

The Management and Organization of Clinical Trials

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This research responds to growing concerns expressed by UK scientists, clinicians and industrialists about the ‘translational gap’ between basic scientific discovery and innovations that will directly benefit patients, and about the decline of the UK’s clinical research base. This ‘translational gap’ *“can only be bridged through the successful application of clinical research, testing and evaluating new concepts and interventions at the bedside and in carefully managed clinical trials”* (AMR, 2003).

The management of clinical trials, however, entails complex networks of relationships often operating on a global basis and increasingly involving large clinical research organizations and/or other service providers working together with industry managers, scientists, clinicians and patient groups, all under tight regulatory approval. Such ‘networked innovation’ processes pose major co-ordination challenges. For example, a recent survey found contract negotiation and approval to be the major cause of delay, even more so than oft-cited patient recruitment problems (CenterWatch, 2006).

This project offers unique systematic research on the processes required to manage and organize different kinds of trials, and the impact on clinical trials management of wider structural changes (e.g. global outsourcing to large CROs) and shifts in regulation in the last decade. Our previous research suggests that industry and academic research organizations often lack required knowledge in trials management. This research will provide a better understanding of how and why trials fail and what kinds of management and organization support success.

The study, which will employ a multi-method design, is in collaboration with the Warwick Clinical Trials Unit, the Institute of Clinical Research (ICR) and the Association of the British Pharmaceutical Industry (ABPI) and will provide much needed policy advice on the challenges of trials management. The overall aim is to identify the major social, organizational and managerial factors that influence clinical trials with a view to improving the clinical research process for key stakeholders involved, including industry, innovating scientists and clinicians, and the NHS.

The specific objectives are to:

1. Map alternative models of clinical research and identify the key challenges they generate.
2. Identify barriers and enablers to clinical trials management in the UK clinical research sector.
3. Identify the macro economic and policy drivers of the move toward outsourcing of clinical trials and consider the implications of this for clinical trials management.
4. Develop new theory on ‘networked innovation’, focusing on clinical research as an exemplar.
5. Produce practically useful reports/briefings for UK Policy Makers, Clinical Research Directors/Managers and focal Professional Associations on the status of the UK clinical research base, focusing on requirements for the successful management and organization of clinical trials in the face of medium term economic, regulatory and policy constraints.

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