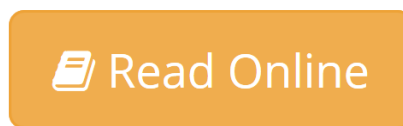


## Practical Guide to Clinical Data Management, Third Edition

By Susanne Prokscha



**Practical Guide to Clinical Data Management, Third Edition** By Susanne Prokscha

The management of clinical data, from its collection during a trial to its extraction for analysis, has become a critical element in the steps to prepare a regulatory submission and to obtain approval to market a treatment. Groundbreaking on its initial publication nearly fourteen years ago, and evolving with the field in each iteration since then, the third edition of **Practical Guide to Clinical Data Management** includes important updates to all chapters to reflect the current industry approach to using electronic data capture (EDC) for most studies.

See what's new in the Third Edition:

- A chapter on the clinical trial process that explains the high level flow of a clinical trial from creation of the protocol through the study lock and provides the context for the clinical data management activities that follow
- Reorganized content reflects an industry trend that divides training and standard operating procedures for clinical data management into the categories of study startup, study conduct, and study closeout
- Coverage of current industry and Food and Drug Administration (FDA) approaches and concerns

The book provides a comprehensive overview of the tasks involved in clinical data management and the computer systems used to perform those tasks. It also details the context of regulations that guide how those systems are used and how those regulations are applied to their installation and maintenance.

Keeping the coverage practical rather than academic, the author hones in on the most critical information that impacts clinical trial conduct, providing a full end-to-end overview or introduction for clinical data managers.

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## Practical Guide to Clinical Data Management, Third Edition By Susanne Prokscha Bibliography

- Sales Rank: #205033 in Books
- Brand: Brand: CRC Press
- Published on: 2011-10-26
- Original language: English
- Number of items: 1
- Dimensions: 9.50" h x 6.25" w x .75" l, 1.20 pounds
- Binding: Hardcover
- 296 pages

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About the Author

**Susanne Prokscha** is an Independent Consultant working with Genentech in South San Francisco, California.

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