

Practical Guide to Clinical Data Management, Second Edition

By Susanne Prokscha



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A new chapter on Necessary Infrastructure, which addresses the expectations of the FDA and auditors for how data management groups carry out their work in compliance with regulations

The edition has been reorganized, covering the basic data management tasks that all data managers must understand. It also focuses on the computer systems, including EDC, that data management groups use and the special procedures that must be in place to support those systems. Every chapter presents a range of successful and, above all, practical options for each element of the process or task.

Focusing on responsibilities that data managers have today, this edition provides practitioners with an approach that will help them conduct their work with efficiency and quality.

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