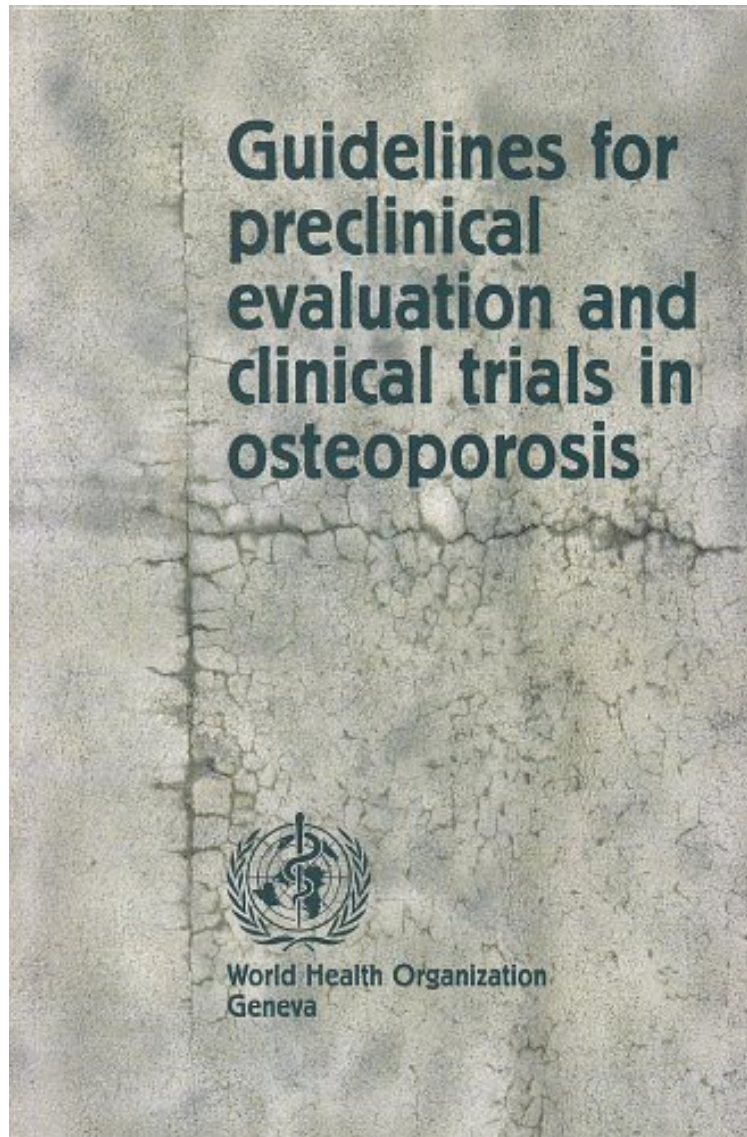


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Guidelines for Preclinical Evaluation and Clinical Trials in Osteoporosis

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World Health Organization : Guidelines for Preclinical Evaluation and Clinical Trials in Osteoporosis before purchasing it in order to gauge whether or not it would be worth my time, and all praised Guidelines for Preclinical Evaluation and Clinical Trials in Osteoporosis:

This book provides comprehensive guidelines for the design, implementation, and interpretation of preclinical studies and clinical trials of agents undergoing investigation for the management of osteoporosis. Noting the magnitude of the public health problem caused by osteoporosis and related fractures, the book responds to the urgent need for a cohesive and rational approach to the search for new therapeutic or preventive agents. Recommended principles and methods reflect the consensus reached by a large number of international experts, representatives of the pharmaceutical industry, and drug regulatory authorities. The book opens with a brief discussion of the current and future public health problem caused by osteoporotic fractures, followed by conceptual and operational definitions of osteoporosis and a recommended classification of four intervention categories that facilitate the definition of treatment objectives and the design of targeted studies. Against this background, the next chapter offers a detailed guide to the aims, design, conduct and interpretation of preclinical studies. Specific recommendations are given for the selection of in vitro and animal models, the design of the study, including dose ranges and duration of treatment, and the most appropriate end-points for assessing efficacy. The most extensive chapter provides a comprehensive description of basic principles and methods to follow during clinical trials. Information ranges from a discussion of problems with the use of bone mineral density to predict fracture risk, through advice on the choice of tests and techniques for measuring the effects of interventions, to a discussion of general principles of trial design, including selection of study population, treatment regimen, duration of studies, sample size, and frequency of measurement. Drawing on these detailed principles and methods, subsequent chapters offer concise guidance specific to phase I and phase II studies, phase III studies in severe osteoporosis, phase III studies in osteoporosis without fragility fractures, and phase III studies in osteopenia. The book concludes with chapters outlining principles and methods for phase III clinical trials in subjects with normal bone mass, and for phase IV studies.

About the Author World Health Organization is a Specialized Agency of the United Nations, charged to act as the world's directing and coordinating authority on questions of human health. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.