

# **AB33 Building Laboratory Capacity in Africa: from Pilot study to Phase 3 MDP 301**

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## **ABSTRACT TEXT**

### **Background:**

African laboratories are increasingly performing the laboratory testing required for international trials. In general, these laboratories are not familiar with the intricacies of Good Laboratory Practice. Contract Laboratory Services (CLS) affiliated to the University of the Witwatersrand was contracted as a "Central Laboratory" to provide laboratory support for the local laboratories at the 6 clinical sites in the following African countries: South Africa (3 sites), Zambia, Uganda and Tanzania.

### **Objectives:**

This abstract describes the baseline status of 6 laboratories, which will be partaking in the MDP 301 study and the capacity built at those laboratories within 12 to 18 months. The most frequently encountered difficulties, while in the process of moving these laboratories to certification, will be defined.

### **Methods:**

For the baseline assessment, the laboratories were requested to complete a questionnaire, and this was followed by a site assessment visit. During the site visit recommendations were made regarding the requirements necessary for Good Laboratory Practice and Laboratory Certification for the phase 3 study. One year later a follow-up visit was performed and readiness of laboratories was re-assessed.

### **Results:**

2 of the 6 laboratories had good capacity at baseline (score > 70%), 3 of the 6 laboratories had a score of approximately 40% and one site was scored as weak (< 30%) in terms of laboratory capacity. The main criteria which needed to be addressed included: lack of sufficient number of staff trained in Good Clinical Laboratory Practice (GCLP), no standardized on-site testing methods, absence of adequate quality control procedures at on-site testing facilities and lacking courier networks. 12 months later, 4 of the 6 laboratories could be certified to start the phase 3 studies.

### **Conclusion:**

This experience demonstrates that MDP laboratory sites differed in their baseline capacity. However, achieving certification is feasible within a 12 to 18 month period, even for sites with a baseline score of < 50%. This has been achieved through "multilevel support" and training, co-ordinated by the Central Laboratory MDP project manager in collaboration with the site laboratory managers.

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