

***tropEd* Masters Programme in International Health**

**Practical implementation of a clinical trial
in a resource-poor country.**

**From a systematic evaluation of *ProCort 1 – Clinical Trial* to a
general checklist of dos and don'ts for the support of
independent and autonomous local research teams.**

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Abstract

Introduction: Medical research in developing countries is generally considered important not only to investigate health problems and diseases of this context but also to improve health care in these countries. As research capacities are comparatively weak and the conditions difficult due to scarcity of technology and adequately trained personnel, the intention of this thesis is to contribute to the implementation of quality research in resource-poor settings. The focus is on the practical implementation of clinical trials performed in collaboration of local institutes and international non-profit partners and on the development of autonomous and independent research structures. For this study, experiences from the practical implementation of *ProCort 1 - Clinical Trial* were systematically evaluated. On the basis of this evaluation and of improvements and the further development of the project, a checklist of things to do and to consider when performing comparable projects in countries with limited resources got produced.

ProCort 1 is a prospective, randomised, double-blind clinical trial to investigate the development of HIV disease under low-dose treatment of prednisolone, performed by Bugando Medical Centre in Mwanza Tanzania and Medical Mission Institute Wuerzburg, Germany. The author was working as a supervisor and clinical trainer of the study physicians in the study centre during the phase of start of recruitment of patients in June and July 2007.

Methods: The systematic evaluation of the project focusses on four strategic targets and is inspired by the “Balanced Score Card Approach” of Norton and Kaplan. Targets: 1. achievement of valid results 2. efficiency of implemented processes 3. warranty of the study protocol and international standards as e.g. GCP. 4. development/improvement of autonomous and independent research capacities in the study centres.

Recommendations for improvements on the different sectors of the project (local coordination, human resources management, patient monitoring, laboratory, etc.) got developed under consideration of different experiences and published literature. After review of the further development of the trial after

2007, the checklist got produced and will be presented and discussed here.

Analysis and findings: During the phase of initiation of ProCort 1, difficulties related to the weakness of local coordination structures, to communication problems and to relevant dependence of the local team on the international partner got visible. Based on the trustful relationship between the partners as well as professional study implementation and additional improvements after June/July 2007, the local study team developed into an autonomous and effective body who recruited and monitored 321 patients. There is evidence to base such research collaboration projects on transparent and mutually agreed sharing of objectives, responsibilities, tasks and benefits of the project. This includes especially the development of local autonomous collaborators. All study-related activities that can be managed in the local study centre should be managed there while the international partner should focus especially on contribution of technical experience in quality research implementation, supervision, training and organisation of funding and other issues that cannot be performed by the local partner. The nature of the approach should be well communicated to the whole team to achieve maximum understanding, cooperation and motivation of all collaborators.

Conclusion: The progress of the ProCort 1 trial improved especially when more responsibility was taken over by local team members ("local coordinator") and when planning and preparations materialised into visible activities.

The achieved "checklist" is not a complete guideline for the implementation of clinical research projects as it would be suitable for an executing team but rather a tool to ensure that a project is being implemented in a proper way and that major errors and misunderstandings are avoided. It provides advice for practical aspects in order to support the development of effectively and efficiently working, autonomous and independent study teams in the field of development cooperation.