

Microscopic imaging enables verification of diagnosis for clinical trials

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DNDi

Drugs for Neglected Diseases initiative



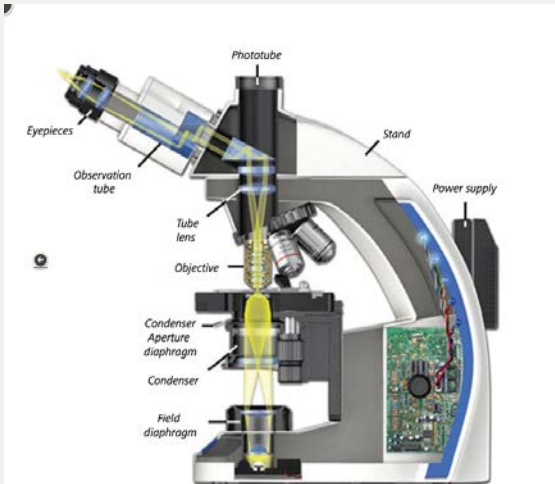
HAT diagnosis and staging

- Diagnosis of human African trypanosomiasis requires **several steps**:
 - Initial serological screening test (CATT/RDT)
 - Lymph node palpation and puncture
 - Blood concentration technique (CTC/mAECT)
- Staging (*determining the stage of disease*) requires:
 - Lumbar puncture and CSF concentration technique (SMC)
 - WBC count in CSF
- All procedures are done in fresh samples *and cannot be stored*

Objectives of the device and set-up

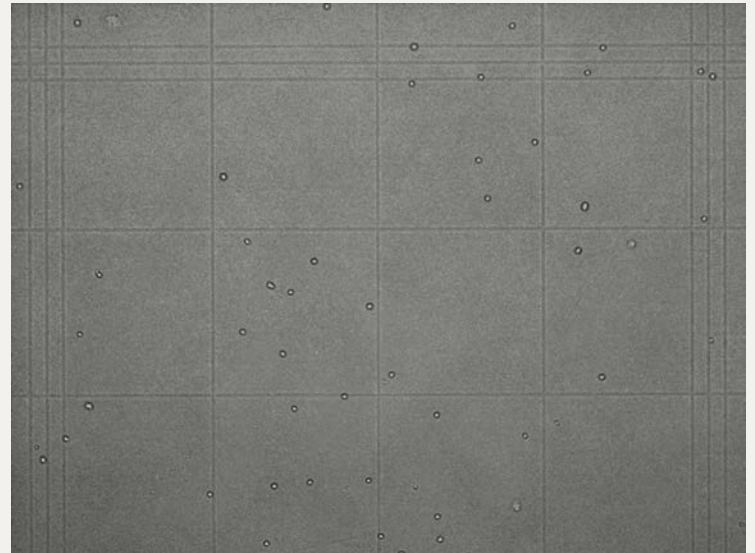
- Microscope with camera:
 - Documents and traces the parasitological diagnosis of HAT, and patients' follow-up exams
 - Impossible to archive fresh slide preparations => solved using pictures and short videos
- Power Folder:
 - Power Folder is an electronic library used to save and transfer pictures and videos

Microscope iLED with camera



Type of images and methodology?

- Microscope used for blood, lymph or CSF fresh samples
- Photos
 - ✓ Objective: To assess counting of white blood cells in CSF
 - ✓ Technique: 10 pictures over 5 fields in Fuchs Rosenthal chamber
- Videos
 - Objective: to see mobile parasites
 - Technique: Short sequence of 2-5 sec if a trypanosome is detected



Images tracing and archiving

- Each image is saved in a memory SD card; a set of numbers and letters appears:

