu, Vanga, Masi Manimba, Dipumba, Dingila, Mushie, Katanda and Isangi (DRC). Only the representative of Batangafo was absent due to the current situation in the Central African Republic.

The presentations highlighted the diversity of the project environments. Discussions were held on the problems and difficulties encountered by the site investigators with a view to finding solutions. Logistical problems and a lower than expected patient inclusion rate were discussed to adjust the provision of recruitment.

The ongoing interim analysis of the data generated by 195 patients followed for up to 12 months will be included in the submission for regulatory approval.

Regarding inclusions, the decision was taken to step up systematic CATT screening in the study sites and reschedule mobile team activities in highly endemic areas, in collaboration with central office. As recruitment will now include patients at any stage of the disease, and to ensure that data are comparable, a request was





made that mobile teams do not perform lumbar punctures in the field, and that the procedure be performed instead at the study site, especially in health areas where patients can be referred to the sites for inclusion in the three studies.

Follow-up visits must be scheduled as of the end of treatment, and efforts must be made to respect the scheduled dates. A visit report must be produced within 5 days of the visit.

Available data on fexinidazole safety and efficacy are encouraging and justify pursuing the DNDiFEX004 study, as well as, along with other arguments, setting up two new complementary studies (DNDiFEX005 and DNDiFEX006). Everyone was asked to ensure that all adverse effects are documented correctly, and that other team members, particularly nurses, contribute by recording the beginning and end dates of the events. A request was also made to discharge patients only once their condition is deemed stable with no sign of danger.

The protocols of the three studies were described, with a special focus on the differences between DNDiFEX004 and the two new studies. The latter being non-randomized, all included patients will receive fexinidazole. A paper version of the patients' case report form will be used, but at each inclusion, some of the patient's information will be sent by email to the data manager. The participants were shown how to complete the case report form. The objective is to include, every month, a total for all sites of approximately 14 patients in the DNDiFEX004 study, 10 patients in DNDiFEX005 and 8 patients in DNDiFEX006.

The Swiss TPH team described the lessons learned during the monitoring visits and the areas that need to be improved. A special mention was made of the white cell count in the CSF and its documentation at the time of diagnosis, at the end of treatment visit and at the follow-up visits. Results are read by two laboratory technicians on site, and recorded in the laboratory register at the time of diagnosis, and in the study's specific form for the end of treatment and follow-up visits.

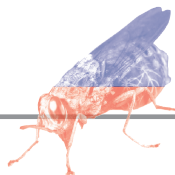
The procedure to obtain the parents' informed consent and the child's assent was discussed. It is preferable that one of the parents is present when obtaining the child's assent.

DNDi's Country Operations Manager in the DRC explained the principles of the management of equipment for the project, and he presented the new tools designed to optimize the financial management. The Swiss TPH team also presented the drug supply chain from the suppliers in Europe, to the central store in Kinshasa, and up to transferral to the sites. Transfer and management tools were also presented.

A presentation on Good Clinical Practice was given, focusing on the responsibilities of the investigators, personnel, nurses, and laboratory technicians, and on drug management. Adverse effects, their characteristics and notification procedure for the three studies were explained. Given the success of the lecture on neurological examination, the participants requested a presentation on the neurological examination in children. Finally, the new members of the fexinidazole family were presented.

There was a friendly and pleasant atmosphere throughout the meeting.





Training of personnel involved in HAT control in Chad

(Peka /Augustin K.E)

As part of its strengthening capacity policy, the HAT Platform regional coordination organized in Bodo parish on 19-22 May 2014, in collaboration with Chad focal points, a training workshop for healthcare personnel on the integration of gambiense trypanosomiasis control and monitoring in healthcare services.

The specific objectives of this workshop were to help the participants:

- Understand the epidemiology of HAT
- Understand the national guidelines on HAT control
- Apply these guidelines to HAT control
-

The training was designed for:

- Physicians at the Moundou, Doba, Bodo, and Moissala hospitals
- Laboratory technicians and nurses at the Moundou, Doba, Bodo, Moissala, and Danamadji hospitals and at the Bodo Centre de Santé Catholique

The training included:

- Lectures followed by discussions
- Group practical sessions (physicians, laboratory technicians and nurses), with demonstrations, diagnostic tests and care/treatment at Bodo Hospital, followed by a restitution in a plenary session
- Films and documentaries on HAT
- An active screening visit in the field with the mobile team

The Prefect of the Department of East Kouh chaired the opening ceremony. In his opening speech, he described the burden of trypanosomiasis on the population in terms of mortality and morbidity, and its impact on the decline of agricultural and animal productivity. He insisted on the importance of an effective HAT control strategy based on the training of personnel, to integrate the activities into the healthcare system. The mayor of the town and the chief medical officer of the Bodo health district were also present at this workshop.

Following the adoption of the training agenda, the activities started with a presentation of the various modules followed by discussions. Theoretical sessions were given over two days. A presentation was given on the HAT Platform. All lectures were followed by questions, debates, and contributions.

The third and fourth days were devoted to group sessions with demonstrations and practical work for nurses, laboratory technicians, and physicians.

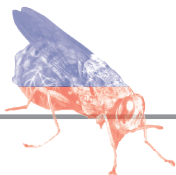
This helped the participants become familiar with trypanocidal drugs, as well as their preparation and administration.

