



# Capacity building in 4 African countries in INTENSE-TBM: Intensified anti-TB regimen to reduce tuberculous meningitis mortality in patients with/without HIV infection

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**INTENSE-TBM** is a phase III multicenter factorial design randomized controlled trial evaluating the efficacy of an intensified antitubercular and anti-inflammatory regimen including increased dose rifampicin, linezolid and aspirin in tuberculous meningitis.

**CAPACITY BUILDING (CB)** ensures all centers have capacity to perform the clinical trial and develops a long-term network of skilled clinical researchers, centers and laboratories.

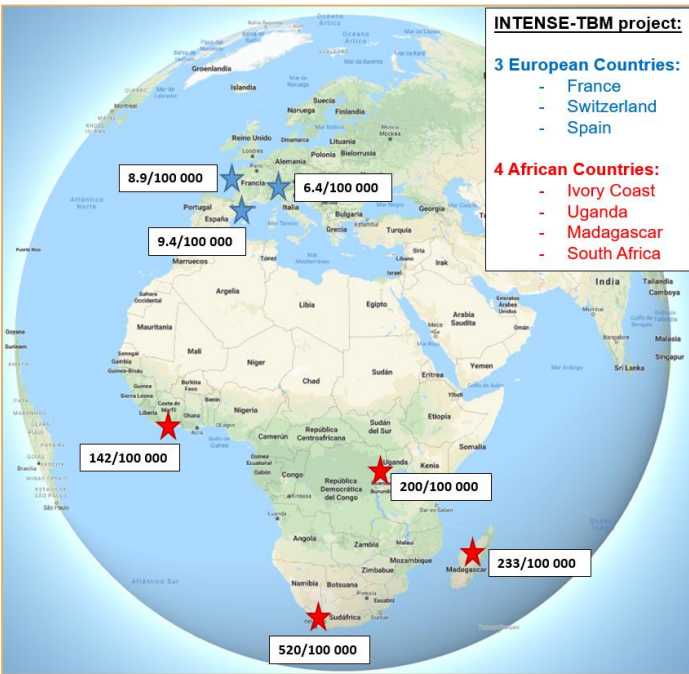


Fig 2: INTENSE-TBM meeting in March 2019 in Abidjan (Ivory Coast)

**RESULTS** Sites evaluation identified a high level of heterogeneity among countries and between referral and regional centers within the same country; in particular sites where clinical trial research had never been performed. **Table 1:**

	Challenges	Interventions
<b>Clinics and Labs</b>	<ul style="list-style-type: none"> <li>- Insufficient networking; patients and samples flow</li> <li>- Limited availability of diagnostic tests</li> <li>- Limited research infrastructures</li> <li>- Insufficient maintenance of available equipment</li> <li>- Supplies management and storage challenges</li> <li>- Absent or insufficient Quality Controls (QC)</li> <li>- Lack of or insufficient data management</li> <li>- Lack of or deviations from Standard operating procedures (SOPs)</li> </ul>	<ul style="list-style-type: none"> <li>- Collaboration between institutions (national and international)</li> <li>- Knowledge transfer between referral and regional centers</li> <li>- New diagnostic techniques (Xpert MTB/RIF Ultra; MGIT liquid culture)</li> <li>- SOPs implementation and training</li> <li>- Equipment purchase and maintenance</li> <li>- QC implementation</li> <li>- Reinforce data management</li> <li>- HIV Clinical training</li> <li>- PK-PD training</li> </ul>
<b>GCP</b>	<ul style="list-style-type: none"> <li>- Irregular level of accreditation</li> <li>- Different experience in research</li> <li>- Capacity for training</li> </ul>	<ul style="list-style-type: none"> <li>- All personnel certified in GCP</li> <li>- Online training</li> <li>- Face to face training in Madagascar</li> </ul>
<b>IC</b>	<ul style="list-style-type: none"> <li>- Lack of previous accreditation</li> <li>- Lack of or insufficient capacity training</li> <li>- Budget and availability limitations</li> </ul>	<ul style="list-style-type: none"> <li>- 5-day accredited training by Infection Control African Network (ICAN) through live streaming</li> </ul>

Fig 1: TB incidence in the countries that participates in INTENSE-TBM

**METHODS:** The INTENSE-TBM project consists of 8 work-packages (WP). WP2-Capacity Building includes 4 main tasks: i) Set-up of clinical centers, ii) Set-up of microbiology laboratories, iii) Good Clinical Practice (GCP) and, iv) Infection Control (IC). WP2 leaders visited clinical and laboratory centers in collaboration with co-investigators at each site. Evaluation tools were developed which aimed to standardize the format of site evaluation, facilitate the collection of information and provide a template to report the visits. The information collected was used to identify individual site requirements to guide site preparation for the clinical trial.

**CONCLUSION:** Evaluation visits showed significant differences in terms of needs and capacities. CB promotes networking and transfer of knowledge, allowing standardization among centers to ensure that the minimal requirements for the clinical trial are achieved. CB interventions must last beyond the project duration, and they advocate for the decentralization of the health care services.