Scores of books have been written in the past two decades on the design of clinical trials and the problems and pitfalls that beset those undertaking such trials. Because of the ever-increasing importance of psychotropic drugs, both therapeutically as well as for the rich source of profit for the pharmaceutical industry, attention has recently been focussed on the special requirements that must be considered in undertaking clinical trials of psychotropic drugs. This volume addresses many of these problems.

The editors have selected a panel of some 32 authors who review the main themes of the monograph. There are three major themes. The first of these, consisting of five chapters, concerns the health care environment and medications and covers the changes in the FDA, the application of genomics to novel drug development, the importance of patenting and licensing in gene based drugs and women’s issues in clinical trials.

The first chapter on FDA reform will appeal particularly to those in the pharmaceutical industry who are undertaking trials of psychotropic drugs. A critical assessment is made of the present role of the FDA and for its re-structuring. Thus the agency has moved from a mainly regulatory role for clinical trials and access to new drugs to a resource for translating science into medical products via the Critical Path Initiative programme, thereby becoming more of a ‘partner’ with the pharmaceutical industry. However, only time will tell if this will lead to a more efficient and dynamic organisation that will stimulate novelty in drug development.

An interesting chapter entitled ‘Do antidepressants cause suicide?’ forms part of this section. I presume this was included here because of the controversy surrounding the SSRI antidepressants. It may be of interest for readers of Human Psychopharmacology to see the conclusions drawn from the US evidence. These may be summarised as follows:

(1) Whereas the suicide rates in adolescents in the USA were falling for the previous decade, since the media/political concerns have been raised particularly regarding the SSRI’s, the suicide rates in this same age group are rising at approximately the same rate as they had dropped previously.

(2) The rates of prescription of all antidepressants have significantly dropped over the same period during which the suicide rates have increased.

(3) The authors conclude that the effect of the change in the policy of the FDA, making it more aware of the media/political concerns irrespective of their scientific validity, may have led to a dramatic rise in suicide, particularly in adolescents.

Similar conclusions have been reached in Europe and Australasia but the truth does not sell newspapers, or radio and TV talk shows, and so the problem continues!

Since the sequencing of the human genome there has been much interest, particularly by the pharmaceutical industry, in the role of genetic variability in psychiatric and neurological disorders that may lead to new therapies. This development has stimulated the concept of personalised medicine, whereby drugs are selected on the basis of the genotype of the individual patient. While this is undoubtedly an attractive theoretical possibility, so far it remains only a goal for the future. With regard to the development of gene based therapies for the treatment of psychiatric disorders, problems arise in licensing and patenting such therapies because, unlike diseases in which one dominant gene is responsible for the symptoms of the disorder (e.g. Huntington’s disease), a plethora of small genes with small effects contribute to the disorders. Epigenetic changes also play a significant part in the final expression of the genome making the patenting of specific gene products complicated.

The final chapter in the first section of the monograph covers ‘Women’s issues in clinical trials’ which argues for the need to recruit more women for clinical trials and how some of the difficulties in recruiting women may be overcome.

Section 2 of the monograph addresses the issues that are specific to the undertaking of clinical trials in patients with mood disorders. The four chapters comprising this section cover the pharmacological treatment of mood disorders, bipolar disorder (and the various types of trials relevant to acute mania, acute bipolar disorder, maintenance treatment and an interesting section on ‘what is a mood stabiliser?’ and ‘what controlled trials cannot tell us about bipolar disorder’), a long and erudite chapter on special issues in research methodology in bipolar disorder and an interesting chapter on the use of low-dose antidepressants for the treatment of insomnia, chronic pain, attention and memory deficits.

Section 3 is concerned with clinical trials in anxiety disorders, substance use disorders, ADHD, Autism and Asperger’s, and impulse control disorders. Each chapter critically reviews the specific issues that must be considered in undertaking clinical trials on patients with these disorders. I found the chapters on clinical trials in ADHD, Asperger’s and Autism and Impulse control disorders particularly

As the authors have noted in the Preface to the current edition of this excellent volume, in the 13 years since the last edition, the field of neuroscience has exploded and has done so exuberantly. The present volume is a valiant attempt by two senior clinical neuroscientists to present a succinct overview of the advances in the main areas of clinical neuroscience.

The book is divided into 13 chapters of which 12 are devoted to the basic principles of biological psychiatry and the major psychiatric and neurological disorders while the final chapter forms a short epilogue.

The first two chapters are concerned with the principles of brain structure and function from the genetic, physiological, biochemical and anatomical aspects, respectively. These chapters are essential for a basic understanding of the subsequent chapters but the contents will be well known to many of the readers who already have some knowledge of biological psychiatry. It would have been useful if the authors had contributed a more detailed discussion of the physiological importance of glucose metabolism in sustaining brain function and how conditions, such as diabetes, detrimentally affect brain function and behaviour. These chapters are followed by a succinct chapter on the important relationship between the brain and behaviour.

The final section contains three interesting chapters. The first of these is devoted to the potential benefit of herbal medicine in schizophrenia with an emphasis on Chinese herbal medicines. It is only in recent years that Western medicine has begun to acknowledge the potential importance of traditional Chinese medicines, particularly now that many of the active ingredients have now been isolated and their pharmacological and therapeutic potential investigated. The authors of this chapter summarise the clinical evidence for L-stepholidine, huperzine-A and a standardised extract of Ginkgo biloba. They summarise the clinical evidence that the negative and cognitive symptoms of schizophrenia may respond beneficially to such drugs.

The second chapter in this section on the adverse effects of antipsychotics with a particular emphasis on the second-generation drugs. This is a useful and extensive summary of the adverse effects.

The final chapter, entitled ‘Meta musings on methodology’, is a short but particularly pertinent and valuable conclusion to the monograph. The section on ‘Criticisms of assumptions about clinical trial methodology’, and ‘Thoughts on alternative study designs’ are particularly thought provoking! This chapter concludes with the important message that ‘Clinical trials deserve periodic re-examination for their relevance, contribution and plasticity’, a view that clearly summarises the intention of many of the contributors to this interesting volume.

In conclusion, this is a valuable addition to the monographs on clinical trial methodology and should be essential reading for all those undertaking trials of psychotropic drugs. The chapters are clearly written, the references are up-to-date and the volume comes at a price of under £50.

BRIAN E. LEONARD
Department of Pharmacology, National University of Ireland, Galway, Ireland

Published online in Wiley Online Library (wileyonlinelibrary.wiley.com) DOI: 10.1002/hup.1151

The clinical classification of neurological and psychiatric disorders, and the methods that are used to undertake clinical investigations, are covered in the chapter that include biochemical procedures, use of the EEG, evoked potential analyses and various brain imaging techniques. The importance of MRI techniques is illustrated by the mapping of the brain regions associated with memory, language and the recognition of specific visual cues such as faces.

The next seven chapters are devoted to specific psychiatric and neurological disorders, each chapter following a similar format in which the symptoms of the disorder are described followed by a discussion of the possible genetic basis and the biochemical changes that may be associated with the aetiology of the disorder. The chapters then conclude with a summary of the neurophysiological and neurological aspects of the disorder with particular emphasis on the application of imaging techniques. These chapters start with the personality disorders followed by the anxiety disorders.

The chapter on the schizophrenias, quite correctly considered to be a group of syndromes, summarises the evidence implicating dysfunctional dopaminergic, noradrenergic, glutamatergic and peptidergic systems. There is also evidence that the neuropyschological disturbances which are prevalent in some types of schizophrenia may be partly linked to the DISC-1 (disrupted-in-schizophrenia gene) which may help to explain the neurodevelopmental basis of the schizophrenias.