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"Can You Handle the Truth?"

"Phase IV Clinical Trials: Post-Marketing Study Management Structure, Strategy and Benchmarks"

Cutting Edge Information, July 2006, 152 pages, \$6,995.00

Review by Norman M. Goldfarb

"Phase IV Clinical Trials: Post-Marketing Study Management Structure, Strategy and Benchmarks" offers comprehensive insights, benchmarking metrics, and "how-to" advice for companies that want higher rewards and lower risks from their Phase IV clinical research.

Phase IV trials help companies expand their markets, differentiate their products, and collect large-scale safety data. It is the fastest-growing segment of clinical trial activity (23% per year), with more trials starting in 2006 than in all other phases combined.

The authors surveyed post-marketing study and medical affairs executives from 24 pharmaceutical, biotech, medical device, and contract research (CRO) companies in 13 therapeutic areas. Of 39 studies analyzed, 34 were interventional and four were registries. Data is presented in 93 tables and charts. The report covers five topics:

- Trial management structure and oversight
- Research strategy
- Study design and execution
- Study timelines and cycle times
- Performance metrics and management
- Operational activities
- Trial budgeting and outsourcing
- Trial staffing

Phase IV cardiovascular studies sponsored by large companies are, by far, the largest, averaging 2,705 subjects. The next largest trials, again by large companies, are in endocrinology, with only 1,228 subjects on average. Over all therapeutic areas, large companies average 848 subjects per trial, compared to 456 for mid-sized companies, and 115 for small companies. Perhaps bigger companies can afford bigger trials (that identify smaller differences and therefore require more subjects) because they play in bigger markets where small percentage increases in sales pay off in large numbers of dollars.

Phase IV trials account for 14% of total R&D spending at the surveyed companies. Average cost/subject ranges from \$8,000 in hematology to \$20,000 in CNS/psychiatry and endocrinology. Surveyed companies average 36 subjects per FTE employee (including CRO employees). The typical CRA monitors eight sites with 160 subjects.

Over half of the surveyed companies rate their Phase IV planning and execution performance average to poor, so there is clearly room for improvement, and these are companies that care enough about Phase IV to participate in the survey.

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

Reviewer

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