(46) Jerome Levine (ed) (1979)
Coordinating Clinical Trials in Psychopharmacology: Planning, Documentation and Analysis
Washington: National Institute of Mental Health, DHEW Pub (ADM) 79-803

Preamble
The book originated from a two-day meeting held in 1973 on documentation of data from a series of clinical trials on a given drug. It was hosted by the Biometric Laboratory of George Washington University and organised by the Psychopharmacology Research Branch of the National Institute of Mental Health, with support from the Neuropharmacology Division of the Food and Drug Administration.

The text references two earlier general publications on the design, methodology, and analysis of clinical trials; these are the WHO Technical Report Series no. 563 (see no. (33) above), and the FDA *General considerations for the clinical evaluation of drugs* (see no. (39) above). It also references a text on clinical trials in psychopharmacology, *Principles and problems in establishing the efficacy of psychotropic agents* (see no. (24) above), as well as two reports that deal with documentation: T McGlashan *The documentation of clinical psychotropic drug trials* (DHEW publication no. (HSM) 73 – 9038, Rockville, Md, 1973), and T McGlashan *Early clinical drug evaluation units sample output package* (DHEW publication no. (HSW) 73 – 9039, Rockville, Md, 1973).

Aims
There has been a longstanding need for techniques to reach conclusions about a drug's efficacy, safety, and role based on data generated from independent clinical trials. How to assimilate such data in a way to be able to reach valid conclusions which can be understood and verified by others is the challenge. It has been a problem for a long time but not one that, to my knowledge, has often been articulated, approached, or written about systematically. In contrast, in recent years there has been much attention given to the design, methodology, and analysis of individual clinical trials in general, and psychopharmacology trials in particular. This volume may be useful in the formulation of "guidelines" for comprehensive documentation and decision-making about a drug's efficacy, safety and therapeutic role, whether this be accomplished for innovative, regulatory, or academic purposes (Chapter 1, pages 1 and 4).

Contents (x+170+154 unnumbered pages of Tables, Figures, and computer programs)
[Sub-sub headings omitted]

Conclusion

Authors

The editor of this volume is Jerome Levine MD (Psychopharmacology Research Branch, National Institute of Mental Health, Rockville, Maryland, USA). The contributors are Robert Downing PhD (Associate Professor of Psychology in Psychiatry, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania, USA); William Guy PhD (Associate Professor, Tennessee Neuropsychiatric Institute, Clinical Research Service, Vanderbilt University, Nashville, Tennessee, USA); Harriet Kiltie MD (Medical Director, Lederle Laboratories Division of American Cyanimid Company, Pearl River, New York, USA); Eugene W Laska PhD (Director, Information Sciences Division, Rockland Research Institute, Orangeburg, New York, USA); John E Overall PhD (Professor, Department of Psychiatry and Behavioral Science, University of Texas Medical School, Houston, Texas, USA); and, J Arthur Woodward PhD (Associate Professor, Department of Psychology, University of California at Los Angeles, Los Angeles, California, USA).