



# HUMAN AFRICAN TRYPANOSOMIASIS: CONDUCTING QUALITY TRIALS IN RESOURCE-POOR SETTINGS

Dr Wilfried MUTOMBO KALONJI  
PNLTHA / DRC  
Local Investigator Dipumba



2nd DNDi Stakeholders' Meeting  
Nairobi, June 23-24, 2009

23.06.2009

1

## OUTLINE

- Introduction
- Implementation stages
- Investigator's daily schedule
- Follow-up Preparation
- Quality Assurance
- Difficulties / Challenges
- Strengths
- Results
- Conclusions

23.06.2009

2



## INTRODUCTION

### Experiences Dipumba, RDC

- Site HATSENTINEL (WHO/CDC)
  - Collection of epidemiological and treatment data since 2001
- THARSAT study (ITM Antwerp)
  
- NECT: Dipumba's first clinical trial
  - Local team's first experience in a clinical trial
  - Members experienced in diagnostic and treatment of HAT
  - Local team
    - 2 physicians
    - 3 lab technicians
    - 8 nurses
  - Capacity: 30 beds, 40 patient treated / month

23.06.2009

3





## IMPLEMENTATION STAGES

- **A) Site rehabilitation** to improve working conditions of the team and hospitalisation conditions of the patients.
  - Laboratory
  - Blood and CSF sampling and examination room
  - Patient wards
  - infirmary
- **B) Mode of transport for the investigator**
  - Motorcycles
  - Fuel

23.06.2009

5





## IMPLEMENTATION STAGES (continued) (with the support of DNDi and STI Basel)

- **C) Equipment** – improving diagnostic methods for HAT and other underlying pathologies
  - Laboratory
    - Reflotron (biochemistry testing)
    - Centrifuge
    - Hemocue (Hemoglobin dosage)
    - Paracheck (quick malaria test)
  - Infirmary
    - Aspirator
    - Rechargeable solar lamps
    - Tension metre, Thermometre, Scales etc...
    - Cell phone (to call the Investigator / on-duty nurse)

23.06.2009

7



23.06.2009

8



## IMPLEMENTATION STAGES (continued) (with the support of DNDi and STI Basel)

### ■ D) Training and capacity strengthening

- Training for the team
  - Refresher course on HAT (DFMO/eflornithine treatment)
  - NECT Protocol
  - Good Clinical Practice
- Capacity strengthening for Investigators
  - Neurology (10 day training in Neuropsychiatry)
  - Diagnosis and treatments, AE et SAE (by Epicentre)
  - Computer softwares (word, excel, power point)
- Capacity strengthening for lab technicians
  - By PNLTHA

23.06.2009

9





## Daily schedule of the Investigator

- Includes
  - Informed consent
  - Physical examination of patients
  - Randomisation
  - Treatment preparation
- Daily clinical evaluation of patients
  - Vital signs, AE and their management
  - SAEs, their management and reporting
- Completing case report forms (CRF) and other documents

