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
The author and course teacher is Cyril Maxwell LLB, ChB, medical adviser, at Geigy (UK) Ltd, Macclesfield, Cheshire.