Marc Hertzman and Lawrence Adler, editors, 2010, 404 pages, Wiley, $104.95
Review by Norman M. Goldfarb

“Clinical Trials in Psychopharmacology: A Better Brain, 2nd Edition” is not a traditional clinical research how-to manual tailored for a specific therapeutic area. Rather, it goes into depth on medical, scientific and operational issues pertaining to clinical trials in psychopharmacology, as in the following passages:

This lack of biological validity in diagnostic entities has direct critical implications in clinical practice and pharmacological trials. For instance, current clinical categories are not effective in everyday practice for predicting the course of mood disorders. Long-term follow-up studies have shown that the course of depressive disorders is rarely clear cut [3]. The majority of patients display a complex sequence of sub-threshold depression, dysthymia and major depressive episodes. Of note, one study showed that many outpatients with a major depressive episode remit without any medication within three months [34]. Numerous patients obviously do not fit into our current nosology.

While the presence of each type of comorbidity — alcohol abuse, substance abuse, or a comorbid anxiety disorder — can yield a more difficult-to-treat bipolar disorder with a less favorable prognosis than in those without these comorbidities, the complexity of illness presentations and the designs required to deal with them has led to a virtual absence of study of these comorbid states in those with bipolar illness. Thus, attempts to generate highly homogeneous patient populations for clinical trial studies has led to a loss of generalizability because, in many instances, 80-90% of the potential subject population is excluded from a given study for a variety of reasons [13].

Eating disorder pharmacotherapy trials are, at times, conducted in unique settings where the inclusion of other active treatments is often the rule rather than the exception. This is particularly exemplified in inpatient studies of anorexia nervosa, where patients are typically undergoing nutritional and/or medical rehabilitation programs, frequently with concomitant psychotherapy. As these treatments often lead to weight gain independently, there may be little opportunity for a medication to demonstrate additional efficacy. Thus, the full effect of the drug alone may not be apparent.

The book also discusses current clinical practices and notable clinical trial results that might be of interest to physicians. In addition, it discusses some broader issues that vex clinical trials, e.g., missing data, “random” samples, placebos (especially with placebo response rates that can exceed 50%), and women as vulnerable subjects.

The book includes 18 essays by 33 contributors:

- FDA Reform: Déjà vu Encore
- Do Antidepressants Cause Suicide?

This book has been selected for
The First Clinical Research Bookshelf
Essential reading for clinical research professionals

Subscribe free at www.firstclinical.com
© 2012 First Clinical Research and the Author(s)
• The Genome, Genes and Brain — Tailored Drugs
• Patenting and Licensing Concerns in Psychiatric Genetics
• Women's Issues in Clinical Trials
• Issues and Clues in the Pharmacological Treatment of Mood Disorders
• Bipolar Disorder
• Special Issues of Research Methodology in Bipolar Disorder Clinical Treatment Trials
• The Utility of Low-dose Antidepressants
• Clinical Trials for Anxiety Disorders
• Pharmacological Trials for the Treatment of Substance Use Disorders
• Clinical Psychopharmacology of Patients with Eating Disorders
• ADHD Clinical Trials
• Autism and Asperger’s Spectrum Disorders
• Pharmacological Treatments of Impulse Control Disorders
• Potential Benefits of Herbal Medicine for Schizophrenia: from Empirical Observations to Clinical Trials
• Adverse Effects of Antipsychotics
• Meta Musings on Methodology

The book is available in bookstores.

Reviewer
Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.