

(17) Cyril Maxwell (1968)
Foundation Course in Clinical Trials
Clinical Research Services Ltd

Preamble

There is little information about this course that was first given in 1968. The Contents list below is taken from the 23rd Edition, 1990, and these reflect changes that would have been made over the intervening years. The numbering of Editions suggests it was given annually. The course was given over a period of five days and comprised lectures, clarification periods, and exercises discussed in small workgroups. It would have been attended by doctors, pharmacologists, and others, particularly from the pharmaceutical industry, interested in learning about all aspects of clinical trials. Unfortunately, the documentation available at the British Library is incomplete.

It is very likely that this is the first publication with a section devoted to the clinical trial protocol; if not then nos. (19) and (20) below, published a year later, would have been..

Aims

Clinical trials are scientific experiments in sick man to evaluate a therapy. Performed to learn about the drug, to study its efficacy and side effects, to protect ourselves and employers from false criticism when the drug is being sold, and usually to convince someone: maybe a doctor or pharmacist, or patient, or advertising authority or drug control authority (Lecture 2: Synopsis: Introduction to clinical trials, page 13).

Contents (iv+83 pages)

1. About this course, Introductions
2. Introduction to clinical trials
3. Placebos and placebo response
4. The choice of design in clinical trials
5. Allocating treatment to patients
6. Assessment and measurement
7. The trial protocol and its supporting documentation
8. The case record form and data from clinical trials
9. The production of supplies
- 10.1 Introduction to statistics – what is P?
- 10.2 Beta, the false negative and how many patients
- 11.1 Introduction to parametric statistics
- 11.2 More parametric statistics: the “sum of squares”
- 11.3 Analysis of variance: what it looks like and what it tells you
- 12.1 Introduction to non-parametric statistics: chi-squared
- 12.2 More non-parametric and ranking tests
- 13 Literature, libraries, reading and references
- 14.1 Analysis: general considerations and the nature of data
- 14.2 Analysis: survival trials and “intention-to-treat”
- 14.3 Analysis: the two-period crossover trial
15. Sequential trials
16. Ethics and clinical research
17. Dynamic balancing and “minimization”

18. Introduction to correlation and regression

ACTIVITY A

Binomial table

Chi-squared table

Hamilton rating scale for depression

“How many patients do we need for a clinical trial”

Random number tables

Referees guidelines, British Medical Journal

References and recommended books

Statisticians’ checklist, British Medical Journal

“Student’s” t-table

Wilcoxon table (matched pairs signed ranks)

“What (statistical tests) do we do when?”

Author

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