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.