TDR CONTRIBUTION TO DEVELOPMENT OF A CAREER IN RESEARCH ON HUMAN AFRICAN TRYPANOSOMIASIS IN THE DEMOCRATIC REPUBLIC OF THE CONGO

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TDR For research on diseases of poverty

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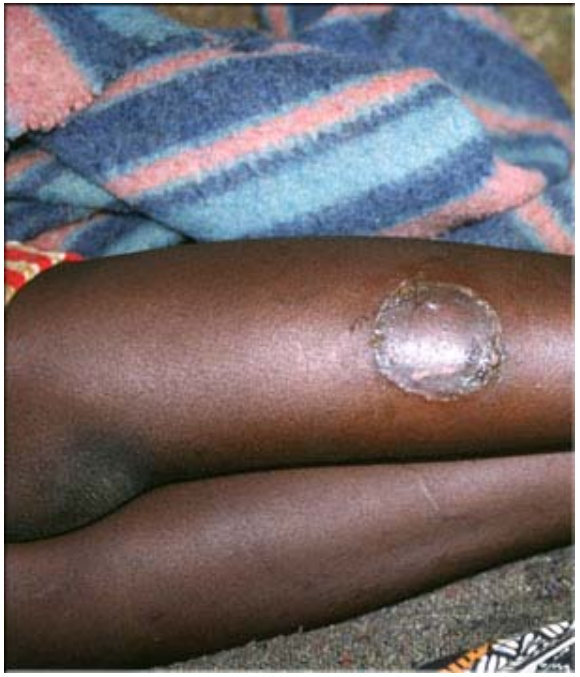
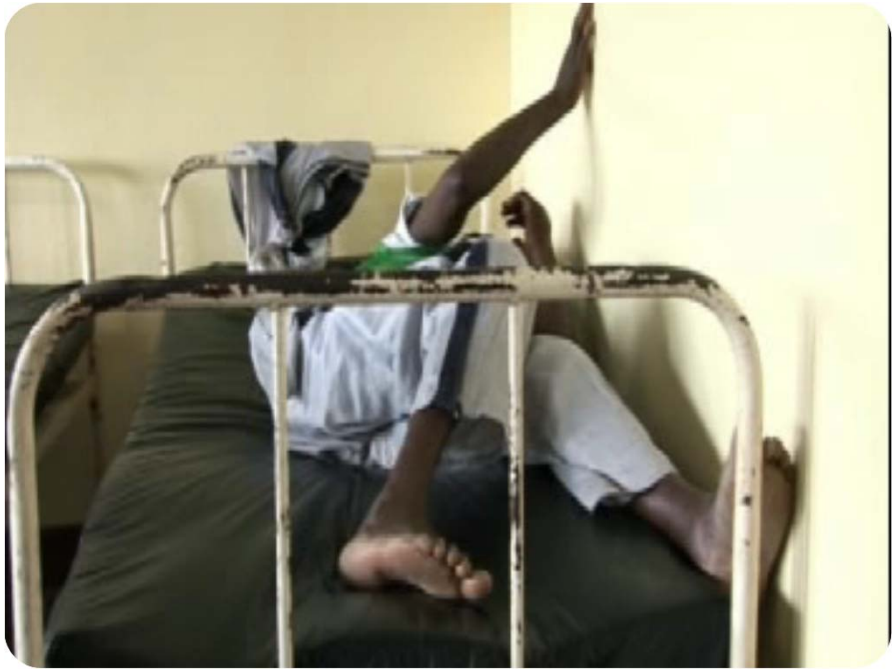
HUMAN AFRICAN TRYPANOSOMIASIS (HAT)