- Picture

ex: F911BA_20140106_120808_432

- Vidéo

ex: /2014-09-04/20140904_182440_227.h264

These codes are unique and shall not be modified
for good traceability

In the laboratory

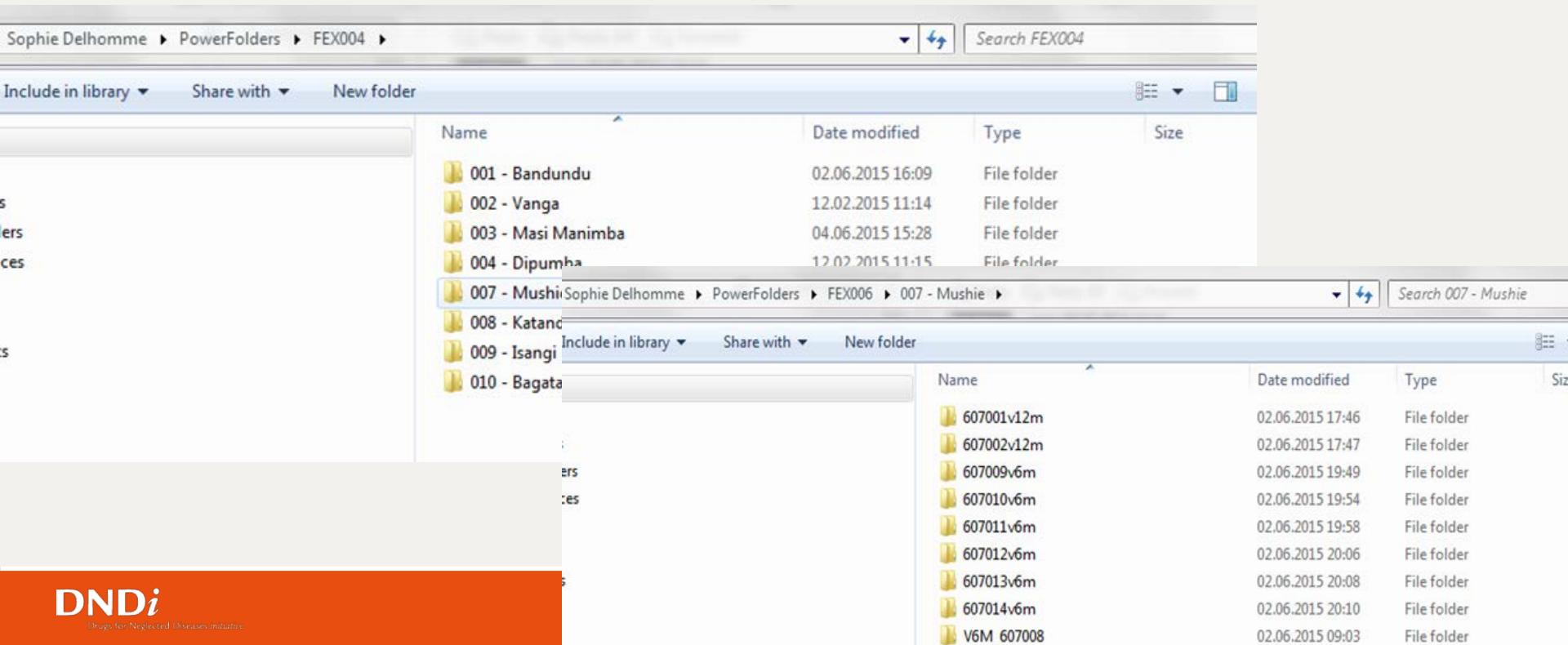
- ✓ Carefully take pictures of relevant images for each patient visit during the clinical trials.
- ✓ Create and maintain a register to link the pictures and videos with the patient's codes and visits

	A	B	C	D	E
L	N°PATIENT	N°PHOTO	N°VIDEO	N° VISITE	
2	503010	888	608	6M	
3	503009	198	978	6M	
4	503011	306		6M	
5	503012	456	259	bilan initial	
5					

- ✓ Transfer the pictures and videos to the investigator as well as the registry

The investigator will create in his/her computer

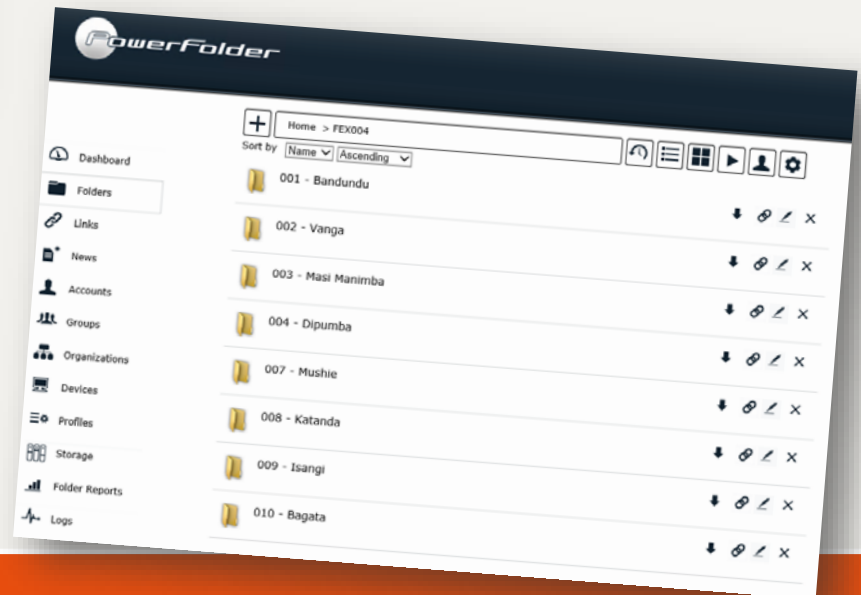
- ✓ Folders for each patient and each visit (ex: 607001-V12M)
- ✓ Save the pictures and videos in power folder



