Capacity building in sub-Saharan Africa as part of the INTENSE-TBM project during the COVID-19 pandemic

P-003

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BACKGROUND The **INTENSE-TBM project** includes a phase III multicentre randomized clinical trial (RCT) on tuberculous meningitis (TBM) in sub-Saharan Africa (SSA) to evaluate the efficacy of an intensified anti-tubercular treatment and an anti-inflammatory treatment, to reduce TBM mortality and morbidity in patients with/without HIV-1 co-infection.

Within this framework, we designed a comprehensive work-package on **capacity-building** (CB) ensuring all centres had, or would acquire, the ability to conduct the RCT.

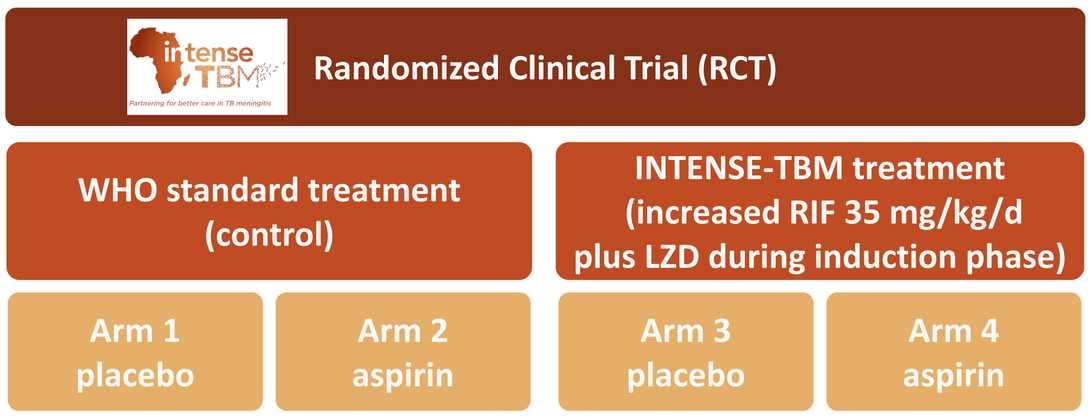

Figure 1. Factorial design and intervention arms in the INTENSE-TBM RCT

OBJECTIVES Describe CB activities, identify strengths and challenges, and share tools adaptable to other projects, particularly in low and lower-middle income countries with heterogeneous settings and during the COVID-19 pandemic.

METHODS CB was structured around four main tasks:

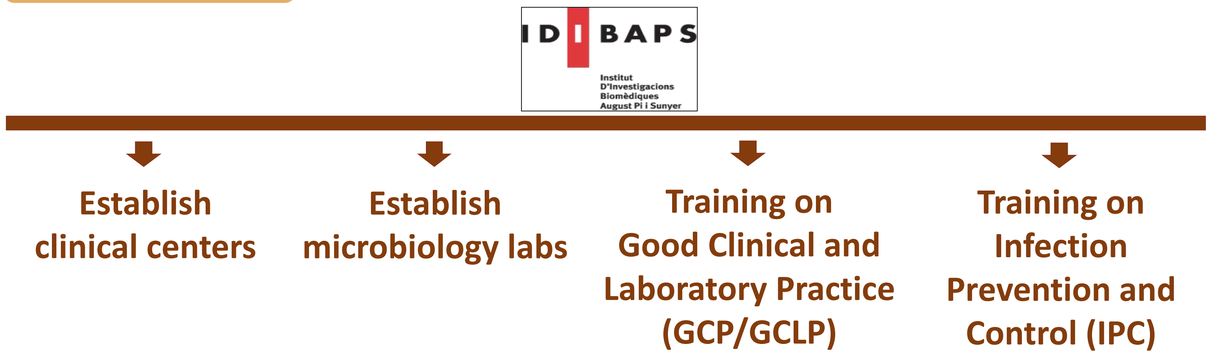

Figure 2. Main tasks in the Capacity Building work-package

Given that sites showed a **high level of heterogeneity**, both among countries and within them between referral and regional centres. CB activities had to be tailored to each individual centre, taking into close account: previous experience in clinical research, geographical location, levels of infrastructure- and resource-centralisation, network access to other institutions, and existing international collaborations.

