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Vol. 4, No. 2, February 2008 "Can You Handle the Truth?"

"Statistical Thinking for Non-Statisticians in Drug Regulation"

Richard Kay, 2007, 276 pages, John Wiley & Sons, $80.00

Review by Norman M. Goldfarb

"Statistical Thinking for Non-Statisticians in Drug Regulation" will have to do until someone invents a way to insert statistics knowledge directly into the brain. The book is designed to help non-statisticians communicate with statisticians, understand scientific articles, and participate intelligently in discussions with regulators.

The book covers the topic step by step in relatively bite-sized pieces. Thirty-four examples supplement the explanations. Nevertheless, there are some difficult concepts for civilians, so readers will have to pay attention.

This passage illustrates the author's expository style:

> One potentially confusing issue here is that there are two standard deviations; one measures the patient-to-patient variability from a single sample/trial while the second estimates the mean-to-mean variation that you would get by repeating the sampling exercise. To help distinguish the two, we reserve the term *standard deviation* for the first of these (patient-to-patient variation), and we call the second *standard error* (se) (mean-to-mean variation).

The book includes 16 chapters:

- Basic ideas in clinical trial design
- Sampling and inferential statistics
- Confidence intervals and p-values
- Tests for simple treatment comparisons
- Multi-centre trials
- Adjusted analyses and analysis of covariance
- Intention-to-treat and analysis sets
- Power and sample size
- Statistical significance and clinical importance
- Multiple testing
- Non-parametric and related methods
- Equivalence and non-inferiority
- The analysis of survival data
- Interim analysis and data monitoring committees
- Meta-analysis
- The role of statistics and statisticians

The book is available in bookstores.

Reviewer

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