(58) Kenneth E Stanley, Jan Stjernsward, and Mary Isley (1981)

The Conduct of a Cooperative Clinical Trial

Recent Results in Cancer Research, volume 77

Berlin: Springer-Verlag

Preamble

The frontispiece, preface and contents list are available online at the Springer website (https://www.springer.com/gb/book/9783642816321). This book is published in the series *Recent Results in Cancer Research* that embraces all aspects of cancer; it started in 1965 and continues to this day with over 200 volumes. At the time of this volume the series was edited by its Founding Editor in Chief P Rentchnick (Geneva, Switzerland) with co-editor HJ Senn (St Gallen, Switzerland).

Aims

The purpose of this monograph is to address the basic mechanisms for organizing trials. It is meant to serve as a guide to individuals planning to form a cooperative group as well as to cooperative groups who wish to review and revise their existing procedures. Current literature deals with many components of conducting clinical trials, such as trial design considerations, randomisation, and methods of analysis. But there is a lack of accessible knowledge concerning data flow, data processing, and group organization which causes difficulties for many multiinstitutional cooperative trials. Multi-institutional cooperative studies require greater attention to detail than studies within a single institution. For single institution studies, a simple protocol document may be sufficient. In a cooperative group, however, it is necessary to standardize various aspects where little variation may be present in a single institution study. Patients must be entered in a uniform fashion, data collection and evaluation should be standardized and there must be a mechanism to insure the timely collection of essential data. The Lung Cancer Study Group was chosen as an example to demonstrate the various aspects of clinical trial organization. Although this monograph describes the mechanism under which a well-functioning cancer therapy trial is operating, the technical procedures detailed should serve as guidelines for cooperative groups in other chronic diseases. One of the most reliable verifications that a particular intervention is effective is by a randomised controlled clinical trial. This is true especially in the area of cancer therapy. Institutions have realised that a collective research effort is needed in order to carry out definitive therapeutic trials. It is our hope that the material in this monograph will be helpful in this respect (Preface, pages v to vii).

Contents (xi + 78 pages)

Preface (Kenneth Stanley)

- 1. General organization
 - 1.1. Introduction and objectives
 - 1.2. General organization
 - 1.3. The coordinating center
 - 1.4. The statistical center
- 2. Overview of group activities
 - 2.1. Introduction
 - 2.2. Protocol generation
 - 2.3. Forms generation
 - 2.4. Patient entry
 - 2.5. Data flow
 - 2.6. Form submission
 - 2.7. Completed forms review

- 2.8. Computerized requests and status lists
- 2.9. Records review
- 2.10. Biostatistical reports
- 3. Institution specific activities
 - 3.1. Institutional data management
 - 3.2. Patient entry
 - 3.3. Forms submission
 - 3.3.1. Clinical and preoperative (Form B)
 - 3.3.2. Surgery (Form C)
 - 3.3.3. Histology and study treatment (Form D)
 - 3.3.4. Follow-up (Form E)
 - 3.3.5. Flow sheet (Form F)
 - 3.3.6. Death report
 - 3.4. Clarification requests
 - 3.5. Computerized requests and status lists
- 4. Coordinating center specific activities
 - 4.1. The administrative office
 - 4.2. Patient entry
 - 4.2.1. Material
 - 4.2.2. The randomisation procedure
 - 4.3. Blank forms distribution
 - 4.4. Patient files
 - 4.5. Reception and distribution of forms
 - 4.6. Mail procedure to the statistical center
 - 4.7. Clarification requests
 - 4.8. Computerized requests and study status lists
 - 4.9. Records review
 - 4.10. Biostatistical reports
 - 4.11. Annual meetings
- 5. Statistical center specific activities
 - 5.1. Mail logging and filing
 - 5.2. General forms review
 - 5.2.1. General rules
 - 5.2.2. Query letters
 - 5.2.3. Comment records
 - 5.2.4. Problems
 - 5.3. Coding conventions
 - 5.4. Review of specific forms
 - 5.4.1. Confirmation of registration form (Form A)
 - 5.4.2. Clinical and preoperative form (Form B)
 - 5.4.3. Surgery form (Form C)
 - 5.4.4. Histology and study treatment form (Form D)
 - 5.4.5. Follow-up form (Form E)
 - 5.4.6. Flow sheet form (Form F)
 - 5.4.7. Eligibility review forms (Forms V1 and V2)
 - 5.5. File organization
 - 5.6. File maintenance
 - 5.6.1. Keypunch
 - 5.6.1. Datapoint
 - 5.6.2. Update program

- 5.7. Data retrieval
- 5.8. Computer listings
 - 5.8.1. Patient listings
 - 5.8.2. Data request
- 5.9. Manuals
- 5.10. Workshops
- Appendix 1. Protocol
- Appendix 2. Forms
- Appendix 3. Example of data request
- Appendix 4. Example of patient listing
- Appendix 5. Participant forms submission log
- Appendix 6. Operations office patient log
- Appendix 7. Sample page of randomisation list
- Appendix 8. Sample data file
- Appendix 9. Statistical center forms log
- Appendix 10. Example of an interim statistical analysis
- Appendix 11. Terminology

Subject index

Authors

Kenneth Stanley PhD (Division of Biostatistics, Sidney Farber Cancer Institute, Boston, MA, USA). Jan Stjernsward MD (Chief, Cancer Unit, World Health Organisation, Geneva, Switzerland), Mary Isley (Frontier Science and Technology Research Foundation Inc, Amherst, NY, USA).