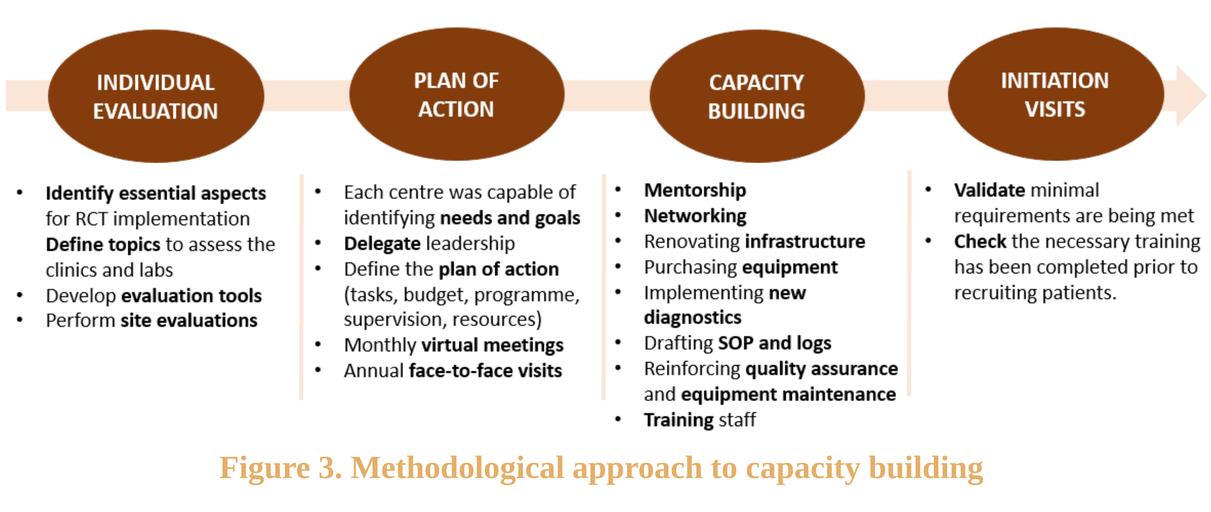

Figure 3. Methodological approach to capacity building

RESULTS RCT began in February 2021, after one-year delay imposed by the COVID-19 pandemic.

Currently, **11 out of 12 sites** have successfully initiated.

Figure 4. African sites participating in the INTENSE-TBM clinical trial.
11 sites initiated (in green) and 1 completing capacity building (in red)

Laboratories minimum requirements for compliance with the study protocol, standard guidelines, and GCLP were defined to standardise laboratory performance and to ensure confidence in the research to be conducted.

