Laszlo Endrenyi, J Bioanal Biomed 2016, 8:5(Suppl)
http://dx.doi.org/10.4172/1948-593X.C1.022



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## Scientific factors in biosimilar product development

When the patent of a biological drug expires biosimilar products are often developed. The practice is complicated, e.g., due to the size and structure of the molecules, the complexity of the manufacturing process and the possibility of immunogenicity. The development of biosimilars calls for the consideration of several features which should be pursued in a stepwise manner and are ultimately jointly assessed based on the total available evidence. The planning and execution of the steps should rely on scientific principles. Thoughts should give, among others, to criteria for biosimilarity and interchangeability, the degree of similarity, the consistency in manufacturing processes, the assessment of quality attributes of structural and functional characterization, and the appropriate design and statistical evaluation of the investigations. The assessment of critical quality attributes for structural and functional characterization should follow the level of their relevance to the clinical outcomes. Quantitative criteria should take into account not averages but also variations. They could be either unscaled or scaled, either unweighted or weighted, either disaggregated or aggregated. A proposed biosimilarity index addresses the question of "how similar is similar" and reflects the sensitivity in the heterogeneity of variation. Quantitative indices characterize also conditions of interchangeability such as switching and alternating between drug products. Study designs should also follow these conditions. For comparative clinical studies, scientific considerations should include the choice of clinically sensitive endpoints, adequate sample size and study duration, and the appropriate design of the investigation(s).

### Biography

Laszlo Endrenyi is the 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. He sat on the Board of Directors of the American Statistical Association and the Canadian Society for Pharmaceutical Scientists; he was President of the latter and received its Lifetime Achievement Award. Externally, he has served on grant review committees and editorial boards of research journals. He has received several recognitions, including an honorary Doctorate from the Semmelweis University of Medicine. He is a Fellow of the Canadian Society for Pharmaceutical Sciences and of the American Association of Pharmaceutical Scientists. He has published a book on Kinetic Data Analysis and over 180 research papers. He has advised and widely consulted with industry and regulatory agencies.

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