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"Clinical Operations: Benchmarking Per-Patient Trial Costs, Staffing and Adaptive Design"

Cutting Edge Information, 2011, 174 pages, $7,695

Review by Norman M. Goldfarb

"Clinical Operations: Benchmarking Per-Patient Trial Costs, Staffing and Adaptive Design" offers numerous process improvement recommendations. The authors surveyed people from 65 pharmaceutical, biotech, medical device and CRO companies. The report includes analysis of over 100 charts and figures in six sections:

- Executive Summary
- Clinical Trial Costs and Outsourcing
- Clinical Trial Staffing Benchmarks
- Clinical Trial Performance Measurement
- Adaptive Clinical Trial Design
- Continuous Process Improvement: Trial Planning to Study Close Out

Some of the many insights in the report include the following:

- Some sponsors have created internal CROs, called clinical research units (CRUs) or clinical science units (CSAs), that compete with external CROs for the company's work.
- In Phase 2 studies, respondents reported outsourcing 63% of costs (62% of staffing), up from 36% in the 2008 report.
- Cost per subject increased substantially (with wide variations across respondents), partly due to a shift in research to more expensive therapeutic areas like oncology and CNS.
- Only 26% of respondents were conducting adaptive clinical trials, despite the fact that 100% agreed that they are more effective than traditional designs. Most respondents reported reductions in project cost and time, but two had unfortunate experiences in which both cost and time increased. The two most popular study designs were adaptive group sequential design (early stopping) and adaptive dose-escalation design.

A few of the process improvement recommendations include:

- Minimize protocol development timelines by making key design decisions early, reducing the number of people involved, and clarifying responsibilities.
- Accelerate trials by eliminating "nice to have" data collection and involving biostatisticians in the planning phase.
- Speed case report form (CRF) development by creating a library of standard modules.
- Ease investigator meeting scheduling by limiting sponsor and supplier invitations to essential personnel.
- Facilitate the medical writing process by inviting medical writers to clinical data review meetings.

The report is available at http://www.cuttingedgeinfo.com.

Reviewer

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