A demonstration of the serological and parasitological diagnostic tests was given at Bodo Hospital for laboratory technicians and physicians. During a field visit with the mobile team present in the villages, the physicians were able to review all the stages of active screening. Two documentaries on the work of Eugène Jamot on trypanosomiasis in the last century and on the activities of PATTEC in Africa were also shown.

Finally, during a restitution of the group workshops in a plenary session, the participants were given the opportunity to make comments and perform a post-test evaluation before the closing ceremony chaired by the Prefect of the Department of Kouh East.

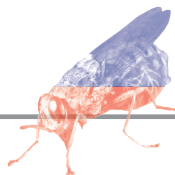


Opening ceremony



In pictures, Training of personnel involved in HAT control in Chad





Sixth International Course for African Trypanosomiasis (ICAT 6)



In 1999, three friends involved in trypanosomiasis control created the Association against Trypanosomiasis in Africa (ATA) to address the issues of the re-emergence of endemic trypanosomiasis in Africa and the gradual loss of knowledge on the disease. In 2000, the first International Course for African Trypanosomiasis (ICAT) was organized during the Pharo meeting in Marseille, France. The objective was to provide the best possible theoretical and practical training to 20 African leaders in HAT control, given by the best international specialists. It was such a success that a second course was organized (ICAT 2) in 2001 in Lyon. Then there was ICAT 3 in Lisbon in 2003, ICAT 4 in Tunis in 2005, ICAT 5 in Nairobi in 2005, and now ICAT 6 in Kinshasa.

ICAT 6 was held at INRB (*Institut National de Recherche Biomédicale*) in Kinshasa on 9-27 June 2014.

A total of 23 participants from seven African countries (Cameroon, Congo, Guinea, Nigeria, CAR, DRC, and Chad) and 24 teachers (11 international and 13 national) attended the course.

This course would not have been possible without the

support of INRB who provided the premises and equipment free of charge, and the financial support of WHO, DNDi, the HAT Platform, and IRD.

IRD was also a joint organizer of the course. The participants' average score rose from 11.5/20 during the initial evaluation to 16.5/20 during the final evaluation, a proof of their high level of commitment.

The training included 74 hours of theory, 16 hours of practical work, one day for tsetse trapping in the field (which produced 3 flies carrying trypanosomes in their digestive tract), and 26 hours of group work with role-playing. The participants worked non-stop from Monday to Saturday, with only one day of rest on Sunday.

The group called itself the 'Promotion Constantin Miaka Mia Bilenge' as a tribute to the great physician and first Congolese to lead the National HAT Control Programme. He was also the facilitator of ICAT 1 in Marseille in 2000. Constantin passed away suddenly a few weeks ago, as we were preparing ICAT 6, which he was due to attend. His family and friends were present in large numbers at the closing ceremony, which was very moving, filled with emotion and sadness. Goodbye Constantin, we know that you are watching over us from wherever you are. We shall never forget you.





Open day, Swiss Tropical and Public Health Institute (Swiss TPH) celebration 70th anniversary

Swiss Tropical and Public Health Institute (Swiss TPH) celebrates its 70th anniversary

Based on a press release

Seventy years ago on 4 May 1944, the Swiss Tropical Institute (now Swiss Tropical and Public Health Institute – Swiss TPH) was founded in Basel, Switzerland, as a public organization. Its mandate was to achieve significant improvement of human health and well-being through a better understanding of diseases and health systems, and to initiate actions based on this knowledge.

Over the years, Swiss TPH evolved from a small institute specialized in tropical diseases to a world-renowned research institution. Swiss TPH currently employs over 700 people in more than 20 countries. In Basel alone, around 450 employees and close to 120 students work at the institute.

Contribution to the improvement of global health

The institute dedicates its research, teaching and health services to society at large, particularly in Africa, Central Asia, the Pacific region, South America and Europe. Its activities cover the entire innovation chain from basic research, to development and clinical testing and application of new medicines for affected populations.

In addition to global diseases like malaria and tuberculosis, which affect the poor, research focuses on so-called neglected tropical diseases, the parasites that cause them, and their respective

treatment strategies. These diseases include for instance sleeping sickness, schistosomiasis, and leishmaniasis.

In addition to research and development of new medicines targeting the diseases of the poor, Swiss TPH engages in strengthening health systems and capacities of health professionals. Swiss TPH is a successful partner in many implementation and development cooperation projects in Africa, Eastern Europe, and Central Asia. Swiss TPH also addresses the challenges of global change.

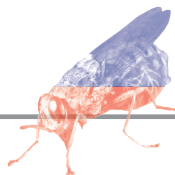
In addition to the traditional communicable diseases, the institute also focuses on non-communicable diseases, such as high blood pressure, the effects of air pollution, or diabetes, and their consequences for the populations in Switzerland, Europe, and overseas. In Basel, as well as in partner institutions in Africa and Asia, Swiss TPH offers different courses given by experts in the field to train health professionals.

From research to development cooperation

In the 1950s, the institute opened two field laboratories in Africa: the Centre Suisse de Recherches Scientifiques (CSRS) in Ivory Coast, and the Swiss Tropical Field Laboratory (STIFL) in Ifakara, Tanzania, from which the now independent Ifakara Health Institute (IHI) originated. Both CSRS and IHI have grown into renowned research institutes.

Following the independence of African countries, the institute shifted its activities from research to active development cooperation.

On 14 June 2014, Swiss TPH celebrated its anniversary with a public event.