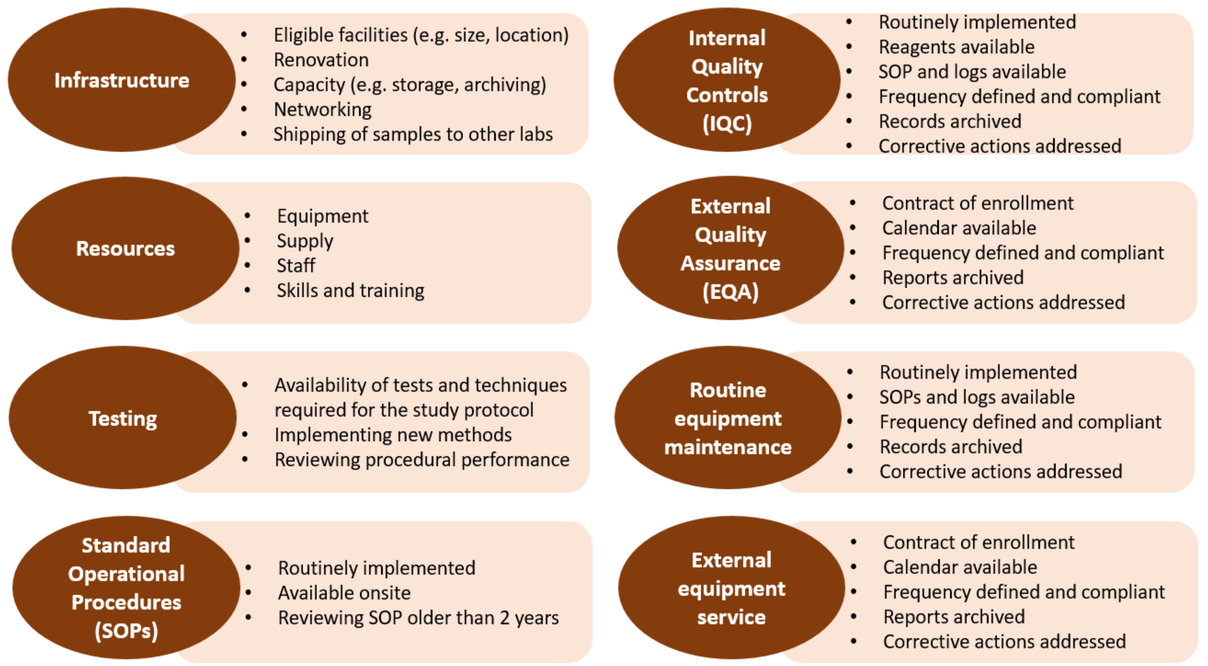

Figure 5. Requirements applied to laboratory standardisation

GCP and GCLP certification achievement levels were 96.6% (113/117) and 95·2% (40/42) of healthcare workers, respectively.

A large bilingual IPC training (hybrid on-line/on-site) was successfully performed. 95·2% healthcare workers completed the course (48 attendees out of 53 enrolled) .

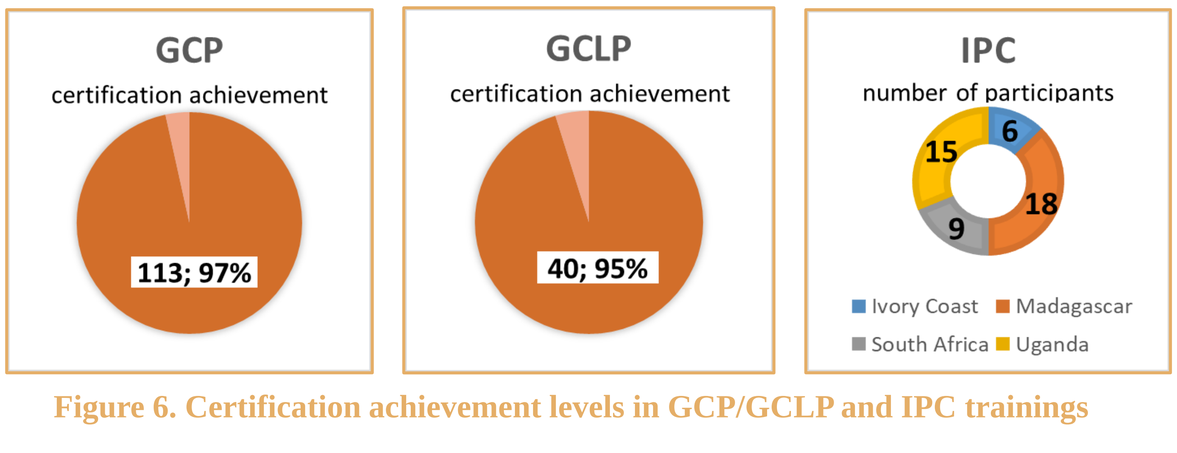

Figure 6. Certification achievement levels in GCP/GCLP and IPC trainings

CONCLUSIONS **Clinical research combined with CB is an effective strategy to promote fairer resource distribution, to redress healthcare inequalities, and to achieve minimum research capacity. Moreover, research platforms developed for a given disease (e.g., TBM and HIV) may later serve in tackling others (e.g., COVID-19).**

The INTENSE-TBM was capable to develop a competent CB program. Despite COVID-19, the RCT initiation was achieved at almost all sites, enhancing local healthcare systems and encouraging further clinical research in SSA.

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