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"Can You Handle the Truth?"

## "Introduction to the Drug Approval Process & Clinical Research Dictionary"

**Clinical Research Resources, 2005, 200 pages, \$13.95**

**Review by Norman M. Goldfarb**

"Introduction to the Drug Approval Process & Clinical Research Dictionary" is a combination of two books:

- Description of FDA drug review and approval processes
- Dictionary of clinical research terms

Attention other publishers! This book's price is so low it almost makes sense to buy a separate copy for each section.

The drug approval process section (83 pages) begins with a brief description of the drug discovery process. It focuses on IND (Investigational New Drug) and NDA (New Drug Application) reviews for clinical research and marketing approvals, respectively. It also covers generic drug reviews, post-marketing surveillance, orphan drug rules, and other topics. It includes six excellent flow charts that summarize the review and approval processes.

The clinical research dictionary (133 pages) is a fairly complete compilation of over 1,200 terms and acronyms related to clinical research and pharmaceutical R&D. The definitions are clearly written and sometimes provide additional explanatory information, for example:

**Data Coordination Center (DCC).** A centralized organization or part of an organization responsible for coordinating and managing data collected during a clinical study. DCCs are particularly useful when the study is conducted by multiple investigators and/or at multiple locations.

The book is available at [www.clinicalresearchresources.com](http://www.clinicalresearchresources.com).

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