

**PA-121 IMPROVING EFFICIENCY AND QUALITY IN CLINICAL TRIALS IN SUB-SAHARAN AFRICA**

Nerina Vischer, Constanze Pfeiffer, Christian Burri. *Swiss TPH, Switzerland*

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**Background** Conduct of clinical trials is significantly regulated and requires substantial infrastructure and human resource investments and efforts. Clinical research centres in sub-Saharan Africa face particular challenges from the increasing trial-related workload and administration, paired with capacity limitations. We investigated the challenges in clinical trial conduct in sub-Saharan Africa to optimising efficiency of processes while maintaining quality. Our working hypothesis was that existing regulations, not adapted to these particular situations, and their possibly overly strict interpretation were the main challenge.

**Methods** We used an exploratory mixed methods design. Firstly, key informant interviews with questions about quality, guidelines, challenges, and inefficiencies in clinical trials were conducted with 60 clinical trial staff of different professional levels in two English- and two French-speaking African countries. Content analysis was performed to identify themes across settings and positions, respectively. Secondly, we developed an online survey to investigate trial protocol suitability based on the main interview themes and targeting trial staff working in sub-Saharan Africa.

**Results** According to the interviewees, constraints to trial efficiency arose from two themes: 'planning' (mainly poor planning and missing context-adaptation), and 'site organisation' (mainly staff turnover and workload). The two themes are of particular relevance since they relate only to sponsors and sites and are therefore independent of external conditions (e.g. lengthy approval processes and population issues). Unexpectedly, the administrative burden resulting from the guidelines was not perceived as a difficulty; rather, researchers were grateful for having guidance in their daily work. The online survey corroborated that trial protocols need to be adapted to local contexts by early involvement of the sites and careful consideration of local capacity, systems and conditions.

**Conclusions** Our data suggest that careful site assessment, appropriate and coherent planning, clear task allocation and management capacity strengthening may increase trial efficiency. Involvement of study sites in protocol development was perceived to be beneficial.