Preamble
The frontispiece, preface and contents list are available online at the Springer website (https://www.springer.com/gb/book/9783540119791). The book is volume 20 in the series Lecture Notes in Medical Informatics edited by DAB Lindberg and PL Reichertz.

Aims
The German edition of this manual appeared in 1979. Its main objective then was to extend help to those engaged in multicentric therapeutic studies, especially with respect to the Federal Government's Program on Promoting Research and Development in the Service of Health. Experience with therapeutic studies in the Federal Republic of Germany showed that considerable problems as to methods and implementation of such studies exist. The manual was an attempt to present current methodological knowledge and the experience obtained from completed studies in the light of the international literature. No radically new methodology was produced; however, the information representing the state-of the art, which is widely scattered up to now, has been compiled. For the American edition of this manual a few changes have been made. These concern especially the literature where references to German unpublished manuscripts were omitted (Publisher’s note).

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