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"A Practical Guide to Human Research and Clinical Trials"

M. U. R. Naidu and P. Usha Rani, editors, 2013, 327 pages, CRC Press, $145.95

Review by Norman M. Goldfarb

"Practical Guide to Human Research and Clinical Trials" provides a broad introduction to clinical research by eight contributors from Hyderabad, India. The book was originally published in India in 2009. It appears that the contents have not been updated for this edition. The book would have been well-served by an attentive, native English-speaking copy editor. Nevertheless, the authors clearly have solid expertise in their topics.

While the book is mostly an overview, it does cover topics not included in most introductory texts, for example the following excerpt from the chapter on case report forms:

> **CRF Design Layout**
>
> There are three types of data: non-time dependent, time dependent, and cumulative data.
>
> **Non-time dependent data:** Non-time dependent data is the data collected at a snapshot in time. Such data include subject demographics and medical history.
>
> **Time dependent data:** Time dependent data is data collected repeatedly over time. A typical example is vital signs recorded at multiple visits. With time dependent data, there are 2 options to the CRF layout: Single page, per visit or a cumulative log. With the first approach, the data is represented at each visit while the second approach is a single page with multiple records representing the "repeated" time measurements. Both approaches have pros and cons. The "per-visit" approach more accurately reflects the schedule of assessments but could lead to a larger [CRF? (text missing)].
>
> **CRF booklet:** The "cumulative log" approach saves number of pages in a CRF booklet and makes variables structured in the same way as the CRF page in the database. However, since it does not allow the CRF retrieval as "per-visit," it may be inconvenient for investigators to frequently flip over pages from the log section to the actual visit section. It also restricts retrieval of data for a plan of data review by scheduled visits. Furthermore, it is more likely to yield data entry errors if too many fields are combined into one page and become cluttered. The "per-visit" approach is preferred for assessments, such as physical examination or laboratory data as they involve many parameters. The "cumulative log" approach may be preferred for groups of assessments, such as vital signs, which involve a fewer number of parameters. Cumulative data: Cumulative data is data collected over time but not linked to a specific visit. Adverse events and concomitant medications are typical examples. The usual approach to designing a CRF for cumulative data is the "cumulative log" approach described in the previous section.

The book consists of 26 chapters:

- Clinical Research – A Clinical Investigator's Perspective
- Medical Device Development, Process and Regulation
- Pre-Clinical Drug Development
- Phases of Clinical Trials
- Microdosing Studies

- Clinical Research Planning
- Clinical Research Design
- Clinical Research Protocol
- Designing Case Report Forms
- Process of Randomization in Clinical Trials
- Investigational Medicinal Products
- Multi-Center Clinical Trials
- Good Clinical Practice
- Role and Responsibilities of Sponsor
- Role and Responsibilities of Principal Investigator
- Ethical Consideration in Clinical Research – Special Reference to Developing Countries
- Informed Consent in Clinical Research
- Monitoring in Clinical Trials
- Quality Assurance in Clinical Research
- Pharmacovigilance and Drug Safety
- Data and Safety Monitoring Board and Monitoring Plan
- Standard Operating Procedures
- Archiving Clinical Research Documents
- Evidence-Based Medicine
- Clinical Research Data Management
- Clinical Biostatistics

The book is available in bookstores.

Reviewer

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