Quality Assurance in HAT clinical trials: Swiss TPH concepts on clinical trial monitoring in low-resource settings

A. Signorell

Clinical trials are usually designed to collect data on the safety and efficacy of new therapies, vaccines, or diagnostic tools. In order for these data to be valid and credible, it is necessary to set up quality management measures from the design of the clinical trial, throughout the conduct of any trial activities, and up to data analysis and reporting. In clinical research, the measurement of quality focuses on two main objectives: subject protection and data integrity.

Clinical trials involve either healthy volunteers or patients affected by the disease being studied. Protecting the rights, safety, and welfare of study subjects is therefore of utmost importance. On the other hand, data quality and integrity need to be guaranteed by ensuring that results are accurate and have been accurately reported, interpreted, and verified.

It is the trial sponsor's obligation to continuously monitor the progress of the trial and to ensure that the clinical investigators follow the study protocol, comply with local rules and regulations and adhere to Good Clinical Practice (GCP), the universal quality

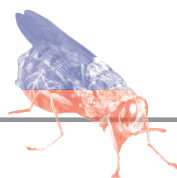
standard for conducting clinical trials. This monitoring process involves regular on-site visits by study monitors throughout the trial.

The decision as to where to conduct a clinical trial on medicines or diagnostic tools in human African trypanosomiasis (HAT) is often dictated by the occurrence of the disease, and potential trial sites may be confined to very remote and resource-limited areas, mostly in the Democratic Republic of the Congo.

The health infrastructure, education, medical expertise, clinical practice, as well as the regulatory processes and ethical issues encountered in these settings are often very different from those found in high-income countries. However, in spite of these disparities between low and high resource countries, the same quality standards must be applied in clinical trials, irrespective of where these trials are conducted in the world.

The conduct and monitoring of clinical trials on poverty-related diseases in the relevant geographic areas are among the core competencies of the Pharmaceutical Medicine Unit at the Swiss Tropical and Public Health Institute (Swiss TPH).

The unit has adapted its monitoring strategy to meet the different challenges encountered in resource-limited regions. To best support clinical research sites to adhere to these quality principles



throughout the study, Swiss TPH applies a comprehensive approach including the training of study staff (investigators training, GCP courses, study initiation visits), regular on-site monitoring, and continuous contact while off-site.

To achieve these goals, the unit has established a wide network of regional monitors based in eight sub-Saharan countries that support the Basel team in the monitoring activities of clinical research sites in Africa. This network of regional monitors is coordinated by the Basel and Kinshasa Swiss TPH offices. To continuously expand this network and to provide monitors with a solid training and the necessary qualifications, Swiss TPH engages in capacity building by regularly holding monitor training courses in Basel, Switzerland. Furthermore, the regional monitors participate in continuing education activities.

The Swiss TPH approach of employing local staff to monitor the clinical research sites has proven very successful. One of the immediate benefits of employing local monitors is the access to the local knowledge and expertise of regional monitors. Reduced travel expenditure for monitoring visits is another benefit of this strategy, which is a very important point considering the cost pressure in this area of research. Continuous and active exchanges between local and Basel-based monitors provide many opportunities for mutual learning.

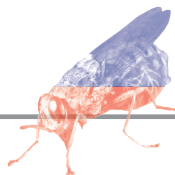
Let's talk finance without taboo

We often talk about Good Clinical practice (GCP) and Good Laboratory Practice (GLP), but we have never before raised the question of good financial practices in the HAT Platform Newsletter. And yet, good practice is necessary in every field, and must be adhered to by everyone. Extracts of a long presentation prepared by Chirac Bulanga, the Country Operations Manager of DNDi DRC, are given below.

Why bring international financial standards to clinical trials?

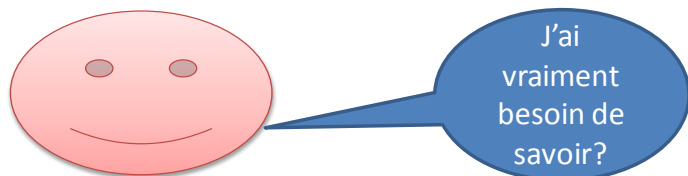
These minimum standards deal mainly with the financial and material aspects of clinical trials conducted by DNDi and its partners (PNLTHA, INRB, MSF, CBCO Vanga) in the DRC. They are defined in the Operations Manual, and their objective is to ensure a good traceability of transactions.

It is important to know which measures are mandatory for the disbursement and management of funds, the management of equipment for studies conducted on site, as well as the policies and procedures applicable to the management of funds and equipment. Indeed, we are all accountable both to the local authorities and to the donors who fund our research, and it is our duty to remain within the budget or revise it if necessary.



What is a budget?

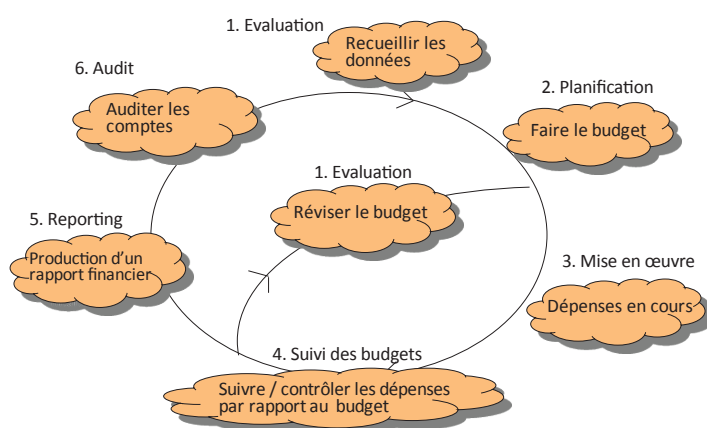
Our budgets



Definition of budget: A budget is an estimation of the costs involved to perform the expected activities, and of the funds available for financial manager. It forms an integral part of the planning process, which may be summarized as follows:

1. Objectives: What do we want to do? What do we want to achieve?
2. Expected activities to achieve the objectives, including the timetable: how are we going to proceed to reach the objective?
3. What are the necessary resources, how much will they cost and how will they be funded?