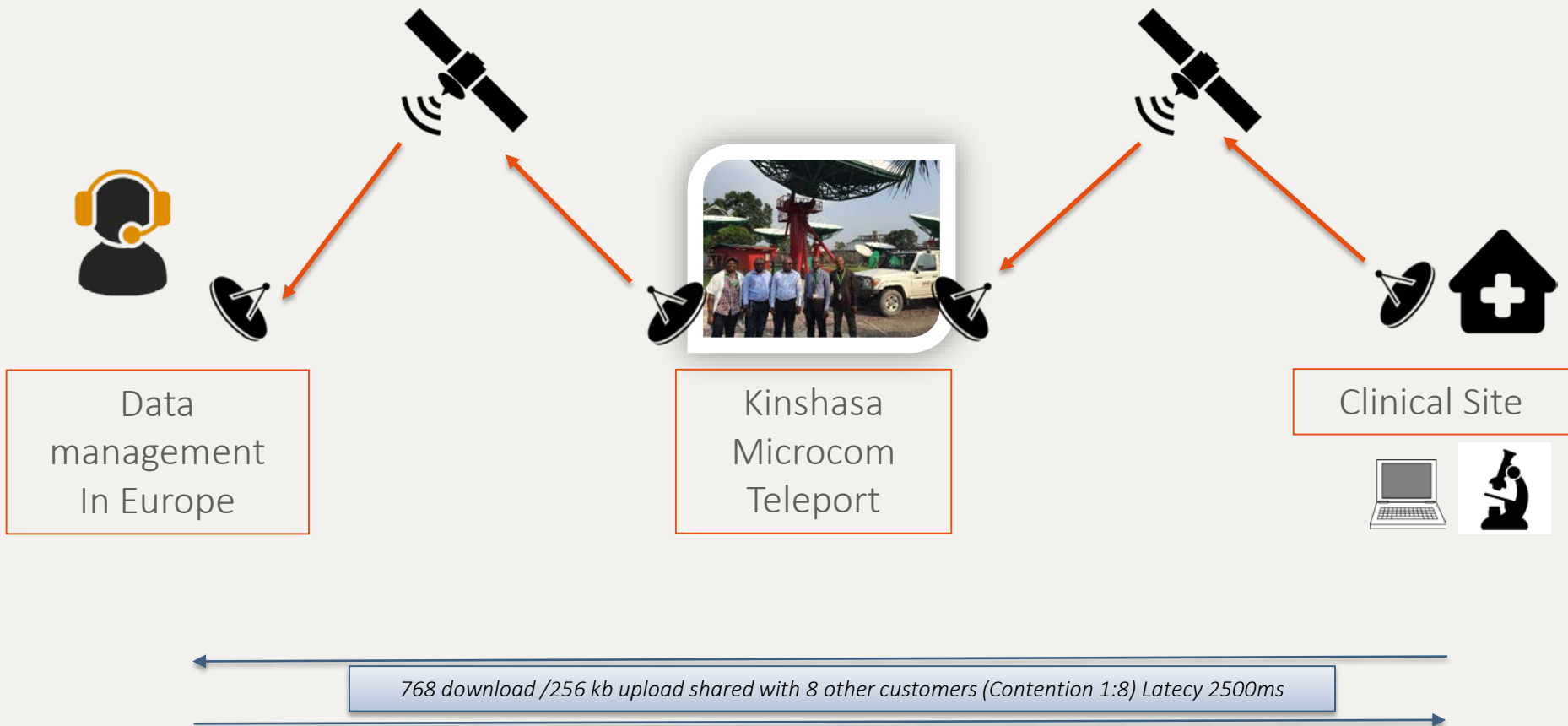
Assessed lab pictures/videos collection and transfer



- Ease of use
- Transmission security
- Adapted to poor connectivity (latency and interruption)
- CRF transmission
- Video and photo transmission



Clinical site internet connectivity



Conclusions

- This was recommended by a WHO 2013 expert committee report:
 - **Control and Surveillance of Human African Trypanosomiasis**
(*WHO Technical Report Series 984, pp.135*)
- Has proven feasible at the site level
- Can be used as a confirmatory/quality assessment/training tool
- The main limitation: it is not a diagnostic tool as negative results can not be guaranteed

Partners on sleeping sickness R&D



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Swiss TPH



Institut National de Recherche Biomédicale (INRB), DRC



CLINICAL PARTNERS: REGIONAL PLATFORM FOR CLINICAL RESEARCH



- National sleeping sickness control programmes, research institutions and national laboratories of public health of the most affected endemic countries:



- Swiss Tropical and Public Health Institute (Swiss TPH), Switzerland; Institute of Tropical Medicine-Antwerp, Belgium; Institut National de Recherche Biomédicale (INRB), DRC; University of Makerere, Uganda; Kenya Agricultural Research Institute – Trypanosomiasis Research Centre (KARI-TRC), Kenya; Tropical Medicine Research Institute (TMRI), Sudan; Institut Pasteur Bangui, University of Juba, South Sudan; CAR; Médecins Sans Frontières (MSF); Foundation for Innovative New Diagnostics (FIND), Switzerland; Eastern Africa Network for Trypanosomiasis (EANETT); Centre interdisciplinaire de Bioéthique pour l'Afrique Francophone (CIBAF); The National Sleeping Sickness Control Programme of Guinea; INZI Project of the University of Edinburgh. WHO Department of Neglected Tropical Diseases, as observer.

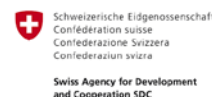
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Thank you!

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