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Geriatric Drug Development

Helen K Edelberg
Bristol-Myers Squibb, USA

This talk discusses biopharmaceutical (drug) development for older adults, including considerations in Phase I (clinical pharmacology), Phase II/III (clinical development), marketing authorization (labeling), and Phase IV (postmarketing risk evaluation and mitigation strategies or risk minimization). After participating in this activity, participants will: (1) Know the key age-associated changes in pharmacokinetics and pharmacodynamics under consideration when developing drugs for older adults - The purpose of Phase I (clinical pharmacology) drug trials in older adults is to determine if there are relevant age-associated changes in pharmacokinetics (absorption, distribution, metabolism, and elimination) and/or pharmacodynamics; (2) Understand why older adults are frequently excluded from clinical trials - There is a shortage of studies focusing on older adults, so clinicians and policy makers frequently rely on clinical trials of the general population to provide supportive evidence for treating complex, older patients. This talk details the challenges of including frail, older adults in clinical trials; (2) Describe different types of product labeling - The talk will review different aspects of product labeling for both healthcare providers and patients/caregivers. The basic rules that govern advertising for prescription drugs, including direct-to-consumer (DTC) advertising, will also be discussed; and (4) Be aware of current and future approaches to understanding drug safety (and effectiveness) in older adults - The speaker will discuss the implications of recent regulatory initiatives and global trends on the safe and effective use of drugs in older adults.

Biography

Helen Edelberg has 6 years of experience in academic medicine and 11+ years of leadership experience in the biopharmaceutical industry. She has held academic clinical research, teaching, and management faculty positions at BIDMC, Harvard Medical School, and Mount Sinai (NY). Since completing her MPH (Columbia) she has held positions of increasing responsibility in global regulatory affairs (RA)/pharmacovigilance including: Therapeutic Area Head, sanofi-aventis; Head, Besins (Thailand); VP, Eurand (Consultant); Head, ContraFect. In her current role (BMS) she leverages her internal medicine/geriatrics and public health knowledge, as well as her industry experience to improve patient safety.

helenedelberg@yahoo.com