Health systems, operational, social and economic research

PO - (8564) - WHAT IS CLINICAL TRIAL QUALITY? A QUALITATIVE STUDY BASED ON INTERVIEWS WITH DIFFERENT STAKEHOLDERS CONDUCTING CLINICAL TRIALS IN SUB-SAHARAN AFRICA

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Background
There is no unified, broad definition for “quality” in clinical trials (CTs). Besides the explicit quality requirements in international guidelines and national legislation, however, there are broader factors to consider, including specific setting-related aspects influencing quality needs and perception and local implementation of guidelines. Our objective was to identify these factors from a resource-limited settings perspective (i.e., sub-Saharan Africa).

Methods
In March-April 2018, we conducted a qualitative study based on semi-structured interviews with participants from three stakeholder groups (monitors, sponsors, investigators) conducting CTs in sub-Saharan Africa (SSA). We identified the interviewees either through CT registry platforms, a web search or by reference. We aimed to include 10-20 participants per stakeholder group. After consent, the interviews were held in person, by Skype or phone, were recorded, and transcribed verbatim. The interview questionnaire addressed a CT quality definition and quality factors during the CT process. We performed the analysis using the framework method.

Results
So far, we included 21 participants (17 investigators, two sponsors, two monitors). Eight originated from SSA and 13 from Non-SSA countries and in total contributed to CTs in 19 different countries in SSA. Quality definitions mentioned so far were variable. A repeated statement was that the quality definition should be broad and include a system of multiple aspects and layers. We will interview more experts with sponsor and monitor experience in May 2018 and elaborate these quality aspects and layers. We will discuss these results with regards to a comprehensive quality framework for CTs currently under development for Northern countries by another Swiss research team.

Conclusions
The CT quality was perceived in variable ways, as did the relevance of the aspects across different CT steps. Structuring the multifaceted layers of CT quality will facilitate appropriate and efficient CT quality management in SSA.