PO - (8490) - PROMOTING GOOD DATA MANAGEMENT PRACTICES IN CLINICAL RESEARCH IN RESOURCE-POOR SETTINGS

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Background: Accurate and timely data management (DM) is of key importance in clinical research in order to generate high quality and GCP-compliant data for analysis and/or sharing. Our objective is to strengthen the capacity for DM in clinical research in resource-poor settings by organizing several teaching initiatives.

Methods: Our teaching initiatives have a twofold approach. First, a generic and comprehensive approach with capacity building on various thematic modules. These include a research component (overviewing the research data management procedures) and a technological component (introducing databases and software). In addition, a component on legislation, guidelines and standards specific towards DM is discussed, as well as a project management component on how to organize DM efficiently and timely. Second, we apply a more focused and study specific approach which details on roles and responsibilities in data management, milestones and documentation practices. Both approaches are based upon successful implementation in EDCTP funded clinical trials, such as the 4 ABC, PREGACT and Microbicide Safety Biomarkers studies, as well as the FP7 sponsored NIDIAG project. Its target audience comprises various study stakeholders such as data managers, IT administrators, clinicians, laboratory researchers and statisticians, coming from sub-Saharan Africa, South-East Asia and Latin America.

Results: A teaching model for promoting Good Data Management Practices has been developed with theory- and practice-based modules. This model is used at face to face workshops in remote settings and has been re-used by colleagues and implemented by other research institutions to promote further capacity building and sustainable development in the South. In addition it has led to mutual learning and enhanced institutional and personal North-South collaborations.

Conclusion: There is a clear case for promoting DM and to provide guidelines for Good Data Management Practices. Our twofold approach has enabled the successful conduct of GCP compliant non-commercial clinical trials in the South.