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Some statistical issues on the evaluation of the similarity and interchangeability of biologics

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With the expiry of many patents for biological drugs, biosimilar generic formulations gain increasing interest from regulatory authorities as well as from the biotechnology industry. Unlike small-molecule drugs which can be chemically synthesized, biological drugs are produced by living organisms or cell cultures. They are generally sensitive to environmental factors. New biological products can not be reproduced but only imitated. Consequently, the issues and problems of assessing biosimilarity are much more difficult than those of evaluating the bioequivalence of small-molecule drug products. Similarities of several factors (including complicated structural and functional features, manufacturing conditions, clinical responses) must be taken into account. Statistical assessment is complicated by the usually high variability. An additional issue involves the interchangeability of biologicals which is a distinct concept from their biosimilarity. Study conditions and statistical evaluation will be discussed for comparing drug products of small molecules by bioequivalence and of biologics by biosimilarity. A procedure for the statistical evaluation of biosimilarity will be presented. The interchangeability of small-molecule drugs and of biologics will also be considered.

Biography

Endrenyi is Professor Emeritus of pharmacology and biostatistics in the University of Toronto. He has served the university in various positions including on its Governing Council and as Associate Dean of Graduate Studies. Externally, he has served on grant review committees and editorial boards of research journals including the Amer. J. Physiol, J. Pharmacokin. Pharmacodyn., J. Pharm. Pharm. Sci., Biosimilars, and J. Pharm. Sci. He has received several recognitions, including an honorary doctorate from Semmelweis University. He published a book on Kinetic Data Analysis and over 160 research papers.

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