

(20) Ben-Zion Taber (1969)

Proving New Drugs: a Guide to Clinical Trials

Los Alamos, California: Geron-X

Preamble

The frontispiece includes the quotation:

“And then, even if the cure should be performed, how can he be sure that this was not because the illness had reached its term, or a result of chance, or the effect of something else he had eaten or drunk or touched that day, or the merit of his grandmother’s prayers? Moreover, even if this proof had been perfect, how many times was the experiment repeated? How many times was the long string of chances and coincidences strung again for a rule to be derived from it? ... Perhaps we would see some light if all the judgments and reasonings of men were known to us.”

Michel de Montaigne (1533 – 1592)

Aims

This book is written for all who will participate in the complex field of drug investigation. No attempt has been made to cover specific pharmacologic techniques or methodology, for numerous texts on these subjects already exist. Rather, I have attempted to characterize the individuals who participate in clinical investigation programs today as well as their activities. For it is these individuals and their extensive experimentation on human subjects and patients that are vital to the evaluation, development, and establishment of new therapeutic agents for medical science (Preface, pages xix and xx).

Contents (xxi+182 pages)

Preface

Part I: The participants

1. The preclinical activities
2. The monitor’s role
3. The statistician’s contribution (Sheldon Kugler, B-Z Taber)
4. The investigator’s obligation
5. The patient’s dilemma
6. The Food and Drug Regulation

Part II: The clinical study

7. Planning and design
8. The protocol package
9. Choosing investigators
10. Filing an IND
11. Experimental observations
12. Conclusions
13. Filing the NDA

Exhibits: Special forms

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