Aims
This is the report of a conference sponsored by The Kroc Foundation held in November 1981 at its headquarters in the Santa Ynez Valley of California. We, the organizers, thought the great number of randomized clinical trials since the mid 1960s and the attention given them in the establishment of new therapies made it advisable to take a broad look at them. Most meetings and publications on randomized clinical trials have dealt with specific trials or specific aspects of the methodology of trials. To keep the subject matter manageable, discussion was limited to the history of trials in cardiovascular disease and cancer. The articles here show that there has been continual innovation in the design of trials and that there is a healthy skepticism about some fundamental aspects of them. One such aspect is the effect on the individual patient of being treated within a trial. The common assumption that care within a trial is on the average better than care outside of a trial was agreed to, and the usefulness of trials to patients who later receive better therapies established by trials is abundantly illustrated. Some striking differences between trials in cardiovascular disease and in cancer emerged during the conference. There was also a lot of attention paid to the interactions between the scientific and ethical goals of trials, including the effects on both of differences in design and execution. The papers published in this volume are edited versions of the oral presentations at the conference. Not all of the authors returned their edited manuscripts, and their formal presentations have been omitted. Discussion after each presentation has been either omitted, summarized by the editors, or included as corrected by the speakers (Introduction, page 163).

Contents (147 pages)
Photograph of participants
Section I: Support of clinical trials
  Introduction
  Funding for clinical trials (Curtis L Meinert)
  RCTs and the Federal Government (H David Banta)
Section II: Cancer trials
  Clinical trials in cancer patients an introduction (C Gordon Zubrod)
  Patient heterogeneity and the need for randomized clinical trials (Sylvan B Green)
  Progress of therapy in acute leukaemia 1948–1981: randomized versus nonrandomized clinical trials (Edmund A Gehan)
  Impact of randomized clinical trials on therapy of primary breast cancer: the NSABP overview (Howard E Rockette, Carol K Redmond, Bernard Fisher, and Participating NSABP Investigators)
  Assessment of the role of randomized clinical trials in establishing treatment policies (HS Garnier, R Flamant, C Fohanno)
Section III: Cardiovascular disease trials
Randomized surgical clinical trials for treatment of coronary artery disease (Lloyd D Fisher, J Ward Kennedy)
Overview of recent clinical and methodological advances from clinical trials of cardiovascular disease (William T Friedewald, James A Schoenberger)
Overview of randomized clinical trials of lipid intervention for atherosclerotic cardiovascular disease (Henry Buchwald, Laurie Fitch, Richard B Moore)

Section IV: General discussion sessions
A potpourri of RCT topics (Thomas C Chalmers)
Conference on Recent History of Randomized Clinical Trials: concluding session general discussion (edited by Thomas C Chalmers and Peter Amacher)

Authors
The Guest Co-Editors are Thomas C. Chalmers MD (Mount Sinai School of Medicine, New York, New York, USA) and Peter Amacher PhD (Santa Barbara, California, USA). The authors are: H David Banta MD, MPH (Assistant Director, Office of Technology Assessment, Congress of the United States, Washington, DC, USA); Henry Buchwald (Department of Surgery, University of Minnesota Medical School, University of Minnesota Hospitals, Minneapolis, Minnesota, USA); Bernard Fisher (NSABP Headquarters, University of Pittsburgh, Pittsburgh, Pennsylvania, USA); Lloyd D Fisher (Cass Coordinating Center, University Building, Seattle, WA, USA); Laurie Fitch (Department of Surgery, University of Minnesota Medical School, University of Minnesota Hospitals, Minneapolis, Minnesota, USA); R Flamant (Department of Medical Statistics, Gustave-Roussy Institute, Villejuif, France); C Fohanno (Department of Medical Statistics, Gustave-Roussy Institute, Villejuif, France); William T Friedewald (National Institutes of Health, Bethesda, Maryland, USA); HS Garnier (Department of Medical Statistics, Gustave-Roussy Institute, Villejuif, France); Edmund A Gehan PhD (Professor of Biometrics, The University of Texas System Cancer Center, MD Anderson Hospital and Tumor Institute, Houston, Texas, USA); Sylvan B Green MD (Clinical and Diagnostic Trials Section, National Cancer Institute, Bethesda, Maryland, USA); J Ward Kennedy (Cass Coordinating Center, University Building, Seattle, WA, USA); Curtis L Meinert PhD (The Johns Hopkins University, School of Hygiene and Public Health, Baltimore, Maryland, USA); Richard B Moore (Department of Surgery, University of Minnesota Medical School, University of Minnesota Hospitals, Minneapolis, Minnesota, USA); Carol K Redmond (NSABP Headquarters, University of Pittsburgh, Pittsburgh, Pennsylvania, USA); Howard E Rockette (Associate Professor, University of Pittsburgh, Pittsburgh, PA, USA); James A Schoenberger (National Institutes of Health, Bethesda, Maryland, USA): and, C Gordon Zubrod MD (Director, Comprehensive Cancer Center of the State of Florida, University of Miami School of Medicine, Miami, Florida, USA).