



Towards A Clinical Research Organization – Major Considerations And Challenges



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MRC track record of clinical trials 2004/08





Building a clinical trial/capacity development



- Training in proposal writing and budget development – adequate training/training courses available?
- What strengthening is needed based on current capacity?
- Geographical locations and potential sites – site readiness/sustainability
- Assessment tools for clinical trials capacity?
- Study feasibility – are you competing with other studies
- Special challenges in setting up and maintaining field sites



GCP and quality control



- Training and re-training courses
- Investigator qualifications
- Adequate resources
- Regulatory requirements
- GCP adherence
- Data records management
- Statistical and data analysis
- IRB review on ongoing trials
- Data and safety monitoring committees



Bioethics



- Informed consent
- Patient vulnerability
- Incentives for patients
- Investigators involved in trial - Financial relationship with sponsor/conflict of interest?
- Judging the real scientific value of the study (avoiding promotional studies)
- International standards to aim for?



Costing



- Infrastructure requirements – big ticket items
- Achieving and affording GLP?
- Laboratory accreditation: government or private sector.
- Adequate training in developing a budget
- Insurance considerations? No fault liability – who pays?
- Contingencies – how to budget for them.
- The institutional tax – what is reasonable and affordable?



Business model



- The product pipeline and what's needed in the near future – areas of special need
- Convergence of medical devices and pharmaceuticals
- Funding opportunities to set up the CRO – government (eg. DTI), funding agencies
- Sustainability of sites - What would increase the likelihood of extension and growth of sites? How to prevent languishing of sites that have already been established?
- Essential staffing?
- 'Relationship' with MRC
- Governance
- Profitability/Not-for-profit



Outcomes of workshop (I)



Conditions of success:

- draw on the collective competence available to the MRC
- meet the national need in the public sector, which would include HIV/AIDS, tuberculosis (including the drug-resistant forms), cancer, diabetes mellitus, diarrhoeal diseases and meningitis, amongst others;
- niche areas should be developed and addressed;
- initiative would be non-profit, in that all profits would be ploughed back into research;
- all activities would be contracted and pursued in the spirit of scientific excellence;
- self-supporting



Outcomes of workshop (II)



Challenges:

- activities must be confined to true science and clinical research;
- enlightened approaches to budgeting and costing;
- ownership issues, including intellectual property of communities;
- limits to clinical trial capacity in the country;
- excellent systems of data management need to be put in place;
- reform of the regulatory process;
- need for assessment tools for clinical trials capacity;
- insurance of patients has to be put in place, including no fault liability;
- policies are needed regarding institutional overheads; and a business and funding plan would be necessary