Implementation of studies in remote areas in countries with limited regulatory and ethics experience

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  - Access, Patients, Hospitals, Staff, Regulatory environment
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Introduction

- Human African Trypanosomiasis (HAT) or Sleeping Sickness is present in sub-Saharan Africa, mostly in remote rural areas
- To carry out clinical trials on HAT we need to go deep into the most prevalent areas
- There are many challenges
Challenges
Access to rural areas (Study sites/centres)

- No roads or road in the poor state (to access remote areas)
- Often no airports nearby
- Many air companies are unsafe: blacklisted
- Long trips in rivers with poorly equipped boats
Enrolment constraints

- Number of patients is decreasing in areas well supported by national control programs
- Patients
  - Mostly rural
  - Poor
  - Low educational level (adapted Consent Form)
  - Totally trust medical staff (ICF)
  - Long follow up (every six months until 18 months)
Hospitals in remote areas

Health care system / social security

- Restricted national budget for hospitals, patients support themselves (No food for patients, minimal sanitation, parallel use of traditional medicine)

Hospitals are mostly built during colonial period

- Deteriorating infrastructure
- Underequipped
- Very limited technical platform
- Water supply system absent or in need of renovation
- No electricity
- No internet access
- Poor waste management
Hospital Staff

- No experience in clinical trials / GCP
- HAT knowledge fading away (experienced staff becoming old, low interest in HAT amongst young staff)
- No specialist doctors, only general practitioners (management of some side effects/AE)
- Nurses, lab technicians routinely pay little attention to **standard precautions**
Ethical and Regulatory environment

- Ethics and Regulatory Committees exist, but few have dealt with complex clinical trials
  - No deadline for submission/response
  - No list of document to be submitted (sometimes)
- Regulatory and ethic committee are sometimes merged into a SCIENTIFIC COMMITTEE (CAR)
What has been done
Access to rural areas
(Study site/centre)

Safe transport to the clinical trial site (hospital)

- By road
  - 4x4 vehicles
  - Safety standards (speed limits, passengers…)
- By river
  - Secure use of rapid boats (provide by the PNLTHA/RDC)
  - Compulsory wearing of life jacket
- Aerial
  - Avoid blacklisted companies
  - Appeal for humanitarian flights when available ASF/UN/ECHO Flight/Missionaries
Patients

- Support to mobile teams (to diagnose and bring patients to the hospital)
- Simplified informed consent
  - Translated into local language
  - Use of images
  - Involving patient’s family and witnesses
- No incentive factor (taken full charge of all patients whether included in the study or not)
- Maximum information collected on the patients, their address and entourage (for follow up)
Based on the recommendation of the pre-review meeting, DNDi rewrote & shortened the consent form and created a toolkit of drawings illustrating key information & interventions to be used to improve understanding by illiterate patients.
Hospitals  (Study sites/centres)

- Free care for all HAT patients (all charges paid by sponsor)
- Rehabilitation and equipment (wards, laboratories, offices, sanitation,…)
- Provide source of electricity (generator, solar)
- Supplying tap water, enhancing work hygiene
- Provide internet connection
- Improve waste management system
- Provide motorbike (for no responder patient follow up)
- Connection with a referral hospital (if needed) via the coordinating project team
Hospital Staff (study staff)

- MD (investigators), lab tech, nurses underwent several trainings
  - General
    - GCP
    - Standard precautions
    - HAT (symptoms, diagnostic, treatment, management of side effects
    - Refreshment on neurology, cardiology, resuscitation
  - Specific to the study
    - Protocol and study SOPs
    - Management of AEs, SAEs
    - Use of e-CRF
    - ECG
  - Possible contact with cardiologist, neurologist, intensive care (of major referral hospital of main towns in DRC): help in best management of potentially complicated AEs, SAEs
Daily management of clinical research projects

- Harmonise practices, detect and correct weaknesses
- Support sites on problem solving (AE, SAE management, logistic issues,...)
- Facilitate information flow between stakeholders
- Communication with IRB/IEC and regulatory authorities
- Follow recruitment for clinical trials and discuss with the site investigators to help maintaining it at a satisfactory level
WHAT NEEDS TO BE IMPROVED

- Regulatory authorities
  - improved procedures and SOPs to facilitate approvals
- Ethics committees
  - to be built with a multi-sectorial approach, including lay people representing civil society
- Health care system, transport system,…
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OPPORTUNITIES
CONCLUSION

- It is possible to carry out clinical trials close to remote patients.
- But there are many necessary expenses around the trial set up and conduct, including screening.
- Carrying out clinical trials in remote areas has a positive impact on general quality of care, and improve capacity of staff.
THANK YOU

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