Preamble
This is a dual language (French and English) book that includes the papers presented at a seminar held in Lyon, France, December 9 – 11, 1977; the two Editors were the organisers and chairmen of the meeting. It is the first text to be devoted to multi-centre trials.

Aims
Every year many drugs or drug combinations are screened and evaluated in order to estimate their potential therapeutic utility. Likewise new surgical, psychotherapeutic, or biophysical procedures are designed. Only a few will – or should – pass successfully throughout the strict control process consisting of animal experiments followed by clinical evaluation. To succeed the very last step of this time and money consuming process is a prerequisite for a treatment to be used routinely for clinical purposes. This book was edited in such a way that anybody looking for an introduction in the growing field of large multicenter controlled trial can find the basic ideas he needs to work on. Contributors from European Countries and United States met together to pool their experiences. The subjects reported cover the most important principles and practical questions of this rapidly evolving matter: how to plan, to carry on and to analyse a randomised intervention clinical trial (Introduction, pages 15 and 16).

Contents (274 pages)
Foreword
Introduction (D Germain, JP Boissel)
I. Controlled clinical trials: basic statements
   Clinical trials: aims and four puzzling points (JP Boissel)
   Principles of multi-center clinical studies (CR Klimt)
II. Examples of cooperative randomized controlled trials in cardio-vascular fields
   Chromic antidysrhythmic treatment after myocardial infarction: design of the Gent-Rotterdam aprindine study (JP Van Durme, F Hugemeijer, M Bogaert, B Glaser, PG Hugenholtz)
   Long term multicenter trial of practolol in patients recovered from acute myocardial infarction: organizational procedure and results related to smoking habits (KG Green)
   An INSERM study of the effects of antiaggregants agents on the course of diabetic microangiopathy (DAMAD program) (PY Scarabin, E Eschwege)
   The US diabetic retinopathy study (GL Knatterud)
   Multcenter two-years prospective study on the prevention of secondary myocardial infarction by ASA in comparison with phenprocoumon and placebo (K Breddin)
III. Design, analysis and management of randomized controlled trials
   Why and how to perform “blind” trials? (TE Prout)
   Required number of subjects (D Schwartz)
   Stratification (P Ducimetière)
   Research strategies if one is unable to conduct a randomized controlled trial (PD Stolley)
   Quality assurance in clinical trials (CL Meinert)
   Monitoring clinical trial data for evidence of adverse or beneficial treatment effects (PL Canner)
   Example of controlled trials management and quality control system PROGET (JP Boissel, A Biron, L Leizorovicz, C Deguerry)
Means of communication and appropriate computer technology (L Gatewood)

IV. Theoretical or practical problems

Life-tables analysis and regression techniques: \textit{a priori} and \textit{a posteriori} subgroups formation (P Meier)

The cost of therapeutic trials: theoretical and practical approach (JP Boissel)

Why and how to perform “blind” trials (A Spriet, P Simon)

Place of drug-essays in biological fluids (JL Brazier, J Descotes, JCL Evreux)

What were the main problems you encountered? (TE Prout)

V. Ethical and legal problems

Legal frame work of clinical drug evaluation in France (G Nicolas, N Granger)

Legal and ethical problems inherent in clinical trials particularly in the United States (CR Klimt)

The ethical problems of human therapeutic trials (JM Rouzioux)

Conclusions – Final remarks (D Schwartz)

Author index

INSERM publications

\textbf{Authors}

The Editors are Dr. JP Boissel (Département de Méthodologie et d’Essais thérapeutiques, Hôpital Cardiologique et INSERM, Lyon, France), and CR Klimt (Maryland Medical Research Institute and University of Maryland, School of Medicine, Baltimore, Maryland, USA). The contributors are A Biron (Service Informatique des Hospices Civils de Lyon, Lyon, France); M Bogaert (Heymans Institution of Pharmacology de Pintelan, Gent, Belgium); JL Brazier (Service de Pharmacologic Clinique, Hôpital Edouard-Herriot, Lyon, France); K Breddin (Zentrum der Inneren Medizin, Abteilung für Angiologie, Frankfurt Main, Germany); PL Canner (Baltimore, Maryland, USA); C Deguerry (Service Informatique des Hospices Civils de Lyon, Lyon, France); J Descotes (Service de Pharmacologie, Hôpital Edouard-Herriot, Lyon, France); P Ducimetiere (INSERM, Villejuif, France); E Eschwege (Unité de Recherches Statistiques, INSERM, Villejuif, France); JC Evreux (Service de Pharmacologie, Hôpital Edouard-Herriot, Lyon, France); L Gatewood (University of Minnesota, Division of Health Computer Sciences, Minneapolis, Minnesota, USA); D Germain (President de l’Universite Claude-Bernard, Lyon Laboratoire d’Hematologie, Hopital Edouard-Herriot, Lyon, France); B Glaser (Thoraxcentrum, Erasmus University, Rotterdam, The Netherlands); N Granger (Centre Hospitalier, Service de Cardiologie, Nantes, France); K Green (Macclesfield, Cheshire, UK); F Hagemeyer (Thoraxcentrum, Erasmus University, Rotterdam, The Netherlands); PG Hugenholtz (Thoraxcentrum, Erasmus University, Rotterdam, The Netherlands); GL Knatterud (Maryland Medical Research Institute and University of Maryland, School of Medicine, Baltimore, Maryland, USA). A Leizorovicz (Département de Méthodologie et d’Essais thérapeutiques, Hôpital Cardiologique, Lyon, France); P Meier (Department of Statistics, University of Chicago, Chicago, Illinois, USA); CL Meinert (University of Maryland, School of Medicine, Maryland, USA); G Nicolaus (Centre Hospitalier, Service de Cardiologie, Nantes, France); TE Prout (Greater Baltimore Medical Center, Baltimore, Maryland, USA); JM Rouzioux (Hôpital Edouard-Herriot, Lyon, France); PY Scarabin (Unité de Recherches Statistiques, INSERM, Villejuif, France); D Schwartz (Unité de Recherches Statistiques, INSERM, Villejuif, France); P Simon (CHU, Laboratoire de Pharmacologie, Hôpital Salpêtrière, Paris, France); A Spriet (Laboratoire Hoechst, Puteaux, France); PD Stolley (University of Pennsylvania, Merion, PA, USA); and, JP van Durme (Akademish Zickenuis de Pintelaan, Gent, Belgium).