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Cost-effective clinical trial design to detect immunogenicity and efficacy differences between biosimilar and innovator product

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Bio-therapeutic products are the fastest growing medicines in the pharmaceutical market. Here, we discuss the major variables that have an impact on cost and timelines of biosimilars' development. Specifically, we report the challenges of duplicating the innovator product results and how the dialogue on indication extrapolation has elicited new interest as the FDA compares extrapolation's core issues. According to the WHO, "it is expected that the elaboration of the data requirements and considerations for the licensing of biosimilar products will facilitate development and worldwide access to bio-therapeutics of assured quality, safety and efficacy at more affordable prices". To address the WHO requirements, we have reviewed trial options that could assess interchangeability between the branded product and the biosimilar. Here, we discuss a case study with the objective of assessing the immunogenicity rate between biosimilar and innovator product and evaluate the data in light of regulatory requirements. Our developed framework based on evidence-based strategies and design-centered trials highlights the factors impacting the potential cost savings in biosimilar development.

Biography

Candida Fratazzi devised the concept of a Strategic Clinical Innovation Organization (SCIO) and founded the first SCIO–Boston Biotech Clinical Research (BBCR), LLC in 2009. She has worked on several Biosimilars' development with special attention to the major variables that impact costs. As the President of BBCR, LLC, she acts as a Consultant to biotech, pharmaceutical medical device companies, and investors on optimum clinical plan development and how to design clinical trials that reduce product development risk. She is a renowned Immunologist with over 15 years of experience in Orphan Petitions in US and EU and phases 1-4 clinical programs, contributed to the registration and approval of 4 successful products. Her expertise includes Drug, Device as well as Combination Products. She is the recipient of 2013, 2014 and 2015 Best Pharmaceutical Consultant, Cambridge Award, 2015 Cambridge Business Hall of Fame Award and 2014 top ranked US executives, National Council of American Executives. She is a Member of Advisory Board and Board of Directors in Life-science Technology companies. She is an Invited Speaker and Chairman at international conferences. She has authored over 50 scientific papers in peer review journals and several book chapters. She helps international companies to enter the US and EU markets. She received her early training in biomedical research at the Johns Hopkins University and Harvard University in the USA and at Imperial College in London, UK.

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