

the alveolus and capillary. As chronicled in *Pulmonary Endothelium*, this narrow conception has given way to research findings showing that the lung vasculature is important to many hemostatic, inflammatory, and metabolic functions. For instance, although the lung is not traditionally viewed as an endocrine organ, several circulating hormones with diverse pharmacologic functions (including biogenic amines, prostaglandins, and peptides) are normally modified during passage through the lungs. Since such metabolic activity of the pulmonary endothelium probably has an important homeostatic function in health, alteration of this activity in disease states may have adverse consequences. For example, studies of patients with the adult respiratory distress syndrome (ARDS), a disease that extensively damages the lung microvasculature, demonstrate depressed lung metabolic activity. It is possible that such dysfunction contributes to the systemic pathophysiology of ARDS.

This volume spans a spectrum of research from in vitro studies of cultured endothelial cells to clinical investigations of patients. The emphasis, however, is clearly on basic science. This fact, along with the high price of the book (\$125), dictates that *Pulmonary Endothelium* will serve primarily as a reference source in libraries and research laboratories. Perusal of this volume by clinicians interested in pulmonary diseases is recommended, however. Such readers will be enlightened by learning of the important "nonrespiratory" functions of the lung, a subject that receives little attention in medical school or training programs.

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## IMMUNOLOGY OF THE MALE REPRODUCTIVE SYSTEM

Edited by Pierluigi E. Bigazzi  
Marcel Dekker

This book is one of a series on immunological aspects of healthy and diseased states. The authors are distinguished for their contributions to the field of reproductive immunology. Initial chapters deal with antibody production and the various laboratory techniques for detecting the presence of those antibodies. Later sections include detailed descriptions of animal and human studies regarding the cause, effect, and potential treatment of immune infertility. A chapter by Mettler and Czuppon illustrates the possible role of a purposefully caused immune state as a means of fertility control in men. The last three sections enumerate what is currently known

about the immunobiology of the normal prostate gland, as well as testis and prostate tumors.

The clinician interested in the field of male infertility should find the sections titled "Immunologic Effects of Vasectomy in Men" and "Treatment of Immunologic Infertility in Men" interesting and easy to read. Some knowledge of laboratory techniques and background in basic immunology is required to appreciate the chapters on the biology of the immune response, particularly the discussions of the animal studies from which much of the information about the immune response is derived. Kosuda and Bigazzi put it quite succinctly in their chapter when they wrote: "After 86 years of research on animal models of testis autoimmunity, the literature on this subject has become overwhelming, often contradictory, and practically impossible to review in its entirety . . ." Despite this difficulty, the authors have made a commendable effort to be all-inclusive. With over 1,000 references (dated from 1899 to 1986), this book should be of use to both the clinician and basic scientist.

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## GUIDE TO CLINICAL INTERPRETATION OF DATA

## GUIDE TO PLANNING AND MANAGING MULTIPLE CLINICAL STUDIES

by Bret Spilker  
Raven Press

The second and third volumes of Dr. Spilker's trilogy, *Guide to Clinical Studies*, emphasize the essential role of clinical interpretation in evaluation of data and examine the processes involved in managing multiple clinical studies. The first of the three volumes, *Guide to Clinical Studies and Developing Protocols* (1984), described the various processes in planning and managing a single clinical study. Its three sections described processes used to choose a study design, write a protocol, and plan, conduct, and terminate a clinical study. Its sequel, *Guide to Clinical Interpretation of Data*, builds upon the previous work, describing various ways of interpreting the data that result from a clinical study, as well as aspects of publishing the data. It is oriented primarily toward interpretation of clinical data insofar as it affects development of drugs. The third volume, *Guide to Planning and Managing Multiple Clinical Studies*, expands consideration from a single study (i.e., conducted at either single or multiple sites) to consideration of processes involved in

planning, conducting, and managing multiple (i.e., different) clinical studies.

In the five-section *Guide to Clinical Interpretation of Data*, the processes used in the clinical interpretation of data are described in the portion titled "Fundamental Principles, Considerations, and Techniques." In the next section, "Interpretation of Safety and Efficacy Data," specific factors are described in terms of how they may bias data as well as how such factors may be measured or controlled. The section titled "Interpretation of Data from Special Studies, Modalities, and Populations" discusses studies of surgery, geriatric, and radiation therapy patients, and many other groups in whom specific factors must be considered to interpret data adequately. The section dealing with "Issues and Problems of Interpretation" covers controversies that arise in many clinical studies, such as reconciling differences in interpretation for multiple studies. The final section, "Publishing Clinical Data and Evaluation of Published Literature," presents information about how to prepare articles for publication and how to evaluate articles published in the literature. Tables and checklists are used extensively throughout.

Although the topic is important and the book obviously is written by an experienced person, it does not meet its objectives entirely. Discussion of many topics lacks depth, although references are provided for the reader interested in more detail. However, the disjointed nature of the individual chapters and the somewhat unusual selection of specific topics makes one question the contribution this book makes over the original references. Although the heavy use of tables and checklists has the advantage of offering exhaustive information in a concise format, this reviewer found it quite tedious to examine the more than 100 tables.

In conclusion, *Guide to Clinical Interpretation of Data* highlights the important role of clinical interpretation in the evaluation of data, beyond purely statistical analysis. The numerous checklists provided to guide the researcher in the interpretation of data may be of assistance and suggest the book may be more useful as a reference than a general review.

*Guide to Planning and Managing Multiple Clinical Studies* continues the style established in the first two volumes by presenting numerous tables of possible interpretations, considerations, and factors to review, as well as a variety of checklists.

The first section presents steps and procedures for (a) choosing a project or drug for evaluation, (b) establishing goals, strategies, and approaches, and (c) designing the project with all of these factors in mind. Specific tech-

niques are presented to investigate efficacy and safety data obtained in multiple studies. Ethical issues involved in both single and multiple clinical studies are also discussed. The second section describes the planning, conduct, and management of nondrug studies such as those relating to surgery and medical devices, as well as factors pertaining to initiating and managing projects in many countries. The third section presents management techniques that include recommendations for academic or private physicians conducting several studies either simultaneously or sequentially. These techniques also apply to sponsors of studies, who often develop elaborate systems to allocate resources and plan and monitor clinical studies. Practical details and suggestions are presented to enable the investigator and staff, sponsors, and managers to monitor and review progress in multiple studies relating to drug development and other medical areas.

A wide variety of topics is discussed in this generally well-written and informative book. There is little redundancy of topics covered in the earlier volumes. Perhaps because of the breadth of coverage, however, the depth of discussion in some areas is not adequate, and at times, the reader is left with the impression that the author jumps from one topic to another. The discussion of the use of computers in managing clinical studies is an example.

Dr. Spilker provides an interesting perspective on issues rarely covered in other books. *Guide to Planning and Managing Multiple Clinical Studies* will appeal primarily to managers and administrators in the pharmaceutical industry and to others who desire a quick, nontechnical overview of issues involved in the pharmaceutical industry's planning and management of multiple clinical studies.

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## MULTIPLE SCLEROSIS: A GUIDE FOR PATIENTS AND THEIR FAMILIES

edited by Labe C. Scheinberg and Nancy J. Holland  
Raven Press

The title of this book aptly describes its intent. Labe Scheinberg, MD, and Nancy Holland, MA, RN, draw from their extensive clinical and academic background to create a well-balanced presentation of current knowledge about multiple sclerosis, including practical suggestions and discussion of issues of concern to patients and