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Aims

Clinical trials are needed more and more as a means of ascertaining whether those new treatments and preventive measures that are laboratory successes actually have a favourable impact on human health. The controlled trial gives us the opportunity to study not only immediate but also long-term effects on outcome. It also has the capacity to reveal subtle effects that are not qualitative, but merely quantitative, differences between treatment groups. One of the most important lessons that trials and other epidemiologic studies have taught us in recent years is that adverse effects of drugs and other treatments may not be responses unique to the drug under study but may instead manifest themselves as an increased incidence of a disorder that already occurs in the absence of treatment. Clinical trials pose a challenge to NIH because the number of significant questions that can be answered through clinical trials clearly exceeds our ability – indeed, the nation's – to plan, execute, and finance all the studies that are needed (Welcoming remarks, page 630).

Contents (138 pages)

Opening remarks (Robert S Gordon Jr) Welcoming remarks (Donald S Fredrickson) When and how to stop a clinical trial (Chairman: Curtis L Meinert, Rapporteur: James H Ware) Introduction (Curtis L Meinert) Terminating a trial – the ethical problem (Paul Meier) Terminating a long-term trial (Christian R Klimt, Paul L Canner) Invited remarks (Michael T Hamilton, Thomas C Chalmers, Jeremiah Stamler) Responses (Paul Meier, Christian R Klimt, Paul L Canner) Who will be effective as a clinical trials investigator and what are adequate incentives? (Chairman: Robert S Gordon Jr; Rapporteur: John W Singleton) Introduction (Robert S Gordon Jr) Problems of university-based scientists associated with clinical trials (Richard D Remington) Effective clinical trials investigators and adequate incentives (Jeremiah Stamler) Appendix 1: A proposed mechanism and set of criteria for the evaluation of the scientific contribution of individual investigators in collaborative studies, including large clinical trials (Rose Stamler) Publications and promotions for the clinical investigator (Arnold S Relman) Discussion Patient recruitment: problems and solutions (Chairmen: Thaddeus Prout; Rapporteur Barbara Hawkins) Introduction (Thaddeus Prout) Recruitment to the Coronary Drug Project and the Aspirin Myocardial Infarction Study (James A Schoenberger) LRC Coronary Prevention Trial: Baltimore (G William Benedict) Recruitment for the Coronary Primary Prevention Trial (W Stewart Agras, Gary Marshall) Recruitment for the National Cooperative Gallstone Study (Gloria Croke) Other examples of recruitment problems and solutions (Thaddeus E Prout) Discussion

Quality assurance of clinical data

(Co-chairmen: O Dale Williams and Fred Ederer; Rapporteur: Clarence E Davis) Introduction (Fred Ederer)

A framework for the quality assurance of clinical data (O Dale Williams)

Diagnostic standardization (Harold A Kahn)

Internal monitoring: patient and study management at the clinic (James T Evans)

Aspects of clinic monitoring in large-scale multiclinic trials (Richard L Mowery, O Dale Williams)

External monitoring in multiclinic trials: applications from ophthalmologic studies (Frederick L Ferris, Fred Ederer)

Invited remarks (PA Lachenbruch, Abraham Silvers)

Discussion

Ethical considerations in clinical trials

- (Chairman: Robert J Levine; Rapporteur: Dale H Cowan)
 - Some ethical considerations in clinical trials (Robert J Levine, Karen Lebacqz)

Invited remarks (John C Fletcher, Roy Branson, Emil J Freireich)

Discussion

Communications: should mechanisms be established for sharing among clinical trial investigators experiences in handling problems in design, execution, and analysis? (Chairman: Harold P Roth; Rapporteur: Genell L Knatterud)

Introduction (Harold P Roth)

Problems in publication of clinical trial methodology (Louis Lasagna)

Methodology: the case for improved communications (Curtis L Meinert, Barbara S Hawkins)

Retrieving information on clinical trial methodology (Harold M Schoolman)

Problems of omission in communications (Frederick Mosteller) Discussion

Concluding remarks (Harold P Roth)

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