



Clinical data management and monitoring in clinical trials: the African experience

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Objectives



- To highlight aspects of clinic, laboratory, fieldwork and data management that are vital to the successful completion of clinical trials; unforeseen problems that can lead to premature or unsuccessful end to trials in Africa.



Methods



- Observational methods and
- Practical examples of several years of clinical monitoring and data management experiences gained from studies conducted in several institutions and countries in Africa (Including **The Gambia, Burkina Faso, Mali, Ghana, Tanzania and Uganda**) are discussed.



Results (1)



- Safety, rights, dignity and confidentiality of study participants
- Informed Consent
 - Community Influence
 - Head of Family Influence
 - Poverty & Fear
- Factors affecting Lost to Follow-up
 - Affects ITT and PP analysis
 - Affects power of the study



Results (2)



- Credible Data
 - Planning and coordination of various study activities and team
 - Careful monitoring of the quality of data collected, entered, cleaned, processed and archived.
- Clinical Monitoring: meet ICH GCP Standard
- IRB/IEC and Regulatory Bodies limitations
- Sufficient funding till end of study



Discussion & Conclusion



- Clinical trials in Africa are complex and expensive
- Basic GCP Principles, Rights, Safety, Dignity of the individual and Credible Data
- Respecting culture is essential for compliance in clinical trials in Africa.
- Most trials require follow ups of hundreds of people (phase II's and IIIs).
 - **Careful planning is needed in the conduct of clinical trials in order to avoid premature and unsuccessful end due to unforeseen circumstances.**
- Role of Clinical Monitoring and Data Management to success of trials in Africa have been underestimated



Future Perspectives



- Adequate pre-study preparations
 - Careful planning is needed in the conduct of clinical trials in order to avoid premature and unsuccessful end due to unforeseen circumstances.
- Understand the culture and possible adaptations of ICH GCP Guidelines for clinical trials in Africa
- Put systems in place that will allow meeting internal and external needs of the clinical trials in Africa.