The budget cycle



The working with partners

- The financial personnel plays an essential role in the work with partners.
- The financial team must work in close collaboration with PNLTHA personnel.
- Disbursement and transfer of funds: this standard requires that a signed agreement is drawn up, with explicit approval of the budget, before releasing any fund, and that a financial report is produced prior to any new payment.
- General procedure for partners: this standard requires that the partner produces documented financial procedures, and that its transactions are authorized and duly documented, with appropriate separation of functions.
- Accounting records: this standard requires that the partner maintains proper books of account, so as to produce records of expenditure related to the projects.
- Banking and cash flow: this standard requires that the partner maintains bank records and books of account, that

monthly reconciliations are performed between bank books and bank statement, that the bank account is registered in the name of the organization, and that cheques are signed by two people as per approved authorizations.

Audit

- An audit is evaluation, a control of the financial management system.
- The audit helps determine whether the systems authorising expenditure (e.g. purchases, disposal of capital assets, recruitment) are adequate.
- It helps us determine whether the budget monitoring and financial reports are presented in a comprehensible format, identical to that of the donor.
- It helps us determine whether the donor funds have really been used to reach the agreed objectives.
- At the end of an audit, an interim report is sent to the coordination to answer any question which has been asked.
- An audit report is sent to help us take into account and comply with the recommendations.
- Once the audit report has been received, the coordination must share the said report with the team members, unless it falls under clearly identified confidentiality issues.

Based on the three concepts defined above, the HAT Platform coordination considers that finances are not a taboo subject, and that everyone must adhere to the international standards of finances, even if it means letting the finance managers deal with the finances.

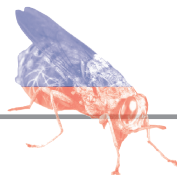
Dr Augustin Kadima Ebeja

First WHO stakeholders meeting and declaration on the elimination of gambiense human African trypanosomiasis

28 March 2014, Geneva, Switzerland

Human African trypanosomiasis (HAT) has been one of the great scourges of mankind. The incidence of gambiense HAT, which was brought to virtual elimination in the 1960s, surged again to epidemic proportions by the end of the 20th century. Efforts towards intervention in this disease over the past decade have enjoyed remarkable success with incidence falling by over 90%. New tools to diagnose and treat the disease and to control the vector are becoming available, and unprecedented political will has led to the World Health Organization (WHO) declaring a programme of global elimination of this disease at a meeting in Geneva on 25-27 March 2014.

WHO included HAT in its roadmap for elimination and control of neglected tropical diseases in 2012, forecasting the elimination of the disease as a public health problem by 2020. An Expert Committee met in April 2013 and approved a strategy to eliminate the disease, subsequently endorsed by the World Health Assembly in a resolution adopted in 2013 (WHA66.12), providing an international mandate to work towards elimination. The stakeholders present at the meeting and who produced this



declaration included national sleeping sickness control programmes, groups developing new tools to fight HAT, international and non-governmental organizations involved in HAT control, and donors. The meeting led to a decision to establish a network under WHO leadership to ensure coordinated, strengthened, and sustained efforts to eliminate the disease. The stakeholders appeal to the international community and disease endemic countries for their commitment, political support, and essential resources to achieve the elimination goal.

Organizations represented at the first stakeholders meeting on *gambiense* HAT elimination having adopted this declaration: National Sleeping Sickness National Control Programmes (SSNCP) of the Ministries of Health of:

- Angola
- Cameroon
- Central African Republic
- Chad
- Ivory Coast
- Democratic Republic of the Congo
- Guinea
- Republic of South Sudan
- Uganda

International organizations:

- African Union Commission (AU) / Pan African Tsetse and Trypanosomiasis Eradication Campaign (PATTEC)
- Food and Agriculture Organization of the United Nations (FAO)
- International Atomic Energy Agency (IAEA)
- Programme Against African Trypanosomosis (PAAT)
- World Health Organization Strategic and Technical Advisory

- Group on Neglected Tropical Diseases (WHO NTD STAG)
- World Health Organization (WHO)

Donors:

- Bayer HealthCare
- Bill & Melinda Gates Foundation (BMGF)
- Sanofi
- The Wellcome Trust, London

Foundations and NGOs involved in HAT:

- Drugs for Neglected Diseases initiative (DNDi)
- Foundation for Innovative New Diagnostics (FIND)
- Médecins Sans Frontières (MSF), including MSF Access Campaign

Scientific institutions developing new tools to fight HAT:

- Erasmus MC, Department of Public Health, University Medical Centre, Rotterdam, The Netherlands
- Institut National de Recherche Biomédicale (INRB) Kinshasa, Democratic Republic of the Congo
- Institut de Recherche pour le Développement (IRD), Montpellier, France
- Institute of Infection and Global Health, University of Liverpool, UK
- Interdepartmental Research Centre for Neglected Diseases, Institute of Tropical Medicine, Antwerp, Belgium
- Liverpool School of Tropical Medicine (LSTM), Liverpool, UK
- Makerere University, Kampala, Uganda
- Spatial Ecology & Epidemiology Group (SEEG), University of Oxford, UK
- Swiss Tropical and Public Health Institute (Swiss TPH), Basel, Switzerland
- University of Glasgow, UK