- HAT, or sleeping sickness, is an endemo-epidemic disease specific to tropical Africa, caused in the DRC by a flagellated parasite called *Trypanosoma brucei gambiense* transmitted to humans from an individual parasitized to a healthy individual by a bite of tsetse fly.
- The Democratic Republic of the Congo bears the majority of the sleeping sickness disease burden, with around 85% of reported cases.
- There are two stages of the disease:
  - Early stage (hemolymphatic stage): with few or specific symptoms such as fever, adenomegaly, facial oedema, pruritus
  - Late stage (meningo-encephalitic): with neuro-psychiatric symptoms such as motor disorders, sensory disorders, behavioral problems, sleep disturbances, coma. Could lead to death if untreated

EARLY STAGE



LATE STAGE



MY PREVIOUS EXPERIENCE BEFORE TDR FELLOWSHIP

- Medical doctor in a small, rural village, practiced clinically
- High endemicity for HAT
- Treating a HAT patient was a real challenge:
  - Flornithrine too complex to administer (56 intravenous injections)
  - Melarsopol treatment only available: **toxic and kills between 5 and 10% of patients**
- In 2006 was Principal Investigator for the Nifurtimox-eflornithine «NECT» clinical trial (DND*i*)

MY EXPERIENCE AS AN INVESTIGATOR

- NECT (nifurtimox eflornithine) clinical trial supported by DND*i*
  - Eflornithine 14 days, infusion 4 times a day, as standard treatment
  - Eflornithine 7 days, infusions twice a day + Nifurtimox 10 days tablet, 3 times a day
- NECT safe and effective
  - Shorter treatment
  - More cost-effective
  - Simplified logistics and staffing needed in treatment centres
- What motivated me
  - New area in the DRC
  - However, needed to improve skills with clinical trials

THE TDR CLINICAL RESEARCH AND DEVELOPMENT FELLOWSHIP (CRDF) OPPORTUNITY

- **1st part**: 6 months at SANOFI in Paris to acquire knowledge on how to develop a clinical trial with high quality standards.
- **2nd part**: 6 months at DND*i* in Geneva, involved in the HAT team which was working on preparation of a fexinidazole clinical trial in the DRC, the first oral treatment for both stages of HAT

RETURN TO DRC AFTER FELLOWSHIP

République Démocratique du Congo

Ministère de la Santé Publique
Secrétariat Général
Direction de la Pharmacie et du Médicament

AUTORISATION DE MISE SUR LE MARCHE DES MEDICAMENTS

(5 ans)

N° MS. 1253/10/05HMG.../..0914...../2018..

- Coordinating investigator of fexinidazole clinical trial (in charge of site selection, preparation and coordination of clinical trial activities in the field)
  - Pivotal study aims to prove the safety and efficacy of Fexinidazole with NECT as comparator
  - First trial on an oral treatment of both stages of HAT
- Results :
  - Fexinidazole is safe and effective
  - One pill per day over 10 days
  - Positive opinion given by the European Medicines Agency in 2018
  - Approved by DRC in 2018
  - Donation from SANOFI to WHO for distribution in the DRC
  - First step toward HAT elimination

MY CURRENT SITUATION

- Senior Clinical Manager at DND*i* in the DRC, Head of the R&D team.
- Leading the team monitoring Fex009 clinical trial (which aims to assess the efficacy of fexinidazole administered to HAT patients at all stages, treated on an outpatient basis or in hospital).
- Member of the commission which worked on the transformation of the 3rd Direction (REGULATORY AUTHORITY) into «ACOREP» (Agence Congolaise de Régulation Pharmaceutique) which will be independent from the Ministry of Health.

IMPACT OF THE CRDF: NETWORKING/TRAININGS/ NEW PROJECTS

Through our clinical trial sites we have developed a network of field workers able to perform a clinical trial on any disease.

40 Investigators

56 Nurses

44 Lab Technicians

14 Clinical Trial Assistants

THANK YOU

TDR is able to conduct its work thanks to the commitment and support from a variety of funders:
See: https://www.who.int/tdr/about/funding/en/

This project is also supported by additional designated funding from
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THANK YOU