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"Can You Handle the Truth?"

"A Clinical Trials Manual from the Duke Clinical Research Institute: Lessons from a Horse Named Jim, 2nd Edition"

Margaret B. Liu and Kate Davis, 2010, 406 pages, Wiley-Blackwell, \$69.95

Review by Norman M. Goldfarb

"A Clinical Trials Manual from the Duke Clinical Research Institute: Lessons from a Horse Named Jim, 2nd Edition" is a good introduction to clinical research, primarily from the site perspective. The book gives readers a solid foundation of principles and knowledge. However, it does not include the practical tips and odd details that add such enchanting complexity to the clinical research enterprise.

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

By the way, the horse named Jim was used in 1901 to prepare an antitoxin for diphtheria. Unfortunately for Jim and the 13 children who received the antitoxin, the horse was also infected with tetanus. Their deaths led to creation of the Biologics Control Act of 1902.

The book consists of 15 chapters:

- Lessons from a Horse Named Jim and Other Events in History Affecting the Regulation of Clinical Research
- The Process: Developing New Drugs, Biologics and Devices
- Good Clinical Practice and the Regulations
- Informed Consent and the Regulations
- Institutional Review Boards
- Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others
- Monitoring, Audits and Inspections
- The Principal Investigator, the Clinical Research Coordinator, and the Study Site
- The Protocol
- Study Feasibility: Reviewing a Specific Protocol
- Study Activities
- Study Documents/Essential Documents
- Management of Study Drugs, Biologics and Devices
- Managing Clinical Trial Data
- Global Health and International Trials

The book is available in bookstores.

Reviewer

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