

"Strategic Clinical Development Planning: Designing Programs for Winning Products"

William K. Sietsema, 2005, 159 pages, FDAnews, \$245.00

Review by Norman M. Goldfarb

"Strategic Clinical Development Planning: Designing Programs for Winning Products" is volume 1 of a five-volume series relating to interaction with the FDA. Although most useful for executives charged with leading new drugs through the clinical research process, it is must-reading for anyone who wants a strategic understanding of clinical research. It is easy for people to focus on their small part of the process. By helping readers see the big picture, this book gives meaning to their lives, or at least helps interpret some of management's crazy decisions. The book is easy to read, and well worth the investment two or three hours.

The key insight in the book is the concept of "reverse engineering".

In manufacturing industries,

reverse engineering is the process

of "unbuilding" competitors' products to see how they work, and then rebuilding your own version without violating their patents. Dr. Sietsema, however, uses the term to mean you shouldn't start marching down the clinical research road without first knowing where you want to go. In other words, first determine who your customers will be and what they want. If your market research says your customers will be elderly women who want once-daily dosing, then design your clinical research program accordingly. Determine what data is required to support your FDA application for that population and dosing regime. Then work your way back through each study phase, knowing what data are required to move to the subsequent phase.

Topics covered include:

- Overview of the Clinical Research Development Process
- Market Research and Focus Groups
- The Package Insert
- Phase 1 Studies
- Proof-of-Concept Studies
- Choosing Clinical Endpoints
- Phase 2 Studies
- Phased 3 Studies
- Drug-Drug Interaction Studies
- Organ Impairment Studies
- Special Populations
- Pharmacokinetics, Metabolism and Bioavailability
- Phase 3b Studies
- Phase 4 Studies
- Healthcare Utilization and Pharmacoeconomic Studies
- Rx to OTC Switches
- Blinding Clinical Studies
- Ethics, Institutional Review Boards, and Independent Ethics Committees and the Informed Consent Process

This book has been selected for
[The First Clinical Research Bookshelf](#)
Essential reading for clinical research professionals

- Estimating Program Timing and Costs
- Life Cycle Management

The book is available at <http://www.fdanews.com/wbi/books-drug>.

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