

“Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk”

Michael J. Klepper and Barton Cobert, editors, 2010, 312 pages, Jones & Bartlett Learning, \$74.95

Review by Norman M. Goldfarb

“Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk” demonstrates how clinical research books should be written, with a practical, straightforward and comprehensive explanation of the collection, preparation, analysis and interpretation of safety data. The book covers both drug development and post-marketing safety.

Examples of practical tips include:

Data mining is a useful tool that helps identify cases that warrant further review. Data mining can generate many false signals or miss important ones and therefore cannot be a substitute for proper case review.

Red blood cells are a rich source of intracellular potassium, and if left too long before processing, the cells can rupture (hemolyze) and release potassium into the plasma. This can result in a spuriously high potassium value (false result) that may mislead one into thinking the patient is at risk of going into cardiac arrest. If the patient has normal creatinine and BUN values (normal renal function) and no evidence of metabolic acidosis, hemolysis due to a lab processing error is a likely culprit.

Liver function tests, lipids (excluding high-density lipoproteins), uric acid, creatinine kinase, and creatinine values that shift to below normal values are usually of little or no clinical importance.

It is both useful and reviewer friendly to group and display laboratory parameters that measure the same organ system or similar physiological functions together rather than in alphabetical order. This helps in the identification of data trends and patterns.

The book includes 25 chapters:

- Benefit-Risk
- Begin at the End
- The Dynamic Integrated Safety Database — Something You Shouldn't Live Without
- Coding Basics
- Determining Causality — The Individual
- Determining Causality — Aggregate Data
- Determining the Weight of Evidence — Patterns and Links
- Determining Clinical Significance...and Then What?
- Clinical Laboratory Tests — What is Measured; What It Means
- 12-Lead Electrocardiograms — What is Measured; What It Means
- Adverse Events that Should be on Everyone's Radar Screen

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Essential reading for clinical research professionals

- Exposure
- Demographics and Other Baseline Characteristics
- Disposition
- Adverse Events Part 1: Common Adverse Events
- Adverse Events Part 2: Deaths, Other Serious Adverse Events, Other Significant Adverse Events, and Analysis of Adverse Events by Organ System or Syndrome
- The Analysis of Laboratory Data
- The Analysis of Vital Signs, Physical Findings, and Other Observations Related to Safety
- The Analysis of Electrocardiogram Data
- Safety in Special Groups and Situations — Intrinsic Factors, Extrinsic Factors, and Drug Interactions
- Use in Pregnancy and Lactation
- Overdose
- Drug Abuse
- Withdrawal and Rebound
- Effect on Ability to Drive or Operate Machinery or Impairment of Mental Ability

Five appendices present sample reports for a fictional drug. The book is available in bookstores.

Reviewer

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