:



HAT Scientific Publications: From August to January 2014

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2. Overview of the Effect and Epidemiology of Parasitic Central Nervous System Infections in African Children by Macpherson Mallewa, Jo M. Wilmshurst, Seminars in Pediatric Neurology 2014, DOI: 10.1016/j.spen.2014.02.003
3. Human African trypanosomiasis with 7-year incubation period: Clinical, laboratory and neuroimaging findings by Oliver Wengert, Marcel Kopp, Eberhard Siebert, Werner Stenzel, Guido Hegasy, Norbert Suttrop, August Stich, Thomas Zoller, Parasitology International 2014, DOI: 10.1016/j.parint.2014.02.003
4. A Mixed Methods Study of a Health Worker Training Intervention to Increase Syndromic Referral for Gambiense Human African Trypanosomiasis in South Sudan by Palmer JJ, Surur EI, Checchi F, Ahmad F, Ackom FK, et al., PLoS Negl Trop Dis 2014, doi: 10.1371/journal.pntd.0002742
5. Changing landscapes, changing practice: Negotiating access to sleeping sickness services in a post-conflict society by Jennifer J. Palmer, Ann H. Kelly, Elizeous I. Surur, Francesco Checchi, Caroline Jones, Social Science & Medicine 2014, DOI: 10.1016/j.socscimed.2014.03.012
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7. Transcription is initiated on silent variant surface glycoprotein expression sites despite monoallelic expression in Trypanosomabrucei by Ali Kassem, Etienne Pays, and Luc Vanhamme, Proceedings of the National Academy of Science 2014, doi: 10.1073/pnas.1404873111
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9. Kenya Trypanosomiasis Research Institute Cryobank for Human and Animal Trypanosome Isolates to Support Research: Opportunities and Challenges by Murilla GA, Ndung'u K, Thuita JK, Gitonga PK, Kahiga DT, et al., PLoS Neglected Tropical Diseases 2014, doi: 10.1371/journal.pntd.0002747
10. Improving the quality of host country ethical oversight of international research: the use of a collaborative 'pre-review' mechanism for a study of fexinidazole for human African trypanosomiasis by Coleman CH, Ardriot C, Blesson S, Bonnin Y, Bompert F, Colonna P, Dhali A, Ecuru J, Edielu A, Hervé C, Hirsch F, Kouyaté B, Mamzer-Bruneel MF, Maoundé D, Martinent E, Ntsiba H, Pelé G, Quéva G, Reinmund MC, Sarr SC, Sepou A, Tarral A, Tetimian D, Valverde O, Van Nieuwenhove S, Strub-Wourgaft N. Developing World Bioethics 2014, doi: 10.1111/dewb.12068.
11. Serological Responses and Biomarker Evaluation in Mice and Pigs Exposed to Tsetse Fly Bites by Caljon G, Duguma R, De Deken R, Schauvliege S, Gasthuys F, et al. PLoS Neglected Tropical Diseases 2014, doi: 10.1371/journal.pntd.0002911
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14. Determination of an optimal dosing regimen for fexinidazole, a novel oral drug for the treatment of human African trypanosomiasis: first-in-human studies by Tarral A, Blesson S, Valverde Mordt O, Torreele E, Sassella D, Bray MA, Hovsepian L, Evène E, Gualano V, Felices M, Strub-Wourgaft N. Clinical Pharmacokinetics 2014, doi: 10.1007/s40262-014-0136-3.
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18. Mating compatibility in the parasitic protist Trypanosomabrucei by Lori Peacock, Vanessa Ferris, Mick Bailey, Wendy Gibson, Parasites & Vectors 2014, doi: 10.1186/1756-3305-7-78
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Obituary

Tribute to Dr MIAKA

A whole library would be necessary to pay tribute to a monument the size of our dear Constantin Miaka Mia Bilenge, but allow us to reproduce below the expressions of sympathy of one of his assistants and two of his many colleagues: Dr Kande Betu Kumeso, Dr Wim Van Der Veken, and Professor Christian Burri.



One silence minute in memorial
of Dr Miaka



Dear Friend and Colleague,
The emotion was so great when I learned you had passed away that words fail me. You have been for me a true brother and a friend, the one who kindled the flame of scientific research in human African trypanosomiasis, or sleeping sickness, in our country, the Democratic Republic of the Congo. Having worked alongside you first as Head to the Programme then as Director of the PNLTHA, I am one of the privileged witnesses of your great achievements.

Dear Constantin, in clinical trials alone, your avant-garde vision was an inspiration to me, and through us your action continues. The next generation is now in place to carry on the fight.

PNLTHA DRC and its numerous partners, such as DNDi, IMT Antwerp, and FIND, in association with WHO, are about to offer the world, and particularly the different HAT control programmes, new diagnostic and treatment tools that will definitely contribute to the elimination of sleeping sickness. This achievement, we all dedicate to you, to honour your memory.

What more can I say, dear Constantin, other than that we are committed to increasing the critical mass of a young generation dedicated to clinical research on sleeping sickness, as shown by the current management of the PNLTHA. The flag of the Democratic Republic of the Congo will fly high.

