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"Can You Handle the Truth?"

## **"Clinical Operations: Accelerating Trials, Allocating Resources & Measuring Performance"**

**Cutting Edge Information, September 2006, 182 pages, \$6,995**

**Review by Norman M. Goldfarb**

"Clinical Operations: Accelerating Trials, Allocating Resources & Measuring Performance" is a terrific source of metrics and process improvement recommendations. If you are a director of clinical operations, you definitely want to read this report before your boss does.

The authors surveyed over 100 clinical development executives and personnel from 37 pharmaceutical and biotech companies. Data is presented in 94 tables and figures. Much of the analysis is broken out by therapeutic area.

The report is divided into four sections:

- Clinical Trial Resource Allocation
- Clinical Trial Performance Measurement
- Continuous Process Improvement
- Recruiting and Retaining Patients and Investigators

Clinical research is definitely expensive, even disregarding the cost of capital and allocations for failed trials behind commonly cited numbers such as \$800 million per drug. According to respondents to this survey, it costs:

- \$12,630 per Phase I subject
- \$26,050 per Phase II subject
- \$19,320 per Phase III subject
- \$15,690 per Phase IV subject

Per-subject costs vary substantially by therapeutic area, in Phase III ranging from \$15,000 for analgesia and rheumatology studies to \$42,000 for CNS and psychiatry studies.

Outsourcing is definitely prevalent, with an average of roughly 60% of budget and 40% of staff outsourced. Outsourcing varies widely by therapeutic area, ranging from 20% of budget in oncology studies to 90% of budget in musculoskeletal studies. The outsourcing trend continues strong, up from 42% of budget in a previous 2004 survey.

Research sponsors use a wide variety of metrics to measure clinical trial performance. Interestingly, the most popular metrics are used by only about three-quarters of study sponsors:

- Time from last subject out to database lock (80%)
- Time to enroll a target number of subjects (80%)
- Time from statistics tables complete to trial report complete (73%)
- Time from first subject in to last subject in (73%)
- Time to completion of trial (73%)
- Budget to completion of trial (73%)
- Subjects per CRA (73%)

Many respondents identify protocol design as a process that takes too long and yields weak protocols that collect the wrong data, require costly amendments, or yield uninterpretable results.

The data cleaning process in many companies is decentralized. In the absence of adequate management software, query counts and status are unknown, work may be duplicated, and sites may even receive duplicate queries.

One clever subject retention technique is to give subjects a puzzle to solve at each visit; they get the answer and a modest prize at the next visit.

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

### **Reviewer**

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or [ngoldfarb@firstclinical.com](mailto:ngoldfarb@firstclinical.com).