

**(25) Cyril Maxwell, FR Smith, and Leong Ket Shing (1972)**

***Instant Experience in Clinical Trials: a computerised teaching aid***

**CIBA Laboratories, Horsham: The Trust for Education and Research in Therapeutics**

***Preamble***

This course may have been one of the earliest attempts to teach clinical trials by computer simulation.

***Aims***

*The Trust for Education and Research in Therapeutics is a charitable trust which was established by the United Kingdom Association of Medical Advisers in the Pharmaceutical Industry. Both organizations have worked for many years to improve the level of knowledge of clinical trial methodology and this book is a further contribution to that end. The device described in this book was invented and developed by the authors whilst employed by Geigy Pharmaceuticals and CIBA-Geigy (UK) Ltd (Acknowledgements, page 3).*

*Controlled clinical trials are requirements in man, scientifically designed and ethically acceptable, performed to evaluate a therapy by making simultaneous comparisons. Controlled clinical trials are fraught with many dangers, many manifesting ultimately in false positive or false negative results and few people have completed such trials without regretting at the end, some of the decisions they made at the start. Such is experience. Experience educates. Often, the experience of the teacher can be passed on to the student but no lesson is as effective as that of experience itself, personally encountered. Teaching with the aid of simulation exercises has gained deserved popularity in recent years and whilst war games have been played by armies for a long time, the use of games in management training is relatively new. Instant Experience in Clinical Trials is the name given to a novel simulation exercise specifically designed for clinical trials and using a computer to generate the simulated material. Briefly, the device takes a specific set of imaginary patients, allocates one of a series of therapies according to the instructions of the student to each patient and thereafter allocates a result according to the rules determined by the game designer. To facilitate the description, this book includes a set of patients and a set of results but there is also sufficient information to allow the reader to invent his own (Chapter 1, Introduction, page 5).*

***Contents (152 pages)***

Acknowledgements

Part 1 – Medical aspects

1. Introduction
2. General description of the mechanism
3. Capabilities of the system
4. The training course
5. How to communicate with the computer
6. The patients
7. The preferred stratification factors
8. The results matrix
9. Crossover, paired and sequential trials
10. Recapitulation

Part 2 – Computer aspects

11. Hardware considerations
  12. The students protocol
  13. Preparation by the organizer
  14. Coding sheets
  15. General method of operation of the system
  16. Validation of the data cards
  17. Allocation of student requested stratification levels
  18. Allocation of treatments to patients
  19. Allocation of response to patients
  20. Report on the results of the exercise
- Appendix 1: Flowcharts and tabulations  
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