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Clinical trials for biosimilars: Principles and challenges

One key factor to regulate the development of biosimilars is to reduce the price of biological therapies by reducing the costs of their clinical development. Even though the manufacturing and quality control of biosimilars is equally expensive for biosimilar companies as for the originator biologic, the costs for the clinical program can be less than for the originator. The development of qualitative biosimilars can lead to overall more affordable treatment alternatives and reduction for the healthcare systems in many therapeutic areas. A focused clinical trial program to show clinical comparability between the reference product and the biosimilar can result in a significant cost reduction of the overall development program. Regulatory agencies have defined high standards and scientific processes for preclinical and clinical evaluations of biosimilars. The clinical trial program depends on the level of similarity and robustness of the analytical and pre-clinical data. Once high similarity is established early in the development, clinical trials are used to confirm the findings through a tailored clinical trial program. The challenge here is scientifically appropriate design of the clinical trials, the defined endpoints, pharmacodynamics, safety data and following the principles of biosimilar development. It is the totality of evidence which might lead to regulatory acceptance, while maintaining the development costs at a level lower than for new biologics.

Biography

Heike Schoen is the Managing Director and Co-Founder of LUMIS International GmbH, headquartered in Germany. She has gained more than 20 years of experience in various management positions overseeing the conduct of international clinical trials Phase I to IV in different indications, within CROs and Biotech companies. She is an active member and regular speaker of the DIA (Drug Information Association) and ACRP (Association of Clinical Research Professionals). At ACRP she was 7 years a member of the voluntary Board of Trustees, and their Chairperson in 2010. She has gained Masters in Science (Psychology) and in Business Administration.

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