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
Index

Author
The author, Ben-Zion Taber MD is Medical Director at Syntex Laboratories, Palo Alto,
California, USA.