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DATA COLLECTION FORMS IN CLINICAL TRIALS

By Bert Spilker, PhD, MD and John Schoenfelder, PhD
Raven Press

A clinical trial is only as good as the form used to assemble the data: so contend Drs. Spilker and Schoenfelder. With this reference book they elevate the task of creating data collection forms from a hurried activity conducted between study design and patient enlistment to a valuable organizational tool that can clearly focus an investigation and ensure that it is processed efficiently and effectively.

Part I explains the background of data collection forms, including the types of forms available, methods of preparation and organization, and the processing of completed forms. One chapter lists specific guidelines, pointers, and pitfalls. An exhaustive compilation of tips includes methods to collect data from multiple patient visits, the value of closed vs open systems of data entry, and the proper way to list adverse events. Everyone from the novice to the expert can gain insight into the mechanics of form construction in this section. It also prepares the reader to critically review the sections that follow.

Part II, comprising the greater part of this reference book, consists of hundreds of high-quality data collection form segments selected to demonstrate the principles laid out in part I. The segments are grouped into subunits such as the background of the clinical trial, physical and other examinations, laboratory tests and evaluations, adverse events, medicines, assays of biologic levels, efficacy, patient termination, and miscellaneous forms. Within this library of form units the researcher can find excellent examples to use as models in designing forms for a specific intent.

This reference is designed to serve in the construction of "level one" data collection forms suitable for all clinical trials. The construction of forms for a specific project or medicine ("level two") and forms to be used in specific clinical trials ("level three") must be extrapolated from the information presented. However, part I gives enough information to accomplish this.

This book tends to focus on pharmaceutical research and large clinical trials, making some of the examples extraneous to the purposes of clinicians or researchers who are not conducting such studies. However, the book contains enough information to make up for this shortcoming. *Data Collection Forms in Clinical Trials* is recommended for all who wish to improve the quality of their conclusions by improving the quality with which they record their observations.

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RESPIRATORY INFECTIONS IN THE ELDERLY

Edited by Michael S. Niederman, MD
Raven Press

Medical care of the elderly significantly affects health care costs in the United States. Individuals over age 65 constitute 11% of the population, and their numbers are on the rise. It is estimated that the number of individuals over age 85 will double by the year 2000. Today, 5% of elderly people reside in 18,000 nursing homes scattered across the country, and the need for nursing home beds is likely to increase by 40% in the next 10 years.

Pulmonary tuberculosis is epidemic in the elderly and in nursing home residents, and its prevalence in these groups is 4 and 15 times higher, respectively, than in the general population. In recent years, the elderly

have shown an increase in the incidence of tuberculosis that is second only to patients with the acquired immunodeficiency syndrome.

Under these circumstances, this monograph is a timely publication. Its contributors are internationally known gerontologists and infectious disease experts.

The book is well organized and covers its subject comprehensively. Important topics such as epidemiology, immunology, nosocomial and community-acquired pneumonia, influenza, tuberculosis, treatment, and prevention are thoroughly discussed, though I would have enjoyed some information on *Listeria monocytogenes* infection, which is not uncommon in malnourished elderly patients.

Each chapter is well written, easy to read, and informative. Appropriate figures, tables, graphs, and algorithms further assist the reader, although some of the tables are superfluous, and some radiographs and computed tomography images could have used better resolution. Sputum Gram's stain and histology figures would have been enhanced by color reproduction. The data are supported by an extensive and up-to-date reference list that includes several 1991 publications.

I enjoyed this book immensely—the chapters "Slowly Resolving Pneumonia in the Elderly" and "Newer or Emerging Pathogens in the Elderly" are its highlights—and read it in one sitting. This monograph would be a ready reference for internists, gerontologists, pulmonologists, infectious disease specialists, and extended care facility physicians who are routinely involved in caring for elderly patients.

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THE FRACTURE CLASSIFICATION MANUAL

By Ramon B. Gustilo
Mosby Yearbook

This manual presents a classification system of musculoskeletal injuries in atlas format. The first part of the book describes the trauma registry, outlines the fracture classification system, discusses the abbreviated injury severity score equation, and classifies long-bone and flat-bone injuries, intra-articular fractures, alignment, and types of fractures.

The remainder of the book discusses injuries of specific areas. Examples of each type of injury are depicted with a line drawing, and each injury is coded by the trauma code and International Classification of Diseases, Ninth Revision, Clinical Modification (ICD 9 CM). There are no radiographs, but the line drawings are more explicit and easier to review. Clinical implications and management are not discussed.

The manual helps standardize musculoskeletal trauma and makes educating those involved simpler whether they are in orthopedics, radiology, emergency medicine, or primary care. The atlas format, index, line diagrams, and ICD 9 CM code makes it a quick reference for billing classification and a source for quick review.

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