“Clinical Trials in Older Adults”
Review by Norman M. Goldfarb

“Clinical Trials in Older Adults” is essential reading for anyone developing drugs or medical devices that could be useful treatments for the elderly. While many older people, with their multiple ailments and treatments, are a formidable challenge for clinical trial design, analysis, safety and cost, the population will continue to grow rapidly and cannot be ignored. At minimum, pharmacokinetic studies should be routinely conducted in older adults.

The book’s preface clearly and concisely explains why conducting clinical trials in older adults is so important:

The remarkable increase in life expectancy during the twentieth century, coupled with a generalized decline in birth rates, has led to the rapid and intense aging of the population worldwide and particularly in industrialized countries. Although many older people are healthy, the majority of them suffer from one or often more chronic conditions requiring long-term pharmacological as well as non-pharmacological treatments.

Unfortunately, older people have been usually excluded from clinical studies aimed at demonstrating the efficacy and safety of therapeutic interventions and, even when some have been included, the presence of extensive inclusion and exclusion criteria has led to highly selected older participants who are not representative of the general older population. This is particularly true for oldest-old subjects, those with multimorbidity, frailty and disability.

As a consequence, drugs and, to a lower extent, non-pharmacological interventions to treat the conditions that affect older subjects, are often used without an adequate knowledge of their utility as well as their potential risks. The majority of treatments have to be prescribed “off label” in many older subjects. This situation is clearly unacceptable both from an ethical point of view, as it is a clear expression of ageism, but also from an economic standpoint, as untested interventions might be either ineffective or risky, potentially leading to unjustified increasing costs or human suffering.

On the other hand, older subjects have peculiar characteristics, such as a high heterogeneity in terms of health status and function, a high prevalence of multimorbidity and polypharmacy, and social issues, such as isolation and poverty, that should be taken into account when designing clinical research.

We believe that the time has come to expect a rapid increase in clinical research studies performed in older subjects.

The book includes the following 13 chapters:

- The exclusion of older subjects from clinical trials: the PREDICT study
• Clinical trials in older adults: a point of view from the industry
• Ethical issues in clinical trials involving older subjects: the right to participate in clinical trials and have access to care; the protection of vulnerable subjects and the issue of informed consent
• Mastering the design of clinical trials for older persons: the tension between external validity and feasibility
• Pharmacokinetic and pharmacodynamic studies in older adults
• The role of comprehensive geriatric assessment (CGA) of older adults in clinical studies
• Statistical issues in designing and interpreting clinical trials in older adults
• Challenges in implementing large-scale clinical trials in moderately functioning older adults
• Clinical trials in Alzheimer’s disease
• Clinical trials in late-life mood disorders
• Clinical trials for conditions of low muscle mass and strength
• Clinical trials of cancer treatment in the elderly
• Clinical trials in nursing homes: challenges and practical solutions

The book is available in bookstores.

**Reviewer**

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