Victor Kande Betu Kumeso

My dear Constantin,
I am not surprised that you have gone to the other world. After such a dynamic and active life, your body was showing signs of tiredness. Without an iron constitution, you could no longer be what you had always been: a great chief, a true leader. Now that you have passed away, allow me to thank you one last time for what you have been for us.

I am not the only one to have appreciated your unparalleled ability to listen. Whatever the time of day, and despite your many occupations, you always found time to see those who sought your advice. Surprisingly, each time we left your office, we felt we had been heard and that we had found the solution to our problems.

I can testify to having seen you arrive at work the first and leave the last, always hard working and amazingly strong. A great advocate of team spirit, consultation, and innovation, you encouraged - without distinction - managers and simple workers alike. Experienced, perceptive, and diplomatic, you knew better than anyone else how to weather the storm, and sail the Ministry's boat to safety.

In the fight against HAT, you were indeed the giant baobab known to all. No effort was ever too great to advance

initiatives in this field you were so passionate about. You were also a true father, proud of your own children and spontaneously interested in the children of others and in the young in general, whom you never ceased to encourage and push into new directions.

I personally thank you for your generosity towards me, for instance when you came to collect me by plane at Idiofa where I had fallen ill. May your bereaved family find here again the expression of my deep and sincere gratitude.

No one is perfect in this world, this is true for each one of us. If we have treated you badly, forgive us. I for one know that God will welcome you after all you have done during your full, intense, and short life.

Farewell Constantin and thank you.

Dr Wim Van der Veken

Dear ATA community,

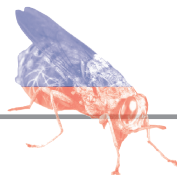
It is with great sadness that we have to announce the death of Dr Miaka Mia Bilenge on 22 March 2014. During his brilliant career, Dr Miaka was Medical Director of the Kwamouth Hospital, Provincial Medical Inspector of East Kasai, National Medical Director of the Expanded Programme on Immunization, National Director of the Bureau Central de la Trypanosomiase (currently PNLTHA), and finally General Secretary of the Ministry of Health. Although a great statesman, he always remained a physician at heart.

We have lost not only a great leader and an example to us all, but also the person who originated the partnership between Swiss TPH and the Ministry of Health of the Democratic Republic of the Congo. It is Dr Miaka who invited us in 2000 to extend our activities to Angola and initiate clinical studies on HAT in the DRC.

In the following years, our enthusiastic and fruitful collaboration went beyond sleeping sickness to include clinical and epidemiological research projects on malaria and health systems. Furthermore, the encouragements of Dr Miaka inspired us to set up a regular office in Kinshasa and create the Alliance for Clinical Research and Clinical Epidemiology in the DRC.

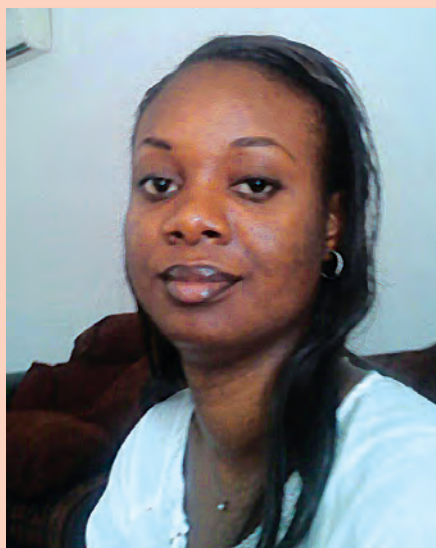
Dr Miaka was an exceptional person; his presence, his energy, his ability to motivate teams, his ability to summarize and his flexibility in negotiations were second to none. We remember with pleasure these moments of collaboration, of scientific and strategic exchange, always with an attitude of 'yes, we can'. We are also very grateful for all the advice Dr Miaka gave us, and all we learned from him.

Christian Burri



Welcome to our new members

The coordination of the HAT Platform and the editorial committee wish to welcome



Alida ATEKANDOYI VAME, Responsable des Finances, DNDi, République Démocratique du Congo (RDC).

She introduced herself with these few lines:

'I have a financial background, with experience in humanitarian organizations, of which five years were spent in the DRC. I also have sound knowledge and experience in administrative management, human resources, and logistics.

I hold a degree in economics from the University of Kinshasa (2006).

I joined the team of DNDi in the DRC in July 2014 as Head of Finances after five years in a similar job, first with Concern Worldwide as Executive Assistant in charge of finances, then with Médecins du Monde France-RDC as Deputy Administrative Coordinator for missions in the DRC.

My motto is: Efficiency and rapidity rhyme with planning and anticipation.'



Dr NKIERI MATSHO MATTHIEU ; Co-investigateur Site FEXINIDAZOLE Bagata

Diplômé en médecine de l'UNIKIN en 2010, j'ai évolué comme médecin traitant à l'hôpital générale de référence de Bandundu, puis médecin Directeur de l'hôpital secondaire de Manza Nsayi. Depuis 2013, je suis Médecin Directeur à l'hôpital général de référence de Bagata.

Ma devise est: On se forge en affrontant même l'inconnu.

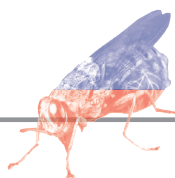


Dr KAVUNGA LUKULA PAPY ; Investigateur principal

Diplômé en médecine de l'UNIKIN en 2010, j'ai accepté de commencer par le plus difficile, à savoir Médecin de brousse, loin de toute ma famille, à Bagata où jusqu' à ce jour, je suis Médecin Chef de Staff à l'hôpital général de référence de Bagata.

