

"Clinical Trials in the Neurosciences"

Katherine M. Woodbury-Harris and Bruce M. Coull, editors, 2009, 213 pages, Karger, \$228

Review by Norman M. Goldfarb

"Clinical Trials in the Neurosciences" is a brief primer on clinical research for neurologists and neurosurgeons. The selection of topics indicates the editors' support for multidisciplinary and multicenter clinical trials, e.g., with the essay, "Committees for Multicenter Trials." Many of the essays are not specific to neuroscience but may utilize neuroscience examples. Most of the essays about specific therapeutic areas and imaging techniques are descriptive, not prescriptive. The best essays are specific to neuroscience and give practical advice. For example, the essay, "Behavioral/Neuropsychological Outcomes and Quality of Life Endpoints," includes these two excerpts:

A word of caution: a test can exhibit high face validity but in fact have low construct validity. This means that a test can look, on the surface, as though it measures a certain skill (that is, face validity) but turns out to measure a different construct. For example, a timed test of visuospatial construction that requires rapid processing may, in fact, be measuring speed of processing and not visuospatial skills in individuals with motor slowing, such as those with Parkinson's disease. Thus, it is important to make sure that face validity mirrors the construct under investigation.

There are several important reasons to assess mood state when examining mental status change. First, depression, anxiety and apathy can directly impact cognitive performance and confound a study, masking a subject's true ability. Second, an investigator may want to measure mood state to exclude subjects exhibiting clinically significant symptomatology... Third, mood states often mirror cognition and may serve as an important indicator of mental status change...

The essay, "Role of Animal Studies in the Design of Clinical Trials," includes a table for assessing pain in rodents after cranial surgery. Anyone with a pet rodent should keep an eye open for the milder signs of stumbling, hugging the sides of the cage, occasional vocalization, pulling head back, kicking at the owner, decreased appetite, and minimal cage exploration. These signs demonstrate why animal trials have limited predictive value for humans since they describe the typical human teenager in a bad mood.

The book includes 35 essays by 45 contributors in eight sections:

- Introduction (2 essays)
- Preclinical Trials (4 essays)
- Pilot Trials (2 essays)
- The Randomized Blinded Trial (7 essays)
- Multicenter Trials (10 essays)
- Special Populations and Genetic Studies (6 essays)
- Imaging (3 essays)
- Training and Education (1 essays)

The book is available in bookstores.

Reviewer

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