

Implementing Multi-Site Protocols: Challenges and Importance to the Scientific Community

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Outline

- Definition
- Importance
- Benefits to scientific community
- Challenges of implementation
- Dealing with challenges
- Conclusion



Definition

- “Sites” may be...
 - ...more than one country
 - ...more than one place (clinics, hospital)
 - ...more than one organization
 - ...a combination of the above.



Importance of multi-site protocols

- Larger sample sizes → increased statistical power.
- More rapid accrual & FUP → timely provision of crucial results.
- Facilitates investigation of diseases or exposures of low incidence.
- Enhances external validity and generalizability of study findings.

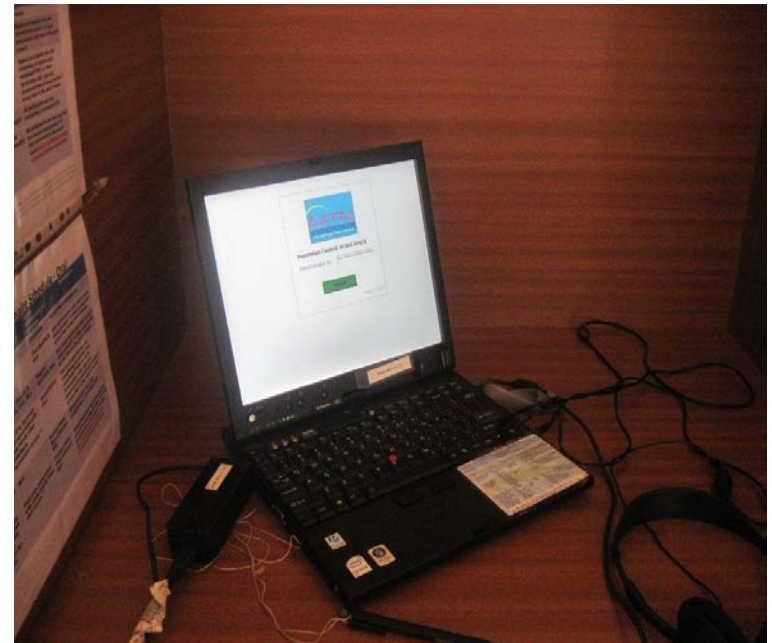


Benefits to scientific community

- ❑ **Synergies:** Combined strengths of different sites can provide a deeper resource pool than those available at each site.
- ❑ **Data sharing:** With the broader scientific community.
- ❑ **Data Quality Assurance:** Multiple layers of quality checks including SCHARP, FHI, Monitors, PSRT, MTN NL.

Benefits to scientific community

- **Benchmarks:** Development of standards such as new data formats, analysis of protocols & acquisition of new technology





New technology unique to Kampala

- **ACASI**; Exciting for the participants and staff gained experience.
- **DXA Machine**; 1st of its kind in Uganda, however it has come with its own challenges . . .

DXA machine

Monitor-**ERROR**
message



THE CAUSE



SOLUTION (Mouse Trapping Network)





Other benefits

- Working within time limits and deadlines.
 - *"Every delay must be treated as a lost opportunity"*
Sharon Hillier

- Staff motivation through awards at MTN meetings

- Travel experience, & net working with other site members during meetings.



Implementation challenges

- Operationalization of documents (ICFs, CRFs) difficult due to varying definitions & reliance on interpreters, differing application of concepts across sites
- Varying laws/ regulations at sites
- IRBs may view protocols from different perspectives
- Varying times of approvals & study initiation



Implementation Challenges

- Protocol and consent document changes may be made without local context consideration
- Coordination of sites – communication/ internet breaks
- Issues of data sharing and acknowledging local contribution
- Shipment of samples



Dealing with challenges

- Sites should be involved in the design and planning of these trials to give the local context
- Involvement of the CAB
- Use of simple language in consents to facilitate standardization & comprehension of information



Dealing with challenges

- Clear allocation of responsibilities and effective communication among all parties involved in the conduct of the study.
- Consult research guidelines (results publication & dissemination) for a given site.




Conclusion

- Study conduct, monitoring, & reporting present a number of potential challenges.
- Proper planning, communication & control of the study are of vital importance.



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