J'ai la grâce de voir s'accomplir mes rêves

Ma devise est: Ce qui n'est pas noté, n'a pas été fait



Testimonies from healthcare personnel and HAT patients



Rebirth of a village (Isangi / Héritier and Espérant) Yabondulu, a new life after the devastation caused by sleeping sickness

Located 12 km southwest of central Isangi (N 0° 45' 12.85946" E 24° 11' 23.80888"), Yabondulu is a small village of some 10 houses, which like numerous villages of the region was severely hit by the re-emergence of human African trypanosomiasis (HAT).

During a mission on HAT conducted in the region in 2003, MSF-Belgium discovered this village practically emptied of its inhabitants, with only two inhabited houses left. Eleven years later, we went there to find out more.

As we entered from the north, we found a situation very different from that in 2003 with a village brimming with activity. At the edge of Yabondulu were the two houses that were still inhabited during the dark period of HAT. In one of them, we met Mr Baliani Loetelagoni Maurice, born in the village and director of the primary school in Yalosuna some 12 km away. Mr Baliani has lived there all his life, he has been married to Ingwey Julienne for 32 years, and they have six children.

Mr Baliani told us about the sad events which befell his village: 'There were many dead in this village' he told us. 'There were 12 houses, households of over 25 people, like that of my neighbour where five people died. In my family, I lost my mother and my wife got sleeping sickness too, and she was treated in Isanti', he continued. Mr Bolimbo Espérant, PNLTHA supervisor at Isangi, told us that this woman was diagnosed 9 years ago with stage 2 HAT. She was treated with melarsoprol but at the third control visit, she was diagnosed with a relapse and treated with NECT. Today she is well, and she even gave birth to two girls, now aged six and four and seemingly in good health.

For these people, it was sorcery that caused all these deaths: 'It created discord between the families and lead the inhabitants to run away from the village', said Mr Baliani.

So what led the inhabitants to return to the village? Mr Baliani explained: 'Once sleeping sickness was designated as the cause of all these deaths, the inhabitants started to return to the village.

Families that accused each other of sorcery were reconciled, and this led to the birth of a new village.'

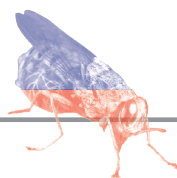
Mr Baliani concluded by thanking the PNLTHA, to whom he thinks the village owes its rebirth. Mr Baliani urged the PNLTHA to carry on with its activities.

The story of Yabondulu is not unheard of: many villages in the region came back to life despite the devastation caused by HAT. This is thanks to the PNLTHA, first with the support of MSF-Belgium who acted urgently during the first few years, then with CTB who has been supporting the PNLTHA over the past few years.



Mr Baliani, his wife and his two daughters born after his wife's treatment and cure

Dr YALUNGU LOBANGA
Treating physician HGR/Isangi
BOLIMBO Espérant
PNLTHA Supervisor /Isangi



Carer/patient relationship: empowering participants through effective communication on the research project

FINA LUBAKI Jean-Pierre, MD, MMED, MPH

Hôpital Évangélique CBCO Vanga, Bandundu Province, DRC

Human African trypanosomiasis and numerous neglected diseases are widespread in rural regions where populations generally have a low socioeconomic status.¹ Patients are poor, often illiterate and faced with stigmatization. In the management of trypanosomiasis, the cure of which is certified only after a prolonged follow-up, the carer/patient relationship is of paramount importance; it must be harmonious and maintained throughout multiple meetings with the patient.

Routine medical consultations in rural areas generally follow a paternalistic model, where the physician, considered as the one who has the knowledge, prescribes treatments and tests without really taking into account the patient who is ill-informed about the disease and unable to discuss it and present his views.² However, although the carer, sometimes portrayed as the expert, has a theoretical knowledge of the disease, the patient has real practical knowledge, based on his signs and symptoms. Good Clinical Practice plays an essential role in current biomedical research, generally centred around the carer/patient couple.³ Good Clinical Practice was set up as medicine evolved towards giving more rights to patients and promoting equality between researchers and those participating in the research. Obtaining

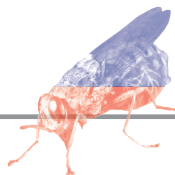
the informed consent is a crucial part of any research, and it requires a meeting between the researcher and the participant. The participant must be given clear information on the study objectives, its procedures and its constraints, as well as on the advantages, disadvantages, and benefits. The participant must then be left free to decide whether s/he wants to take part in the study or not.

It is not easy for the patient to understand all the information given during this meeting, given his/her situation and background, and it is the researcher's duty to empower the patient. Empowerment is the process of reinforcing the ability of individuals or groups to make choices and transform these choices into actions and desired results.⁴ Empowerment must take into account the participant as a person in his/her own right, with his/her values, culture, and right to be different.

One of the key elements of this process is the sharing of information, which must go beyond a simple description of the study, and include a discussion with the participant.⁴

A HAT patient participating in a study and feeling unwell after his admission to hospital was about to be taken by his relatives to a traditional healer. However, the patient remembered having read and discussed the possibility of such symptoms when he signed the informed consent form, and managed to convince his family that he should consult the study team and that there was no point in going to the healer. Information is power.⁴

Communication is the key to a harmonious carer/patient relationship, as much in clinical practice as in research. For many



people offered to take part in a study, signing the informed consent form can be a stressful process, and having to do new tests and take new medicines may cause fear, worries, incomprehension, and impatience.