23.06.2009

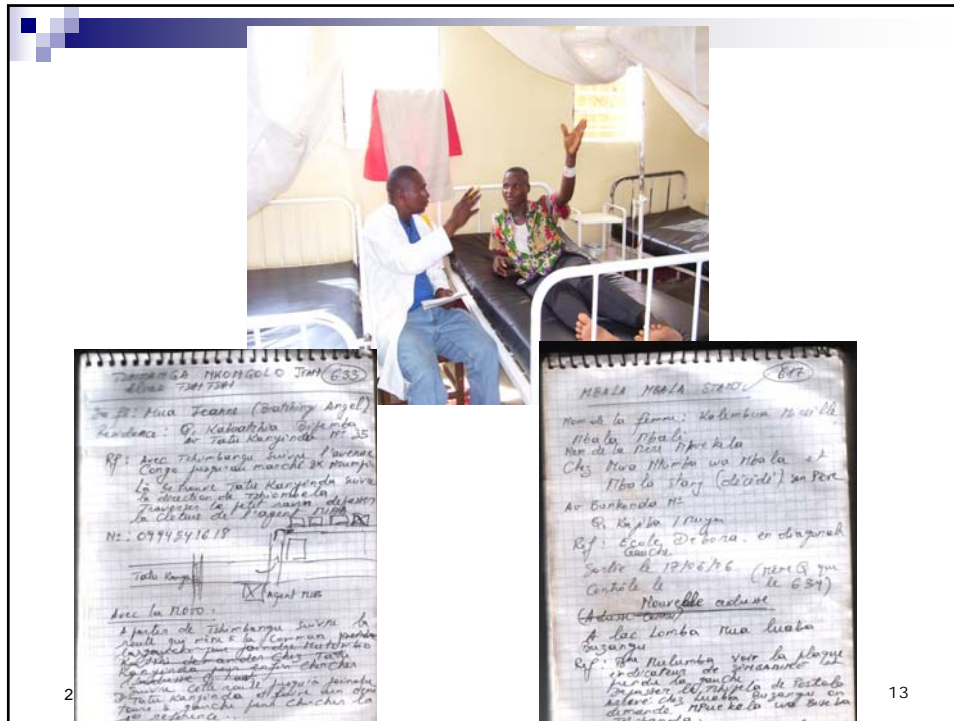
11

## Follow-up Preparation

- Patient history and details : personal address, address of relatives, telephone number, etc.
- Validation of patient's description of their address (during patient hospitalization)
- Incentive offered to patients when completing follow up at 6-12-18 months (mosquito net)
- Excellent patient/Doctor Relationship

23.06.2009

12



## Quality Control

- By investigator
  - Respecting the trial protocol and its annexes
  - Collecting data (patient file - CRF)
  - Drug supply management
- By monitors (numerous visits of the STI team)
  - Verify source data and trial documents (CRF, inventories, consent forms etc.)
  - Validating lab equipment and quality control
- By auditor
  - Confirming data quality and integrity by an independent auditor
- By sponsor (DNDi)
  - visits of the DNDi Team, making resources available (supplies, finances and equipment)



## Challenges

- Throughout inclusions
  - Numerous documents (some in English only)
  - Limited technical means (paraclinical)
  - Limited internet access
  - Poverty of patients and lack of education
  - Refusal of signing informed consent forms
  - Non-included patients frustrated (food)
- Challenge to get receipts for some expenses





## Challenges (continued)

- During follow up
  - Repeated address changes or phone number of patients
  - Bad road conditions
  - Motorcycles not well-adapted for bad road conditions (numerous technical problems)
  - Streets without names or not known within community
  - Feeling of being harassed
- No archive system (15 years)

17



18



## Strengths

- The team's determination working in the Trial (Local team, PNLTHA, Epicentre, STI, DNDi)
- Efficient logistical support
- Efficient communication with partners
- Excellent Patient / Doctor Relationship

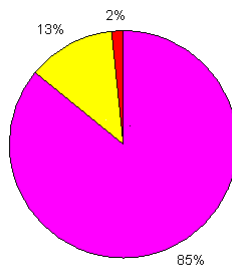


## RESULTS

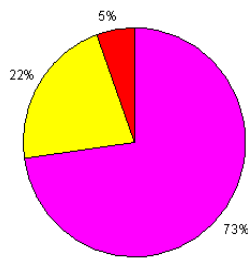
60 patients included at Dipumba

- 55 „available" at 18 month follow-up (f-u)
- 52 controlled at 18 months (95%)**

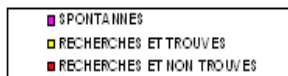
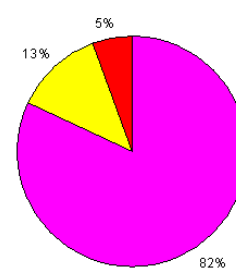
F-u at 6 months



F-u at 12 months



F-u at 18 months



23.06.2009

21

## CONCLUSION

- NECT is a success
  - Final results of the multicentre study will be published in the *Lancet* online 25 June
- Enriching experience for the local team
  - Its first clinical trial
- NECT FIELD in progress
  - 20 patients included
- To come: FEXINIDAZOLE or others?

23.06.2009

22



DNDi's  
2nd Stakeholders' Meeting  
and 3rd African Meeting

Nairobi, Kenya,  
June 23, 2009

**DNDi**  
Drugs for Neglected Diseases initiative

Thank you!

