JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 3, No. 5, May 2007 "Can You Handle the Truth?"

"Strategic Research: A Practical Handbook for Phase IIIB and Phase IV Clinical Studies"

Hugo Stephenson, 2005, 173 pages, Quintiles Transnational, $5.95

Review by Norman M. Goldfarb

"Strategic Research: A Practical Handbook for Phase IIIB and Phase IV Clinical Studies" will open the eyes of anyone unfamiliar with the possibilities and limitations of last-stage research. Phase IV is not just Phase III on a diet. Nor is it a license for the marketing department to run amok. Phase II and Phase IV are almost different worlds, with their own scientific objectives, regulatory constraints, and practical circumstances.

This book is intended for anyone involved in designing or managing last-stage clinical research studies. Many a Phase IV ship has sunk because the captain had not learned the lessons in this book.

This book has been selected for

The First Clinical Research Bookshelf

Essential reading for clinical research professionals

Phase IIIB research is research conducted after a marketing application (NDA) has been submitted to the FDA. Phase IV research is research conducted after the FDA has approved the application, within the limitations of the label. While spending on Phase II and Phase III research has been growing at about 7% per year, spending on Phase IIIB and Phase IV research has been growing at almost triple that rate – 20% per year.

The book provides a wealth of practical advice, such as:

- To avoid delays, prepare a portfolio of possible Phase IV protocols before a drug is approved.
- Simplify the paperwork for investigators, and then simplify it further. For example, it is easier to collect age than birth date. A full C.V. can be replaced with a short form.
- Investigator and subject motivation typically drops after a drug is approved, and again after reimbursement becomes available, so plan to reduce the workload or increase incentives accordingly.
- Using the sales force to collect study forms increases opportunities for interaction with investigators, but also annoyance; investigators are more interested in hearing about the progress and results of their studies.

The book has 15 chapters:

- What is Strategic Research?
- Why is it Growing?
- What Makes it Different?
- Design Possibilities
- Regulatory Considerations
- Maximizing Value
- Minimizing Risk
- Optimizing Site Performance

- Minimizing Study Workload
- Maximizing Investigator Motivation
- Working with Market Changes
- Registries
- Expanded Access Programs
- Post-Marketing Surveillance
- Conclusion: In the Wake of Vioxx

The book is available at Amazon.com.

Reviewer

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