Good communication between the physician and the patient can help alleviate such worries, help the patient understand the medical information, and help the physician identify his needs, perceptions, and expectations.⁵

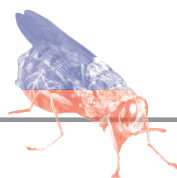
Health literacy improves these populations' access to health information and their ability to use it effectively, and it is essential to emancipation.⁶

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Dr FINA LUBAKI (First in the left), during Investigators meeting.





A second valuable peer coaching experience

*based on the Bagata team report (Dr Kavunga Papy,
Principal Investigator)*

This second peer coaching experience follows the first one, related in our Newsletter Issue 14, where a physician, a nurse and a laboratory technician of the Bandundu site had gone to train their counterparts at the Mushie site.

However, things were done differently this time, when the fexinidazole clinical trials DNDiFEX004, DNDiFEX005 and DNDiFEX006 were being launched at the Bagata site. A team of two physicians, a laboratory technician and a nurse from Bagata

days: from 27 July to 5 August 2014 for the principal investigator, the laboratory technician and the nurse, and from 7 to 16 August 2014 for the co-investigator.

ACTIVITIES

The first day started with an introductory meeting, during which the Mushie principal investigator outlined the agenda. Each participant from Bagata was entrusted to the responsibility of his/her counterpart from Mushie.

A short reminder on Good Clinical Practice was given during the meeting, followed by explanations on the work plan and the necessity to adhere to the set working hours.

On the second day, all the team members returned to their work place to resume their normal activities, presented below.



travelled to Mushie for a 10-day practical training by their peers.

TRAINING OBJECTIVES

- Learn how to include patients in the FEXI study once their informed consent has been given, and how to conduct the various tests and administer treatments until their discharge from hospital.
- Understand the tasks allocated to each team member, from the principal investigator to the nurse, and how to carry them out.

TEAM COMPOSITION

- The Bagata team included 4 members:
 - Physicians:
 - Dr Kavunga Papy (principal investigator)
 - Dr Nkieri Matthieu (co-investigator)
 - Nurse: Tawaba Watson
 - Laboratory technician: Miss Ndombe Ned (laboratory manager)

DURATION OF THE TRAINING

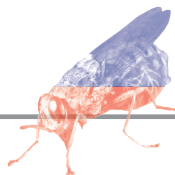
The training was given over two sessions, each one lasting 10

Principal investigator:

- Review of the various Investigator files, with a special focus on each heading and its importance.
- Information exchanges, correspondence between the various players involved in the study (Coordination, Cardibase, Cardinal Systems...)
- Use of Infogate software for data encoding
- Informed consent procedure
- General physical examination and neurological examination
- Use of ECG machine
- Treatment initiation in patients included in the study
- Daily care of patients, including clinical examination, notification, and adverse event management and reporting
- Patient follow-up
- Administrative procedures, including the management of inputs (drugs, Piccolo discs, PK), finances, foodservices to patients, and transport

Nurse:

Use of flow charts for bedside activities, e.g. drug administration



Renovation of Bagata site (General Hospital of Reference)



Before



Before



After



After

after meals, and reporting of any adverse event observed in patients participating in the study

Drug management, including low inventory warnings

Completion of various patient documents, including treatment sheet, follow-up sheet and patient register

Laboratory technician:

Review of the laboratory procedures as specified in the study protocol

Handling of the various instruments, including microscope, Piccolo, Woo test centrifuge, mAECT, and modified simple centrifugation

Demonstration of urine analysis with Combur 9, pregnancy tests, and differential leukocyte count

Focus on biosecurity measures for waste management, and on compliance with the diagnostic tree as outlined in the study protocol

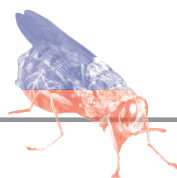
Completion of test result forms, and recording of the refrigerator temperature morning and afternoon

CONCLUSION

The practical course in Mushie reviewed the Good Clinical Practice and its implementation. Each member of the Bagata team was able to watch as well as perform the tasks he/she will need to do in compliance with the study protocol.

The presence at the site of patients eligible to participate in the study was a great help. Some of these patients were screened at the hospital, and included in the study by the Bagata team under the supervision of the Mushie team.

All difficulties identified during this training session were recorded, and recommendations were made to solve them.



Scientific events scheduled for 2014-2015

Event date	Location	Event name
17-19 September 2014	Kinshasa DRC	3rd Joint EANETT/ HAT Platform Scientific Meeting
29 September - 1 October 2014	Addis-Ababa, Ethiopia	LEAP Platform Meeting and Scientific Conference
15-18 January 2015	Phnom Penh, Cambodia	ICITD International Conference on Infectious & Tropical diseases http://ictid.webs.com/
25-28 April 2015	Copenhagen, Denmark	ECCMID http://www.eccmid.org/eccmid_2015/
6-10 September 2015	Basel, Switzerland	9th ECTMIH - European Congress on Tropical Medicine and International Health http://www.festmih.eu/Page/WebObjects/PageFestE.woa/wa/displayPage?name=ectmihbasel2015
September 2015 (TBC)		33rd International Scientific Council for Trypanosomiasis Research and Control (ISCTRC): http://www.au-ibar.org/isctrc
25-29 October 2015	Philadelphia, PAUSA	64th ASTMH http://www.astmh.org/Future_Meetings.htm

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