Clinical Trials in Psychopharmacology

A Better Brain

SECOND EDITION

Editors

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Clinical trials have become the major vehicle by which medical treatments now gain official approval for widespread application. They are the focus of much of the major work by pharmaceutical companies, and certainly their greatest expenditures. Regulatory bodies such as the American Food and Drug Administration (FDA) rely heavily, sometimes almost exclusively, on the results of clinical trials to confer their blessing for purposes of marketing pharmaceuticals.

Psychopharmacology is, in certain respects, a microcosm of developments in clinical trials; more so over the past decade. During that time the extent of trials has expanded greatly. A number of trends have become discernible, largely reflective of the general direction of pharmaceuticals in medicine.

This volume attempts to update and reflect developments in psychopharmacology trials. The authors have selected a series of international experts to assist by preparing reviews of their own areas of expertise. A number of themes emerge from the chapters comprising this collection.

Theme one: clinical trials in psychopharmacology have become institutionalized

Conducting a large trial was unusual half a century ago, not to say controversial. These days, it would be unthinkable to consider the utility of a pharmacological treatment without at least a large (three-digit), usually placebo-controlled, trial and generally multiple experiments. However, the formats for such trials, at least in the United States, have taken on the distinct sense of a cookbook formula. Not only is a microscopically prescribed recipe to be followed, but the focus of review has been more and more upon executing the steps exactly as dictated, without necessarily tailoring trials to the questions at hand or to the populations being treated. The result is to accommodate professional staff at both government agencies, for example the FDA, and at pharmaceutical industry firms who may have limited knowledge of the actual subject matter, of medicine in general and of research.

In addition, a cottage industry has now grown into a sizeable oligarchy of firms which cater to the large, so-called ‘ethical’ pharmaceutical firms, offering to conduct various aspects of the trials. Their ethos seems to be: this is what the FDA requires.